

Future Skills Needs of the Biopharma Industry in Ireland

August 2016





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We would like to acknowledge the valuable inputs made into this review by BioPharmaChem Ireland, IDA Ireland, Enterprise Ireland, Science Foundation Ireland, Department of Social Protection, Higher Education Authority, and the many industry executives and education and training participants who attended the regional workshops held in Dublin and Cork as well as those Biopharma company representatives who responded to the questionnaire-based survey.

The EGFSN Secretariat based in the Department of Jobs, Enterprise and Innovation conducted the research for the Study and was responsible for the management and writing up of the report. The Skills and Labour Market Research Unit in SOLAS provided data on the occupational profile of the Industry.



Introduction to the Expert Group on Future Skills Needs

The Expert Group on Future Skills Needs (EGFSN) advises the Irish Government on current and future skills needs of the economy and on other labour market issues that impact on Ireland's enterprise and employment growth. It has a central role in ensuring that labour market needs for skilled workers are anticipated and met.

Established in 1997, the EGFSN reports to the Minister for Education and Skills and the Minister for Jobs, Enterprise and Innovation.

The Department of Jobs, Enterprise and Innovation, in conjunction with the Skills and Labour Market Research Unit in SOLAS, provides the EGFSN with research and analysis support.



Foreword

The Biopharma industry is one of the fastest growing sectors in Ireland. In 2015, the sector employed 28,200 people in Ireland and accounted for over €30bn in exports. The sector also creates significant secondary employment in construction and other services while investment in new plant construction is under way.

Ireland is winning significant investments in Bipoharma, with capital projects amounting to over €4bn in the pipeline over the coming years. The availability of people with the right skills and talent to work in Biopharma will be critical to the continued growth of the industry as these new plants come on stream.



The objective of this report is to review the supply of, and demand for, skills within the Biopharma Industry in Ireland up to 2020. There is a specific focus in the report on Biologics manufacturing as a growing sub-sector within the industry.

Given anticipated expansion and replacement demand, it is estimated that 8,400 potential job openings will arise within the Biopharma industry in Ireland over the next five years. This study finds that the quantity of skills supply should be available to meet this demand, albeit with a need to improve alignment of provision with industry's needs, particularly for Biologics manufacturing. There is also both a challenge and an opportunity for the Biopharma industry, working in collaboration with education and training providers and other stakeholders, to increase awareness of the range of careers available in the sector and attract a greater share of available graduates from the fields of science, engineering, and business studies. There is also scope to upskill jobseekers, continue the upskilling of those already working in the sector, and to attract international talent to Ireland to increase the depth of experience in companies.

I would like to thank all of those who contributed to the preparation of this report. Particular thanks are due to the many enterprises and stakeholders who contributed their time and expertise through workshops and other engagements with the EGFSN Secretariat. I would also like to express my thanks to the members of the Validation Group for their insights and support in finalising the report. Finally, I would like to thank the EGFSN Secretariat within the Department of Jobs, Enterprise and Innovation for managing and leading the study to a successful conclusion.

I would encourage the prompt implementation of the set of practical recommendations made in this report which will, when implemented, help to address the skills requirements of the Biopharma industry over the next five years.

Una Halligan

Chairperson, Expert Group on Future Skills Needs



Key Findings

The objective of the study is to review the supply of, and demand for, skills required to address the skill needs of the Biopharma industry in Ireland up to 2020. There is a specific focus on Biologics manufacturing which is a growing sector of the industry with its own specific skill needs. The term "Biopharma" covers both Pharma chemically processed drugs, and Biologics medicines which are manufactured in living organisms. An estimated 28,200 people were employed in the Biopharma industry in 2015 in Ireland. Of these, 21,500 were engaged in Pharma manufacturing and related services, while 6,700 were employed in Biologics. A significant number of Biopharma investment announcements have been made recently with most being within Biologics manufacturing.

The availability of skills and talent is seen by the industry as a key prerequisite for future competitiveness, investment and employment. The need for a collaborative approach to ensure the adequacy of the supply of Biopharma skills and talent has been raised by the industry in discussions with the Department of Jobs, Enterprise and Innovation and State agencies.

There are a several large sized companies within the industry with around 35 companies comprising 85% of employment. The Biopharma industry exported products to the value of €30.2bn in 2015 and contributed €1.7bn in payroll expenditure to the economy. It creates significant secondary employment in construction and other services while the investment in new plant construction is under way. The industry is regionally based with main operations located in the South-West, Dublin, Mid-East, and West regions.

Global and domestic drivers of growth are impacting on Biopharma skills demand. These includes the general challenge of achieving innovation and operational excellence, maintaining global standards of product and process compliance, and delivering on the specific skills required for both Pharma and Biologics manufacturing. Other countries are undertaking initiatives to ensure a supply of talent for the Biopharma industry, in particular for Biologics manufacturing. Features include the close engagement and collaboration of companies and academics in the design and delivery of education and training programmes.

The Biopharma Industry in Ireland has several key strengths including an international reputation based on manufacturing excellence. It has a strong representative body, BioPharmaChem Ireland, which is proactively looking at its skill needs through its Biopharma Skills Forum (which is taking into account the recommendations made in this report). The Industry is making active use of Springboard+ and the Skillnets training programmes, supported respectively by the Department of Education and Skills and the Department of Social Protection, to address its skills needs. The Government has also invested in NIBRT¹, which has become an internationally renowned centre for Biologics process research and training.

¹ National Institute for Bioprocessing Research and Training.



The Biopharma industry is highly regulated with stringent clean and safe operational requirements. A particular difficulty cited is the sourcing of experienced staff especially for Process Engineering and for Quality Assurance/Validation roles. Over the next five years, it is anticipated that the industry will create a diverse range of roles requiring specific science, engineering, technology, and business skills across NFQ levels 6-9. "Soft" skills including communications, teamworking, problem solving, and influencing skills are essential for all roles. All staff must have knowledge of contamination, sterile processing and cleanroom operations. There is a demand for staff with awareness across a range of related disciplines who understand the manufacturing process and the drug and medicines life cycle. Data analytics is a key emerging skills requirement.

Research work undertaken with stakeholders highlights the need for an improved alignment of programme provision. More regular reviews of biopharma education and training programmes are required to ensure that they remain market-informed. Companies also need to engage in more forward planning of their skills needs. Companies cite a lack of "soft skills" among graduates, including teamworking, communications, and problem solving skills. Many students on Biopharma related programmes do not receive structured work place training. Academia also requires greater access to the facilities and funding resources to provide experiential learning for students.

It is estimated that 810 graduates of various NFQ levels entered employment in the Biopharma Industry in 2014. Around half of these graduates were from science and maths disciplines, with another 24% coming from engineering, 12% from health and welfare, and 7% from business disciplines. The remaining 9% came from a combination of different discipline areas.

Given recent investment plans, it is anticipated that an additional 5,000 staff will be employed in Biologics manufacturing over the next five years in Ireland, a 75% increase on the current employment level. Of this 5,000 employment increase, it is estimated that around 1,000 will be for roles such as facility maintenance, supply chain/logistics, human resources, finance, legal and warehousing. These are roles found in other sectors, albeit with a need for Biopharma domain knowledge. The remaining 4,000 roles will require more specific Biopharma science, technology and engineering skillsets. Pharmaceutical employment (manufacturing and service activities) is anticipated to remain stable at around 21,500, although there will be continuing change in the nature of these activities which will have implications for skill demand.

Between anticipated expansion and the replacement employment demand arising within the Biopharma industry, there will be 8,400 potential job openings in the period up to 2020. It is considered that this level of job openings can be met through a combination of increased graduate recruitment by industry from the required range of science, technology, engineering and business disciplines² and the upskilling of job seekers with relevant qualifications on Springboard+/Skillnets training programmes. The industry can also continue to draw upon a flow of international talent,

² This can be against the background of the stated objective of "Irelands National Skills Strategy 2025" for participation in STEM disciplines to increase.



including expatriates, to add necessary experience and diversity of skillsets. The pace of change in Biopharma markets, technology and processes means that the investment by companies in the continuing professional development of their workforce is essential.

This increased inflow of graduates is considered feasible given the industry's relative share of recruitment from the main science, technology, engineering and business disciplines that it is drawing upon, albeit with a need for an improved alignment of this provision (especially for Biologics) and for structured work experience placements to become an integral part of all programme provision. Companies also need to increase public awareness of the range of career opportunities available and to increase the scale of their graduate entry recruitment programmes.

The set of recommendations in this report can serve as an Action Plan for addressing the skills needs of the Biopharma Industry up to 2020. Recommendations that can be delivered in the short-term and have an immediate effect are focused on the following ten key actions. Their successful implementation requires the commitment and collaboration of all stakeholders. The Lead Bodies responsible for the implementation of recommendations are provided in Chapter 8 of the report.

Key Actions in the short-term for addressing the Skills needs of the Biopharma industry

	Develop Communications tools to better promote the sector.
	Maximise use of Springboard+ and Skillnets programmes to upskill jobseekers (935 Springboard+ Biopharma training places are approved for 2016).
	Improve the alignment of Biopharma education and training programmes.
	Increase the scale of Graduate Entry Development Programmes.
OPPORTUNITY	Raise awareness of the range of rewarding careers in Biopharma including through increased Industry presence at Career Fairs, and Open Days.
Leton Mass	Engage with the Regional Skills Fora to highlight skills requirements and career opportunities in Biopharma.
	Utilise the Biopharma Skills Forum established by BioPhamaChem Ireland including finalising the Biopharma Skill Forums Action Plan for Skills.
	Increase the provision of work placements on a regional basis.
	Invest in the continuing professional development of the Workforce.
3	Increase awareness of Ireland as a location of choice for workers with Biopharma skills.
	Develop a Biopharma Apprenticeship and Biopharma Career Traineeship.



Chapter 1: Introduction

1.1 Introduction

The objective of the study is to review the supply of, and demand for, skills required to address the skills needs of the Biopharma industry³ in Ireland up to 2020. This is to ensure that the right skills are available to drive business and employment growth. The term Biopharma covers both Pharma and Biologics drugs. There is a specific focus in the study on Biologics manufacturing which is a growing sector of the industry with its own particular skill needs. The study forms part of the work programme of the Expert Group on Future Skills Needs for 2016 and is included as an action within the Action Plan for Jobs 2016

The most recent previous study in this area was carried out in 2010 when the Expert Group on Future Skills Needs published a report on the Future Skills Requirements of the Biopharma-Pharmachem Sector⁴. At that time, patent expiries, coupled with global consolidation, were considered to be changing the face of the industry. The study concluded that while some job losses were inevitable in the pharmachem sector, these were likely to be balanced by job gains between 2010 and 2015. Additional jobs were forecast in the Biologics sector and in new activities for Pharmaceutical companies, including higher value-added activities such as process and product development, and services such as supply-chain management and corporate services. The study concluded that if the industry succeeded in transforming to these new activities, employment in the five years to 2015 was likely to hold firm.

Research on other countries which was conducted as part of the report noted that in North Carolina, Singapore and Switzerland there was strong industry-academia collaboration, which played a critical role in ensuring that graduates were equipped with skills required by industry. In contrast, many links between industry and academia in Ireland were informal and relied on individuals rather than formal structures and processes. This informal approach was not deemed to be sustainable.

Student work placements were a critical part of Biopharma Third Level programmes in overseas countries examined, and key to the employability of graduates. In Ireland, there were still large numbers of third level students in this discipline who did not have access to a work placement. The EGFSN recommended a placement of at least 6-9 months duration for all Third Level Biopharmarelated courses.

The 2010 report concluded that there appeared to be sufficient numbers of graduates and postgraduates to meet industry demand. However, the industry would require a more highly skilled workforce, given the transformation within the sector. The need for multi-disciplinary skills and soft skills such as team-working and communications skills was highlighted in the report.

³ The Industrial Classification used comprises NACE Rav 2 20 (manufacturing of chemicals and chemical products), NACE Rev 2 21 (manufacturing of pharmaceutical products), and NACE Rev 2 72 (Scientific R&D).

See http://egfsn.ie/Publications/2010/Future-Skills-Requirements-of-the-Biopharma-Pharmachem-Sector.html.



The report contained a series of recommendations focused on the following headings:

- Strengthening business skills within the sector.
- Aligning education and training provision with industry requirements.
- Enhancing industry-academia collaboration.
- Developing structured postgraduate programmes.
- Developing standardised student work placements.
- Providing the sector with dedicated research and training.
- Developing an operative upskilling programme.

While progress has been made in a number of respects since 2010 (for example, NIBRT was only beginning to roll out its training programmes at that time), other recommendation areas still require attention and feature in this current review of the skills needs of the industry.

The clustering of a number of patented drugs going off patent in quick succession around 2012/2013 presented particular challenges for the industry at that time. However, the industry has come through that period and has seen the emergence of business opportunities in new areas, particularly in Biologics manufacturing.

1.2 Objectives of Study

The objective of the current study is to review the skill and talent needs of the Biopharma industry in Ireland up to 2020. The term "Biopharma" covers both traditional chemically processed drugs, and Biologics medicines which are manufactured in living organisms. There is a specific focus in the study on the skills needs of Biologics manufacturing which is a growing sector of the industry. The aim is to ensure that the right skills (to meet both expansion and replacement demand) are available to drive business and employment growth and help graduates and job seekers fill potential job openings. The availability of talent will help to sustain and grow Biopharma inward investment. The Terms of Reference for the study are given in Appendix 1.

This study assesses the current and future skills needs of the Biopharma industry and how any identified skills gaps may be addressed, including through:

- raising awareness of the interesting and rewarding career opportunities in the Industry;
- higher education provision and further education and training;
- continuing professional development of the workforce;
- talent recruitment and retention practices;
- retraining of jobseekers to fill available positions; and
- attracting experienced international Biopharma talent, including expatriates.

The Study does not include companies engaged in basic chemical or plastics production.



The outline of the report is as follows:

Chapter 1 - Introduction

Chapter 2 - Profile of the Biopharma industry in Ireland

Chapter 3 - Drivers of Change impacting on Biopharma skills demand

Chapter 4 - International Country Review

Chapter 5 - Views from Stakeholder Research

Chapter 6 - Supply of Biopharma relevant Skills

Chapter 7 - Demand for Biopharma Skills

Chapter 8 - Conclusions and Recommendations

A Glossary of technical terms used in the study is provided in Appendix 6.

1.3 Background

A significant number of Biopharma investment announcements have been made recently with most being within Biologics manufacturing. It is estimated that the number of Biologics manufacturing sites in Ireland has risen from 2 in 2003 to 18 in 2015⁵. An increasing proportion of new medicines are Biologics "large molecule" based, rather than chemically-processed "small molecule".

The primary difference between Biologics drugs and traditional pharmaceuticals drugs is the method by which the drugs are produced. The former are manufactured in living organisms such as bacteria, yeast and mammalian cells, whereas the latter are manufactured through a series of chemical synthetic steps. Whereas a pharmaceutical "small molecule" of aspirin consists of 21 atoms, a Biologics "large molecule" might contain from 2,000 to 25,000 atoms. This sophistication involves a high level of investment, with large scale Biologics manufacturing facilities requiring \$200m to \$500m or more to build, compared to similar "small molecule" facilities that may cost between \$30m to \$100m. Globally, Biologics generates annual revenues of \$163bn making up about 20% of the global Biopharma market. The current Biologics annual growth rate of 8% is double that of conventional Pharma. Growth is expected to continue at that rate for the foreseeable future.

The skills needed for the research and development, manufacturing and commercialisation of "large molecule" Biologics medicines are very specific and key to the ability of the industry to deliver innovative medicines to patients. Table 1 outlines the main differences between the production processes for Pharmaceutical drugs versus Biologics drugs.

⁵ Source: Pharmchemical Ireland.

http://www.mckinsey.com/insights/health_systems_and_services/rapid_growth_in_biopharma, Dec 2014.



Table 1: Differences between Pharmaceutical versus Biologics Drugs

Pharmaceutical drugs (small molecules)	Biologics drugs (large molecules)
Less complex production Process	Complex production Process
Product robust - Can be taken as a tablet	Fragile product, most are administered by injection as they would be digested if swallowed.
Low risk of product degradation	High risk of product degradation
Process is well defined	High process variability
Process losses not very high	Process losses can be high - 30% and upwards
Low risk of contamination	High risk of contamination
Simple analytical techniques used	Complex analytical techniques required

Source: NIBRT presentation, 2016.

It is estimated that 28,200 people were employed within the Biopharma Industry in 2015. Within this total, it is estimated that Biologics manufacturing accounts for some 6,700 employees. Given recent investment plan announcements it is anticipated that an additional 5,000 staff will be employed in Biologics manufacturing over the next five years, with Pharmaceutical activities (manufacturing and service related) employment remaining stable at around 21,500.

The need for a collaborative approach to ensure the adequacy of the supply of Biopharma skills and talent has been raised by the industry in discussions with the Department of Jobs, Enterprise and Innovation (DJEI) and State agencies. Skills and talent availability is seen by the industry as a key prerequisite in terms of future competitiveness, investment and employment.

Ireland's key Biopharma competitor locations are Puerto Rico (for manufacturing); Singapore (for manufacturing and R&D); North Carolina & Massachusetts (for clinical trial management); Netherlands (for clinical R&D); Belgium (for Bio Manufacturing); Switzerland; Danish/Swedish Medicon Valley (Life Science Cluster); and China & India (for generics manufacturing).

1.4 Methodology for Study

The methodology comprises several integrated elements. These are outlined as follows:

- Review the main trends and drivers of change impacting on the industry's current and future skills and competency requirements.
- Determine the current workforce profile of the industry.
- Undertake a structured survey of 20 Key Informants enterprises and organisations on skill demand needs and how to address them (the questionnaire is presented in Appendix 4).

⁷ IDA Ireland.



- Hold two workshops (Cork and Dublin) on Biopharma skill needs and supply provision with selected companies, organisations, training and education providers, and State Agencies including IDA Ireland, Enterprise Ireland, and Science Foundation Ireland (SFI).
- Profile the current supply of relevant skills from training and education provision.
- Consider the scope for the upskilling of jobseekers to fill potential job openings.
- Consider how any identified gaps in skill provision quantity, quality and diversity may be addressed, particularly for Biologics manufacturing.
- Review actions taken by other countries to develop a supply of relevant talent.
- Recommend responses to address any identified gaps in skills provision taking into account the skill needs requirements of Biologics manufacturing.

A "Validation Group" was established to "sense test" the research findings and recommendations of the report. This included representatives from BioPharmaChem Ireland, IDA Ireland, Enterprise Ireland, Science Foundation Ireland, Higher Education Authority, Cork Institute of Technology, NIBRT and Bristol Myers Squibb. A list of members is provided in Appendix 3.

1.5 Typology of Companies covered in the Study

The typology of companies covered in the study includes those that are engaged in one, or a combination of, the following activities:

- 1 Biologics "large molecule" drug manufacturing.
- 2 Pharmaceutical "small molecule" drug manufacturing.
- Biopharma Related Services including supply chain models for the supply of Biopharma products globally, shared services and headquarter activities.

Note: The study does not include companies engaged in basic chemical or plastics production.

Vaccine



Source: IDA



1.6 Typology of Skills covered in the Study

The typology of skills covered in the study includes those within the main functional areas of a typical Biologics manufacturing operation. The employment level within each functional area increases at different rates as a plant scales up from the start-up stage towards full production, over a 2-3 year period. An outline of the main functional areas within a typical Biologics production plant and the roles within them is outlined below. A balance of both technical and "soft skills" (communications, teamworking, critical thinking, problem solving, business acumen), and health and safety awareness are essential for all of these roles.

A. Manufacturing/Production

Typically this functional area comprises 50% of total employment. Skills required include good manufacturing practice, aseptic and sterile manufacturing, upstream processing, cell culture, downstream processing, drug substance production, media and buffer preparation, viral clearance and Lean Six Sigma manufacturing. This functional area comprises the following activities:

- Upstream and downstream activities⁸-the number working within these roles increases as a facility is scaled up to full production, when on average they comprise 30% of total employment. The typical qualification level for these engineers, scientists and technicians roles is NFQ Levels 8/9 with relevant experience.
- Manufacturing Science & Technology at full production these roles typically comprise 10% of total employment. The qualification level for these engineers, scientists and technicians roles is NFO Levels 7/8.
- Fill Finish/Packaging at full production these roles typically comprise 10% of total employment. The qualification level for these roles is NFQ Levels 7/8+ with relevant experience, although those at NFQ Level 6 with relevant experience may be upskilled to fill such positions.

B. Quality Assurance/Quality Control/Validation

This functional area plays a key role in ensuring that the production process and products meet stringent manufacturing standards. It is critical at all stages of the scaling up of an operation. At full production these quality assurance/quality validation roles typically comprise 30% of total employment⁹. The qualification level for such roles is NFQ Levels 8/9 with relevant experience. Skills required are good lab practice, molecular biology, protein characterisation, bioanalytics, biochemistry, protein chemistry, glycan analysis, microbiology, ultra performance liquid technology /ultra high performance liquid technology (UPLC/HPLC), bioassays, mass spectrometry, documentation management, batch release, and regulatory filings.

⁸ See Appendix 5 for an Overview of Upstream and Downstream Processing of Biopharmaceuticals.

In comparison, within "small molecule" manufacturing, the Quality Assurance/Quality Control/Validation functional area is likely to comprise around 20% of total plant employment.



C. Plant Operations

Roles within this functional area ensure the continuous functioning of highly complex plant and equipment. Skills include facility management, equipment maintenance, clean utilities, calibration, and automation. Such roles typically comprise 10% of total employment broken down as follows:

- Technical Services these roles increase in number as a plant scales up to full production when they may average 6% of staff numbers. The typical qualification level for these roles is NFQ Level 7+ with relevant experience. However, those at NFQ Level 6 with a craft qualification may also be upskilled to fill such positions.
- IT/Automation at full production these roles typically comprise 4% of total employment. The qualification level for such roles is NFQ Level 7 with relevant experience.

D. Management Supply Chain/ Logistics Marketing/HR/Finance/Warehousing

Typically these roles comprise around 10% of total employment in a fully operational plant depending upon whether such activities are located within the facility or centralised elsewhere. The numbers increase as a plant operation is scaled up. The typical qualification level for these roles is NFQ levels 7/8+ in a range of business disciplines and with domain-specific knowledge. Skills required include good distribution practice, project management, production planning, procurement, stock management, and distribution. Warehousing roles may be at NFQ level 6 with upskilling.

E. Research and Development

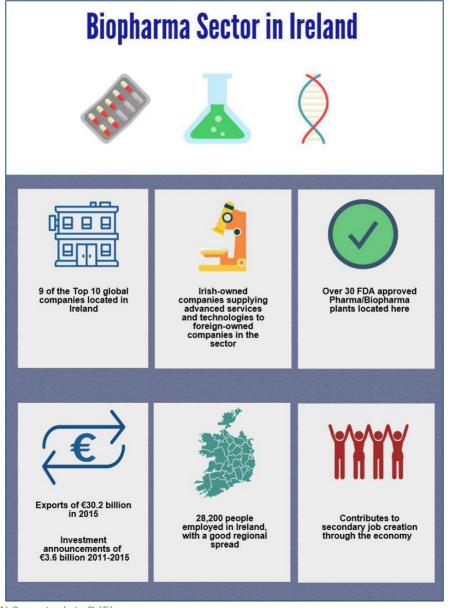
The R&D functional area comprises staff engaged in making improvements and modifications to existing production processes and identifying possible new production technologies and applications. These roles can comprise around 5% of the workforce depending upon whether the R&D function is located within the facility or centralised at another location. The typical qualifications level is NFQ Levels 8/9/10 with relevant experience.



Chapter 2: Profile of the Biopharma industry in Ireland

2.1 Activity Profile

It is estimated that the Biopharma industry employed 28,200 people in 2015. Of this total 21,500 were engaged in Pharma "small molecule" manufacturing and related services (supply chain management, shared services and headquarter activities) while 6,700 were employed in Biologics "large molecule" manufacturing. There is a significant representation of large sized companies within the industry, with around 35 companies comprising 85% of total employment. The industry contributes €1.7bn in payroll expenditure to the economy. It also creates significant secondary employment in construction and other services while the investment in new plant construction is under way. The Biopharma industry is regionally based with main concentrations of operations located in the South-West, Dublin, Mid-East, and West regions.



Source: EGFSN Secretariat, DJEI



There are over 30 US Federal Drug Administration (FDA) approved pharma/biologics plants located in Ireland. Biologics manufacturing activities are being undertaken both by companies who are diversifying their activities from "small molecule" chemical based production towards "large molecule" biologics medicines, as well as new Biologics companies. The IDA notes that Biologics manufacturing has grown in the last 10 years and has accounted for over €10bn of investment. The Biologics manufacturing cluster in Ireland is seen as the fastest growing sector of the wider Biopharma industry.

While there are fewer new "blockbuster" drugs that require large Pharma production facilities Ireland is still very competitive for the many new "niche buster" drugs that have specialised production requirements such as high containment or aseptic suites. Ireland is also well placed to win new investment conjugating large molecule antibodies with traditional drugs to enhance their effectiveness. Antibody Drug Conjugate (ADC) manufacturing requires both large and small molecule production expertise and is a growing area.

Nine out of the top 10 pharma/bio companies globally with research, manufacturing & services activities have operations in Ireland. Indigenous companies also supply advanced services and technologies into the foreign owned manufacturing company base.

The Biopharma industry exported products to the value of €30.2bn in 2015, an increase of 36% over the previous year. Imports also went up to €5.7bn, an increase of 26% or €1.2bn over the year. These trends are presented in Figure 1.

These trends are presented in Figure 1.

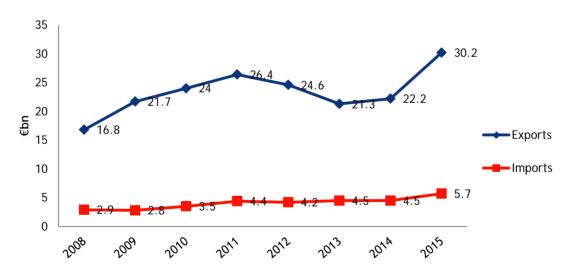


Figure 1: Ireland - Pharmaceutical and Medical Products Exports and Imports 2008-2015

Source: 2016 CSO Trade Statistics.

(Note: Standard International Trade Classification (SITC) (Rev 4) Commodity code 54 Medical and Pharmaceutical Products).



2.2 Profile of the Biopharma Workforce

Over the period 2010-2015, the share of professional occupations within the total Biopharma industry employment increased from 23% to 29% while Craft and related occupations increased from 5% to 7%. There was a slight reduction in the share of plant and machine operatives – down from 20% to 18%, and a greater fall for managers and administrators – from 18% to 10%. The occupational profile of the Biopharma industry in 2015 is outlined in Figure 2.

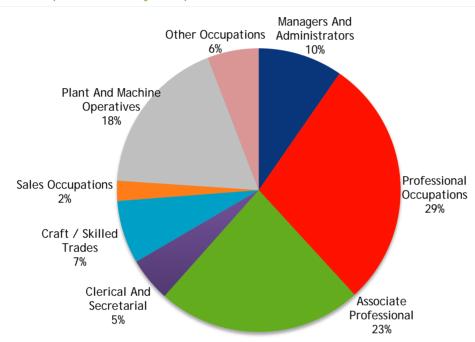


Figure 2: Biopharma Industry Occupational Profile 2015

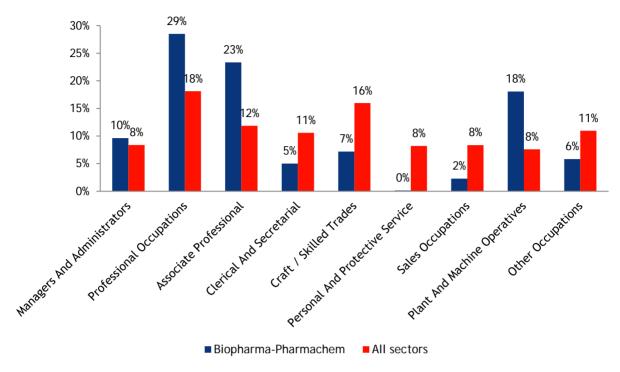
Source: Skills and Labour Market Research Unit, SOLAS, Q3, 2015.

Sixty-two percent of the Biopharma industry workforce in 2015 was male and 38% female. This is a similar gender profile as in 2010.

In 2015, around 85% of the Biopharma workforce was Irish nationals and 15% non-nationals. This can be compared to 90% Irish nationals and 10% non-nationals in 2010.

When comparing the Biopharma industry occupational profile to "all sectors" of the economy, it can be seen that there is a higher share of Higher Professionals/Associate Professionals occupations within the Biopharma industry. This comparison is outlined in Figure 3.

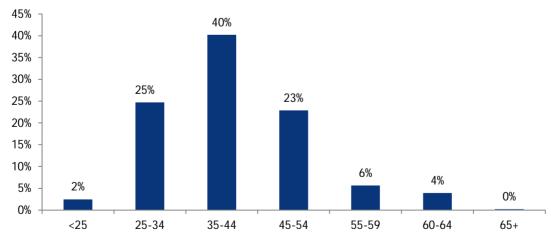
Figure 3: Biopharma Industry by Broad Occupation 2015 - vis-a-vis all Sectors



Source: Skills and Labour Market Research Unit, SOLAS, Q3, 2015.

The age profile of the Biopharma industry is presented in Figure 4. When compared to 2010, a main difference is that there are fewer workers under 34 years of age - 27% in 2015 compared to 38% in 2010. This is perhaps an indication that the industry reduced its graduate recruitment intake in recent years.

Figure 4: Biopharma Industry Age Profile



Source: Skills and Labour Market Research Unit, SOLAS, Q3, 2015.



Chapter 3: Drivers of Change impacting on Biopharma Skills **Demand**

3.1 Global Drivers of Change

Competiveness and productivity are key issues for the Biopharma industry. Operational excellence is essential. This encompasses keeping up-to-date with trends in manufacturing technology including single use equipment, process intensification, a move from batch to continuous manufacturing, and the principles of Lean Six Sigma.

An increasing proportion of new medicines are "large molecule" Biological based drugs rather than "small molecule" chemical based drugs. This has implications for the retraining/upskilling of staff within those companies that are diversifying into Biologics manufacturing and for the design/delivery of education and training programmes.

There are stringent quality compliance and regulatory demands, primarily from the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and the Irish Health Products Regulatory Authority (HPRA). This has implications for quality assurance/control/validation skillsets. The risk of a virus infection in the Biologics manufacturing process is such that it can lead to a suspension of the process, a loss of high value product and a failure to meet customer orders. This requires a high level of training and awareness of this risk among all staff working in a Biologics manufacturing facility.

As the number of products rises and new process technologies such as continuous manufacturing are introduced, the complexity of biopharma operations and the need for consistency and security of the biopharma supply chain will increase. Evidence indicates that current production programs are already stretching the industry. This challenge is likely to increase as sites move from the current "one line, one product" setup toward nimble and flexible multiple-product operations.

The use of new technologies such as process analytical technology (PAT), continuous processing technologies, single use equipment, and advanced analytics is helping to improve capabilities in both "small molecule" and "large molecule" in relation to consistent product quality, process optimisation and reduced inventory and storage needs.

The growth of more advanced data capture from patients (diagnostics, medical imaging and patient monitoring) and more complex therapeutic approaches is driving the need for information-based medicine and innovative monitoring and delivery mechanisms. This is resulting in a growing demand for bioinformatics and advanced data analytics healthcare skillsets at the interface of drug manufacturing and medical devices. More data is being captured from the production plant process, prompting improved optimisation.



The trend towards personalised healthcare is leading a shift from blockbuster products applicable to large patient populations towards niche buster products for more targeted patient populations. This is resulting in a requirement for more flexible, technology-enabled manufacturing processes and operational productivity enhancements, manufacturing of smaller batches of drugs, and the manufacturing of biologics, biosimilars, biobetters and new therapeutic platforms¹⁰.

Rising incidences of chronic diseases, due to lifestyle and dietary changes, is increasing the demand for preventive drugs and medical devices. Increased Government funding and broader insurance coverage in developed economies is generating demand for services across the health care industry. This indicates a continuing strong business and employment growth potential for the industry.

3.2 Domestic Drivers of Change

Biopharma companies in Ireland have responded in a positive way to the post-patent-cliff environment by focusing on increasing productivity and competitiveness through operational excellence, process R&D and diversification into new areas. The impact of patent expiry on drugs produced has eased significantly since 2012, although this continues to feature as a challenge, albeit to a lesser extent, as drugs that have expired since 2012 have been of less value. The most significant drug left to come off patent that is produced in Ireland is due to expire in 2016¹¹.

There is a strong pipeline of Biologic manufacturing plant capital investments amounting to over €4bn. Biologics manufacturing activity here is the fastest growing sector of the Biopharma industry. There are also opportunities arising in key services/support function activities as a result of consolidation and mergers. Ireland is developing into an important supply chain hub for the Biopharma industry. This calls for improved skills capabilities in high tech process development and support services including HR, supply chain management, regulatory affairs, finance, as well as those emerging in the areas of clinical trial management and customer/sales support functions.

Pharma "small molecule" production is moving towards lower volume, high value products runs. For example, to support this move Lilly in Kinsale is now investing €20m to build a dedicated small volume continuous manufacturing plant with a planned 2017 start-up date.

Ireland has an international reputation based on process development and manufacturing excellence. There is a strong collaboration in the research field between the Biopharma industry and State supported research centres, including the Pharmaceutical Manufacturing Technology Centre hosted by the University of Limerick, the Synthesis and Solid State Pharmaceutical Centre in the University of Limerick, the National Institute for Bioprocess Research & Training, and the

Future Skills Needs of the Biopharma Industry in Ireland

There is no unified definition of these terms. Biosimilars are terms used to describe officially approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. Unlike the more common small molecule medicines, biologics generally exhibit high molecular complexity.
Source: The Impact of the Patent Cliff on Pharma-Chem output in Ireland, Department of Finance, Working Paper Series.
No 1, 2013.



Pharmaceutical & Molecular Biotechnology Research Centre in Waterford Institute of Technology. The development of this academic/industry research capability is supported by Science Foundation Ireland (SFI), IDA Ireland, Enterprise Ireland and the Higher Education Authority (HEA).

Ireland has also invested in NIBRT as a centre of process research and training for the Biopharma industry on par or better than other competitor locations in the world. The biologics facility has been cited as a key factor in the attraction of several recent major investments. Students can gain hands-on-experience with upstream processing (including cell culture), downstream processing, bioanalytics, aseptic processing (including fill finish) and facilities/utilities. These are all operated in a realistic good manufacturing practice environment.

Ireland's Biopharma industry has an excellent track record in terms of compliance with statutory and quality regulations. The US Food and Drug Administration (FDA) and the Irish Health Products Regulatory Authority (HPRA) consistently rate Irish manufacturing practice as world class. This is an important advantage in Ireland's proposition to sustain and attract investment.

3.3 Conclusions

Global and Domestic drivers of growth are impacting on Biopharma skills demand in terms of quantity, quality and diversity of skills. This includes the general challenge of achieving innovation and operational excellence, maintaining global standards of product and process compliance, and delivering on the specific skills required for both Pharma "small molecules" as well as Biologics "large molecules" drug manufacturing.

Quality Assurance/Quality Control



Source: IDA



Chapter 4: International Country Review

4.1 Introduction

This section highlights a number of relevant skill development initiatives within several main Biopharma manufacturing hubs - UK, Switzerland, the Netherlands and Singapore. The examples provided underscore the international growth of Biologics and the recognition of the need to skill/upskill people to meet the demand in the growing part of the industry.

4.2 UK

The UK Pharmaceutical Industry employs over 70,000 people. A recent report by the Association of the British Pharmaceutical Industry (ABPI) found that the industry was experiencing difficulties sourcing workers with the skills to make vaccines, biologics, and advanced therapy medicinal products. As large molecule manufacturing grows, the Pharmaceutical industry in Britain is reporting "major skills gaps," especially in maths and computing, which need to be rectified to keep manufacturing going. ABPI speculate that this gap is probably due to the relatively small number of trained and experienced people who currently work in this sector, with increased demand driven by rapid development of biotechnology-outstripping supply. By contrast "small molecule" Active Product Ingredient manufacturing in the UK has declined in recent years as companies outsourced their production or built facilities abroad. This has reduced the size of the workforce in this area, making it harder to find skilled and experienced people for Biologics manufacturing. While MSc graduates were the biggest need within general drug production, manufacturers' major concern was the lack of PhD candidates needed for vaccines, and clinical trial manufacturing.

Process engineering skills required for process development and scale-up were identified as a major skills gap as well as quality operations, validation skills and cleaning validation (given the recently revised EU guidelines for health-based cleaning criteria). Data Analytics training is seen as important for Biologics manufacturing and companies were concerned about meeting such future needs in this area. ABPI singled out maths as an important subject for biopharmaceutical employees and recommended that students study maths alongside science subjects after the age of 16; that more emphasis be placed on maths in bioscience courses; and that there should be an increase in the number of Masters and PhD graduates with training in statistics, data mining, mathematical modelling and related disciplines.

The Biopharmaceutical Bioprocessing Technology Centre at Newcastle University, in addition to providing industry bioprocessing research, also delivers a range of continuing professional development programmes including process understanding, process analytical technology, and quality by design. These are delivered by a combination of academic and industry experts. A new £38m National Biologics Manufacturing Centre has been opened in North-East England by the Centre for Process Innovation. The centre will provide companies with open access and expertise to help them develop, prove and commercialise new and improved processes and technologies for Biologics manufacturing. Its aim is to act as a bridge between business and academia and help turn ideas into commercial reality. The new centre is part of the UK strategy for Life Science.



4.3 Switzerland

In total there are some 95,000 people employed in the 750 life science companies in Switzerland. Within this, some 250 companies are involved in biotechnology employing 15,000 people. Around 40% of these companies perform R&D activities and around 45% have manufacturing operations. Many stakeholders participate in the Swiss biotech system, supporting close ties between academia and industry. The main clusters are to be found in Geneva, Basel and Zurich. The Swiss Commission for Technology and Innovation recognises Swiss Biotech¹² as a main network for the pharmaceutical, diagnostic and health care sector in Switzerland. The Swiss Biotech network of academic institutions, enterprises suppliers and start-up companies holds regular international education courses. Its aim is to support the transfer of knowledge to fresh talent. The courses also help in identifying new specialists for companies at home.

In response to current needs, Roche is offering its employees an intensive course in biotechnology under the auspices of Biotechnet Switzerland. Lecturers from the Zurich University of Applied Sciences give participants the benefit of their expertise in theory and laboratory practice. One valuable spin-off is that this extra-mural course allows participants to create a permanent network.

4.4 Netherlands

There are around 450 life science companies operating in the Netherlands employing over 55,000 people, a majority of which are involved in medical device technology and biotechnology.

A new Biotech Training Facility (BTF) was opened in February 2016 in Leiden's Bio Science Park. The Training Facility is a production centre where pharmaceutical training is given in an actual, real-life environment. The facility can also be used as a pilot plant for testing equipment and processes. BTF is completely equipped with cleanrooms, laboratories and a technical area full of state-of-the-art, easily accessible utilities. It can also be used as a pilot plant for testing equipment and processes. BTF is completely equipped with cleanrooms, laboratories and a technical area full of state-of-theart, easily accessible utilities.

4.5 Singapore

In Singapore, several leading Biopharma companies operate multi-purpose plants with the capability to manufacture a wide range of active biopharmaceutical ingredients, Biologics and nutritionals. The Biopharma sector in Singapore currently employs 1,700 people and over the next 3-4 years is expected to create an additional 700-1,000 Biologics jobs. Singapore's Workforce Development Agency (WDA) has rolled out the Development and Apprenticeship programme to support the costs of trainees undergoing local on the job training. Some 300 places have been committed to Biopharmaceutical manufacturing in the first phase of the programme.

The Biologics Overseas Skills Training Programme (BOOST) is a manpower talent development programme aimed at building up a pipeline of specialists for Singapore's biologics manufacturing sector. The programme is jointly supported by the Singapore Economic Development Board and

¹² http://www.swissbiotech.org/ecosystem-biotech/education



Singapore Workforce Development Agency. The BOOST training model combines both workforce skills qualifications conducted at Temasek Polytechnic, and overseas structured in-house training with biologics companies in locations in the USA and Europe. A total of 150 candidates complete a 3-month full time structured training in Temasek Polytechnic and then embark on 9 to 18 months of overseas training. The training duration will take up to 21 months and competent candidates will receive a Higher Certificate in Process Technology (Biologics Manufacturing) awarded by WDA. Upon completion of training, successfully candidates are required to serve a minimum service period of 24 months in Singapore-based biologics manufacturing companies. Trainees under BOOST are supported with course fee funding, training allowances and one return economy class air ticket for the training duration.

4.6 Conclusions

Other countries are undertaking skill development initiatives in order to ensure a supply of skills and talent for the Biopharma industry, in particular for Biologics manufacturing. Features of this include the close engagement and collaboration of companies and education and training providers and also the focus on the development of the specific skills needed for Biologics manufacturing as a growing sector within the industry. If Ireland is to continue to win investment from global Biopharma companies, it must continue to invest in the skills needed to support the sector, as outlined in Chapter 6, through education, training, re-skilling and Continuous Professional Development.



Chapter 5: Views from Stakeholder Research

5.1 Introduction

The following research findings are based upon (a) structured discussions at two workshops - held in Dublin and Cork - which a range of relevant stakeholders attended, including from companies, industry representative bodies, education and training providers, and enterprise development agencies, and (b) feedback from structured questionnaires completed by Biopharma companies and other relevant stakeholders.

5.2 Trends in Biopharma Skills Demand

The Biopharma industry is in a constant state of renewal, with new products being introduced and processes changing. Demands on business are to deliver faster, guicker, better and cheaper products. Manufacturing operations are regionally based and provide sustainable well-paid employment opportunities. Many operations are run on a 24/7 operational cycle.

Over the last five years there has been a consolidation and merger of firms manufacturing Pharma "small molecule" drugs. Meanwhile, Biologics manufacturing operations (also run by companies manufacturing Pharma drugs) are expanding, with a stream of significant capital investments being made.

Improved efficiency is required in the supply chain to better manage inventories and distribution. There is an ongoing need to reduce operating costs across manufacturing and quality divisions by adopting lean practices (eliminating waste and improving energy, labour and asset efficiency), improving process technology, and new ways to improve the performance of the production process.

The Biopharma jobs market has opened up. It is a fluid labour market sector with significant labour churn. People are now willing to be more mobile and to leave a permanent job. They may have 2 or 3 job offers and are not seeking a "job for life". The career expectation of "millennials" is different. People will move more, and there is less loyalty to a single company. While firms report a relatively high level of job churn within the industry, they cite a relatively low level of replacement demand, through retirements etc. given their relatively young workforce demographic profile (more so within Biologics manufacturing).

Globally it is recognised that there is a shortage of Biopharma talent with experience. Other global Biologics Manufacturing hubs are seeking to source experienced talent. Ireland is competing with countries such as Singapore, UK, Switzerland and the Netherlands for such international skillsets.

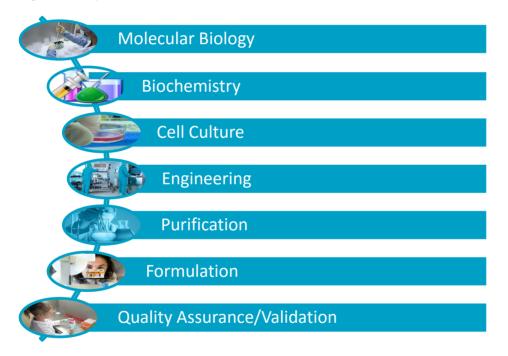


5.3 Anticipated changes in the nature of employment over next 3-5 years

It is considered likely that the recent investment in Biologics manufacturing will continue while the level of activity/employment in Pharma activities will be modest / static.

Current recruitment demand is for NFQ Level 8 for Process Engineering and Scientist roles, with a stream at NFQ Level 9 - particularly for persons with experience (companies such as Regeneron are hiring high potential graduates at Level 8 without prior experience. These are trained further by Regeneron and NIBRT). A level of recruitment and training is also taking place at NFQ Levels 6/7 supported by in-company upskilling to fill Quality Assurance/Validation and Operator roles. Soft skills such as leadership, teamworking, communications and problem solving are essential for all roles. There is a strong demand for Quality Assurance/Validation skills with analytical experience as start-up operations scale up, and for technicians with analytic skills due to ongoing plant automation. A lot of project managers and schedulers are being hired during the start-up stage.

Figure 5: Biopharma Related Roles



Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

Companies indicate an intense competition for the same skillsets and talent - especially those persons with several years' experience. Currently companies are sourcing talent from each other and there is a high reported level of turnover. There is a view that SMEs are finding it more difficult to compete for talent against large companies because, it was stated "these are able to offer higher remuneration".

Some firms' manpower planning tended to be project-driven with less emphasis on forward planning. This has implications for the formulation of education/training provision because it can take 3 to 4 years to effect any change in the quantum of supply once highlighted - although the programme content can be more readily modified by institutes through a process of minor and major programme changes and the updating of modules.



5.4 Skills challenges facing the Biopharma industry over next 3-5 years

The Biopharma industry is highly regulated with stringent clean and safe operational requirements. A particular difficulty cited is sourcing staff with over 5 years' experience. These are needed to head up teams comprised of professionals of different qualification levels including new graduate entrants. Skillsets identified as being in demand are outlined in Table 2.

Table 2: Specific Skillsets in demand within the Biopharma industry

Specific Skillsets in demand within the Biopharma industry

Bioprocess engineering/technical skills - people with several years' experience.

Biochemists and biological and chemical technicians.

Cell culture/Biologics skills - people with several years' experience.

Automation/IT systems skills.

Quality/Regulatory Affairs skills - these skills can be sourced from basic science disciplines.

Awareness of cross-functional discipline areas.

"Soft skills" - leadership, teamworking, influencing, communications, problem solving etc.

Data analytics skills - currently demand is small in numbers but rapidly growing especially as a skillset for Biochemists/Microbiologists engaged in Biologics manufacturing 13.

Strategic leaders to exploit key innovative opportunities and drive business performance requirements are small in number but key for global business innovation and growth in Ireland.

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

It is feasible to retrain/convert engineering, validation and technical personnel working in Pharma "small molecule" manufacturing to work in Biologics "large molecule" manufacturing.

Some companies are seeking to attract talent from abroad - Germany, Switzerland, UK, France, Netherlands and Poland were mentioned. This is against a background of a strong global demand for those with Biopharma skillsets. It was felt that companies could improve their approach to attracting overseas talent. There is need for a small number of strategic people within organisations to exploit key innovative opportunities and create business value with the leadership skills to lead inter-disciplinary staff. They need business acumen to envision and drive change for business performance, and with the technical knowledge to innovate business and operating models.

¹³ In this regard, the recommendations made in the EGFSN report "Assessing the Demand for Big data and Analytics Skills Data, 2013-2020, (2014), on the importance of building up the domestic supply of data analytics talent to support a strong growth in these roles across the economy is relevant.



5.5 Specific skillsets needed for Biologics Manufacturing

For Biologics manufacturing there is a strong commonality with traditional Pharma in relation to good manufacturing practice, quality risk management and operational excellence and knowledge. Such skills do not substantially differ from those required for "small molecules". There is an additional requirement for knowledge of the biologics process (upstream and downstream), aseptic techniques in manufacturing and basic knowledge of structure and stability used in biologics (DNA, protein, cells, tissues). All staff must have knowledge of contamination risks, sterile processing and cleanroom operations. The application and use of data analytics is a key emerging skills area. The specific skillsets identified for Biologics manufacturing are outlined in Table 3.

Table 3: Specific Skills Sets identified for Biologics Manufacturing

Specific Skills Sets identified for Biologics Manufacturing		
Bioprocess Engineers and Scientists with experience (from engineering or science disciplines) for both technical and management roles.	Companies are finding it hard to recruit these skillsets and are seeking to meet such needs through the upskilling of their workforce.	
Commissioning and Validation (C+V) engineers.	Required for process commissioning, qualification and validation (CQV) and the design of plants.	
Biochemists/Microbiologists with knowledge of cell culture, purification process and bioanalytical techniques with several years' experience.	Roles in Biologics can be filled by graduates with core science experience.	
Quality Assurance/Validation and Regulatory Affairs.	These roles typically comprise 30% of the workforce in a Biologics manufacturing plant. There is currently no specific qualification or academic routes into these positions. These are skillsets which are mainly being learnt in industry. Many new graduates from a science background and other discipline areas go into these roles.	
IT technicians with skills such as SAP, Oracle, enterprise resource planning and analytical skills.	The manufacturing process in a Biologics plant is highly automated with the result that the industry is seeking more of these skills.	
Sterile facility operatives and technicians with process knowledge with experience.	It is considered that in Pharma "small molecule" production that "the product can harm the operator", whereas in Biologics manufacturing "the operator can harm the product". More care and attention needs to be paid around contamination, cleanroom and critical operations. Technicians need to understand what and why they are doing things, to monitor trends and troubleshoot.	
Data Analytic Skillsets	These are in growing demand across several roles including for health product development, quality control/validation and process optimisation.	
Project Schedulers	These provide project planning/scheduling services to the project engineer within a plant. Such staff may be contracted in during the start-up period.	

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.



There is a demand for staff with awareness across a range of related disciplines who understand the manufacturing process and the drug and medicines life cycle. Soft skills including leadership, teamworking, communications, critical thinking, problem solving and a commitment to lifelong learning are essential. The 'cultural fit' of an individual within an organisation is considered important. In many cases there is a requirement for staff to work different shift hours.

Cell culture analysis



Source: IDA

5.6 Views on Biopharma related education/training provision

Given the recent surge in Biologics manufacturing investments, with all going through the same start-up lifecycle, companies have concerns around the future availability and cost of the supply of skills above existing levels. Companies are experiencing a difficulty in filling positions requiring several years' experience. It is considered more difficult to attract talent to manufacturing plants located in rural areas. Firms are making use of contract staff for roles they do not currently have the expertise in-house to perform. Competition in the jobs market is said to be driving up contractor payment rates.

A clear message is that engagement between academia and companies needs to be strengthened and that this is a two-way responsibility. It was stated by some stakeholders that the quality of higher education courses is variable, with some courses delivering what was taught 10-15 years ago. Courses need to have a stronger focus on Biologics manufacturing and sterile processing. Institutions need to undertake more regular programmatic reviews of Biopharma related programmes courses in collaboration with industry.



It was suggested that some academic staff would benefit from spending a short period in industry. Their new learning could then be incorporated into programme content and delivery. Academic staff would then have a contact within industry to refer issues to whenever necessary and vice versa. It was stated that academic research staff do this as a matter of course because of their remit.

It was stated that some Higher Education courses are being branded to attract students, with for example "medical technology" branding being used for courses that would provide a path to validation/regulatory affairs roles. However, such branding does not convey to students and parents what potential roles such programmes could lead to within the industry. Related to this is the difficulty that companies themselves have in defining and describing the roles they have on offer.

It is acknowledged that the NIBRT training is highly regarded by companies and is a key resource for research and training for the Biopharma industry in Ireland.

While firms recognise the important role that continuing professional development has to play, several cited difficulty due to pressure of work in having the time to upskill/reskill their staff. There are however several best practice examples of companies making a significant investment in the development of their staff. AbbVie was recently singled out by the "Great Place to Work Institute" for its efforts to promote employee development. Bristol-Myers Squibb has moved from "small molecule" to "larger molecule" production, involving a period of training both within NIBRT and the company - in Ireland and the USA.

The positive engagement of industry in the Springboard+ programme was highlighted as being valuable in providing additional sources of talent. Skillnets programmes run in collaboration with companies (PPD, BMS and Regeneron) and with the Department of Social Protection have been successful in placing job seekers into roles within the industry, particularly Quality/Validation roles.

There is a general lack of awareness among graduates and the public at large of the range of rewarding Biopharma career opportunities available. There is a view that many graduates do not envisage working in Biopharma - that they perceive the business as a big "grey box" - where everything is automated - and cannot imagine working there.

This perception problem may be because the Biopharma industry has mainly been recruiting to meet its replacement demand over recent years and not for expansion demand. Consequently the industry has not been marketing itself as well to students and parents compared, for example, to the IT sector. Many potential graduates are choosing careers in other sectors. This lack of a marketing effort is beginning to change with the example of a Biopharma "career village" at the recent Career Zoo exhibition, planned career days in NIBRT and companies linking into secondary schools (i.e. the Amgen Teach and Biotech Experience programmes are designed to equip secondary school teachers with the skills to increase students' interest in scientific careers).



Several companies, such as Biomarin, are visiting colleges to meet the students and lecturers in order to address the "disconnect" that current exists between students' and lecturers' knowledge of the industry and to explain their interviewing and assessment process.

5.7 Skills profile required for graduate entrants into the industry

It was felt by industry stakeholders that the quality of graduates is variable, especially with respect to interpersonal and "business ready" skills. Embedding the development of "soft skills" such as interpersonal, communications and problem solving skills and relevant Lean/Six Sigma skills into programmes and through work experience would help produce more balanced skillsets. There was some concern over the level of mathematical proficiency of graduates. It was felt that graduates could benefit from learning more about the companies selection and recruitment processes and what would be expected of them at interview.

Research feedback from companies indicates that they require graduates with strong professional effectiveness competences or potential to develop such competences, and knowledge of complementary disciplines as well as expertise in at least one main Biopharma related discipline and knowledge of the manufacturing process. These "T" shaped skills requirements for a Biopharma professional are outlined in Figure 6.

Professional Effectiveness Competences Leadership, Communications, Teamworking, Problem solving, Business **Acumen Technical Breath** "Connecting the Dots" - Knowledge of complementary disciplines **Technical Depth** Expertise in a Biopharma Discipline and manufacturing process

Figure 6: T-Shaped Professional Skills requirements for a Biopharma Professional

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

Companies now recognise that they need to open up their job search for graduate entrants. However, some seem to have an unrealistic expectation that graduates will come in and "hit the ground running". This high expectation is as much because some companies are not allocating the time necessary to provide the training that would bring new entrants up the learning curve. However, others are recognising the need to align jobs to new entrants' strengths and the need to



coach and expose new entrants to all situations, jobs/roles in the industry. Finding the right fit of person in terms of the mix of cultural, soft skills and technical skills is crucial.

Several firms consider a lack of experiential learning experience to be an initial barrier to graduate recruitment. However, some have worked around this by providing the graduate entrant with a combination of training in NIBRT and in-company training. The majority of students on Third level Biopharma programmes do not undertake experiential learning. The required facilities within institutions are not there to do this. Some institutions send their final year students to NIBRT for two day programmes to gain this practical experience. The cost for this has been met from within their own budgets, as specific funding is not available to them for this purpose and NIBRT has a requirement to be financially self-sustaining. Companies value the benefit of their workforce having participated in NIBRT training. It was mentioned that such is the demand for training in NIBRT that some firms have experienced delays in availing of it.

It was stated that work placements have a key role to play in terms of developing students' technical and soft skills. Companies consider that a 3 month placement is too short for them and that the student only becomes useful after 6 months' work experience. It was concluded that structured placements should be at least 6-9 months duration. The optimal time for placements would be at the end of the third year of a Degree programme so that students would have gained the learning to make the placement most valuable. The possibility of delivering programme modules online to students during their placement was raised.

Institutions reported that they have experienced difficulty in sourcing placements in companies. They are in competition with other institutions for available placements. Some academics do not know who the HR contacts are within each company. There is need for a resource within companies to manage work experience placements to ensure that they are structured and of benefit both to the student/graduate and the company.

Over recent years, several graduate entrant programmes have ceased because companies were not taking on as many graduates. Given the new phase of expansion, companies now recognise the need to market themselves and the industry better in order to attract the necessary skills and talent. Several graduate/internship programmes are currently in place such as those run by Genzyme, Pfizer and Regeneron. Graduate development/internship programmes have a key role to play in:

- Helping graduates to make a connection between what they are studying and the range of roles available within the industry.
- Increasing graduates' awareness of other related disciplines.
- Developing the "soft skills" of graduates especially interpersonal skills.
- Getting to know what actually happens within a Biopharma manufacturing plant.



Chapter 6: Supply of Biopharma related Skills

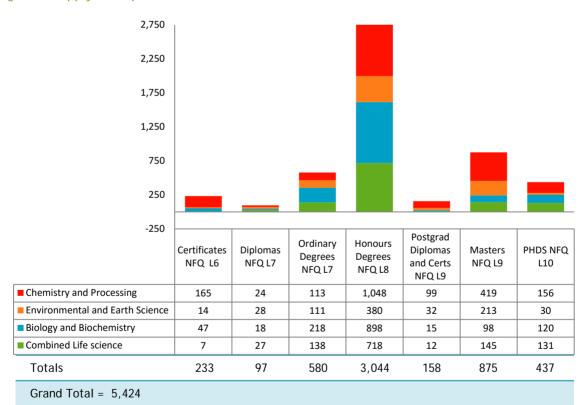
6.1 Introduction

This section assesses the supply of relevant skills available to the Biopharma industry both from the mainline education and training system, the upskilling of jobseekers and, where necessary, the attraction of international talent. Figures for graduate output are derived from an analysis of data supplied by the Higher Education Authority.

6.2 Indicative labour market inflow of Biopharma Science related graduates

In 2014 (the most recent year for which HEA awards data is available) there were 5,424 Third level awards made in Biopharma related science disciplines¹⁴. These awards are outlined in Figure 7. A significant proportion of the roles within the Biopharma industry are sourced from these disciplines. These awards are provided primarily through mainline education and training provision and also through the Springboard+ and Skillnets programmes.

Figure 7: Supply of Biopharma related Science Graduates, NFQ levels 6-10, for Year 2014



Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation Analysis of HEA Awards

 $^{^{14}}$ Chemistry & Processing includes Chemistry, Chemical Engineering and processes and Pharmacy.



Of these 5,424 graduates, a proportion will enter the labour market while others will elect to proceed directly to further studies at a higher NFQ level, take up work abroad, or otherwise be unavailable for work. In order to estimate the potential annual supply from Biopharma related science disciplines, it is assumed that the exit rates into the labour market at various NFQ levels are similar to those derived by the HEA for ICT computing graduates in the EGFSN study of High-Level ICT skills¹⁵. Applying these exit rates to the Biopharma related Science Award data for 2014 suggests an indicative labour market inflow of 3,320 as presented in Table 4.

Table 4: Indicative labour market inflow of Biopharma related Science Graduates 2014

NFQ levels of Biopharma related Science Graduates	Inflows into Labour Force
Level 6/7 Undergraduate Certificates/Diplomas and Ordinary Degree Awards (assumption that 35% enter the labour market).	320
Level 8 Honours Awards (assuming that 61% enter the labour market).	1,880
Level 9 PG Diploma/Certs/Masters (assuming that 70% enter labour market).	725
PHDs (assumption that 90% enter the labour market).	395
Total estimated numbers who entered the labour market in 2014.	3,320

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation Analysis of HEA Awards

Of this 3,320 labour market inflow, a proportion will enter employment in the Biopharma industry, but some will find employment in other sectors such as the Health sector (56% of biological scientists and biochemists work in the Health sector ¹⁶). At the same time, the Biopharma industry will attract graduates from other non-science disciplines particularly engineering, and also the health, business, maths and statistics and ICT disciplines¹⁷. Estimates of the total number of graduates entering employment in the Biopharma industry across all disciplines are elaborated on below.

6.3 Inflow of Total Graduate Talent into the Biopharma industry

Table 5 provides a breakdown provided by the HEA of the total 2014 employed graduate inflow from all fields of study whose initial employment destination was the Chemicals, Rubber & Plastic Products industry in Ireland (the Biopharma industry would comprise 80% of employment within this wider definition).

¹⁵ As outlined in EGFSN Report "Addressing Future Demand for High-Level ICT Skills", Nov 2013.

Derived from CSO 2011 Census Data.

There were also relevant QQI awards for programmes provided by ETBs including 186 NFQ level 5 laboratory techniques awards in 2014.



Table 5: Percentage of employed Graduates by NFQ levels who entered employment in the Chemicals, Rubber & Plastic Products industry in Ireland 2013 - 2014

NFQ levels	2013	2014
NFQ level 8 Honours Bachelor Degree	3.2%	2.9%
NFQ level 9 Postgraduate Diploma	1.4%	1.1%
NFQ level 9 Masters Taught	2.6%	3.0%
NFQ level 9 Masters Research	6.8%	6.1%
NFQ level 10 Doctorate	6.2%	8.0%

Source: HEA publications "What do Graduates Do" - The Classes of 2013 and 2014 - An Analysis of the First Destination of University and College of Education Graduates 9 months after graduation.

The HEA First Destination of 2014 graduates report is only available for the graduate output of the Universities and Colleges of Education. For the purpose of this exercise it is assumed that there is a similar first destination breakdown for the graduate output of the Institutes of Technology - the HEA also consider this likely.

In order to estimate the numbers entering employment in the Chemicals, Rubber & Plastic Products industry, the above percentage ratios in Table 5 are applied to the total Third Level graduate output in 2014, as published by the HEA. The resulting analysis as presented in Table 6 provides an estimated 1,005 graduates at various NFQ levels whose first destination of employment was the Chemicals, Rubber & Plastic Products industry in 2014. Of this number, it is estimated that 80% (810) would have entered the Biopharma industry. This graduate recruitment inflow includes those from science, engineering, health and business discipline areas.

Table 6: Number of Graduates by NFQ Level entering the Biopharma industry in Ireland 2014

	NFQ L6/7	NFQ L 8	NFQ L 9	NFQ L 10	Total
Total National Graduate Output (source: HEA)	16,280	30,460	18,040	1,750	66,530
% of Total National Graduate output entering employment in Ireland (source: HEA)	35% (est)	48%	62%	62%	49%
Resulting numbers entering employment in Ireland	5,700	14,620	11,185	1,085	32,590
% employed in the Chemical, Rubber & Plastics Sector (source: HEA)	2.5% estimate	3%	3% ¹⁸	8%	3.1%
Numbers entering the Chemical, Rubber & Plastics Sector	140	440	335	90	1,005
Number of graduates entering the Biopharma industry (estimated 80% of those entering the Chemical, Rubber & Plastics Sector)	110	355	270	75	810

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation - based on analysis of published HEA data.

¹⁸ The majority of Level 9 awards are Taught Masters



This estimated breakdown by NFQ levels of the estimated 810 graduates who entered employment in the Biopharma industry in Ireland in 2014 is presented in Table 7. It shows that overall three quarters of graduates are at Levels 8 or 9.

Table 7: Breakdown of graduates by NFQ levels who entered the Biopharma industry in Ireland 2014

NFQ level	Number	%
NFQ levels 6/7	110	14%
NFQ levels 8	355	43%
NFQ levels 9	270	34%
NFQ levels 10	75	9%
Total	810	100%

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

6.4 Inflow of Graduates into the Biopharma industry by main disciplines

Table 8 provides a breakdown for Years 2013 and 2014 of the percentage of employed Honour Bachelor Degree Graduates by Field of Study who entered the Chemicals, Rubber & Plastic Products industry in Ireland. This analysis illustrates that there is a significant inflow of Engineering honours graduates recruited by the Biopharma industry in addition to graduates from Science and Maths disciplines. This inflow should be taken into account in determining the potential graduate supply pool and the scope that exists for the industry to attract a greater share of available talent.

Table 8: Breakdown of NFQ Level 8 Honours Bachelor Degree Graduates by Field of Study who entered the Chemicals, Rubber & Plastic Products industry in Ireland 2014

Main Discipline Areas	2013	2014
Science & Maths ¹⁹	13%	14%
Engineering	8.2%	5.5%
Business & Social Science	1.3%	0.7%
Health and Welfare	0.6%	1.4%
Agriculture and Veterinary	1.4%	0.25%
Computer Science	1.3%	0.25%
Arts & Humanities	0.7%	0.7%
Education	1%	1%

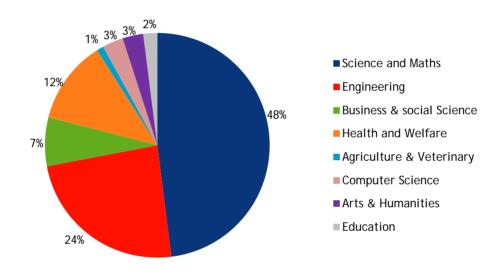
Source: HEA data "What do Graduates Do" for Years 2013 and 2014. "An Analysis of the First Destination of University and College of Education Graduates" 9 months after graduation.

¹⁹ These may include other science discipline areas in addition to those presented in Figure 7.



For indicative purposes, it is assumed that the composition for NFQ level 8 Honours Bachelor Degree Graduates, by Field of Study who entered employment in the Biopharma industry, as derived from the breakdown presented in Table 8, would pertain for graduates of all NFQ levels who entered the industry. This then would indicate that 48% of graduates who entered the Biopharma industry in 2014 were from science and maths disciplines, 24% were from engineering disciplines, 12% from health and welfare disciplines, and 7% from business disciplines. The remaining 9% were sourced from a combination of computer science, agriculture & veterinary education, and arts/humanities disciplines. The indicative breakdown of graduates entering the Biopharma industry in Ireland by main discipline areas is presented in Figure 8.

Figure 8: Breakdown of graduates by main discipline areas who entered the Biopharma industry in Ireland - 2014



Source: EGFSN Secretariat, Department Jobs, Enterprise and Innovation.

6.5 Springboard+

Springboard began in 2011 as part of the Governments' Jobs Initiative. It is managed by the Higher Education Authority on behalf of the Department of Education and Skills. The initiative provides free upskilling for unemployed jobseekers within Higher Education in areas of identified current or future skills needs. Springboard+ supports part-time courses of twelve months or less in duration (and NFQ Level 8 ICT Skills conversion courses of up to one year by full-time delivery, or part-time over two years). Its primary objective is to help unemployed people who hold a qualification at NFQ Levels 6 to 9, to re-enter employment. Both enterprise and Higher Education are engaged in the design and delivery of relevant courses. Around 90% of Springboard+ courses have included a work placement.

A sixth phase of Springboard+ was rolled out in 2016. Under the 2016 Springboard+ programme, some 935 Biopharma training places have been approved to be delivered by a range of public and private education and training providers. This investment in the upskilling of jobseekers for the Biopharma sector will provide an immediate additional source of supply for the Biopharma industry. There is also potential for further Biopharma Springboard+ provision in subsequent years.



6.6 Skillnets Training Programmes

The Pharmachem Skillnet has provided training to the industry for ten Years. It also allows companies to discuss the best training practices in good manufacturing production, environment health and safety and continuing professional development. In 2015, Pharmachem Skillnet, in collaboration with BioPharmaChem Ireland, delivered two Bio-Pharma upskilling programmes to 36 life science graduates on the Live Register. A case study on this initiative is presented below.

Pharmachem Skillnet Case Study

In 2015, the Pharmachem Jobseeker Programme run in collaboration between BioPharmaChem Ireland and Pharmachem Skillnet, delivered two Bio-Pharma upskilling programmes to 36 life science graduates on the Live Register. Of these, six gained employment in the industry at the commencement of the programmes while 30 students



completed the full course. The programmes were supported by the Department of Social Protection, Skillnets, IBEC, IDA Ireland, Tallaght IT and The Compliance Group. They were developed to address an identified skills need within the Biopharma industry and to help jobseekers with Third Level life science qualifications gain employment in the industry.

Six companies, Regeneron, Pharmaceutical Product Development Athlone (PPD), Alexion, Genzyme, MSD Brinny, and Hovione collaborated together to agree the course content, student entry requirements, programme delivery, temporary contracts and the rate of pay. The companies offered three-month paid placements allowing the job seekers to gain practical industrial experience. The participants completed a *Level 8 Certificate in BioManufacturing and Laboratory Practices* awarded by IT Tallaght, and a Level 6 award in *The Fundamentals of Working in a Regulatory Environment (GXP)* which was accredited by the School of Pharmacy in UCC.

Regeneron had a different skill requirement to the five other companies and so therefore had a stand-alone programme with twelve students. Eleven of these completed their 3 months temporary contract with Regeneron in April 2016 (one student emigrated). Of these, 7 now have full time permanent positions in Regeneron and one is working in Eurofins Lancaster Labs. The remaining three students had scheduled job interviews. The other 5 companies agreed the content of the remaining programme which 18 students completed. As of June 2016, following the completion of their temporary contracts, nine of these students have gained permanent positions, eight have received 12 month contract extensions, and one is at interview stage. All of these are in Biopharma related positions. One student gained a full time position in an unrelated area.

Overall, the retention rate of the students in the companies in which they were originally placed is high. This is a testament to the collaboration of a range of stakeholders and work put in by the Department of Social Protection Employment Services in ensuring the candidates put forward matched the companies' job specifications and having the funding available from Skillnets through the Department of Education and Skills to upskill the jobseekers, and the active participation and engagement by companies in the initiatives.



6.7 Employment Permits issued under Highly Skilled Eligible Occupations List

Table 9 provides an overview of the supply of Biopharma related occupations coming through the Employment Permit Highly Skilled Eligible Occupations List (HSOL). Roles requiring several years' experience are in demand not only within Ireland but also globally. The current number of employment permits being issued for Biopharma related occupations are relatively small compared to the overall numbers issued. (2% to 3% of the total). If necessary, there should be scope for an increased level of demand for Biopharma talent to be sourced under the HSOL, during the ramp-up stages of Biologics manufacturing operations, especially for those positions requiring several years' experience around which a team at various NFQ levels can be formed.

Table 9: Biopharma Employment Permits issued under Highly Skilled Eligible Occupations List

SOC Code	Occupation	2014	2015
2112	Biological Scientists and Biochemists	10	19
2119	Natural and Social Science Professionals	12	8
2111	Chemical Scientists	3	24
2213	Industrial Pharmacists	3	3
2113	Physical Scientists	13	6
2142	Environmental Professionals	2	1
2150	Research & Development Managers	11	11
2461	Quality Control and Planning Engineers	23	26
2462	Quality Assurance and Regulatory Professionals	23	34
2127	Production and Process Engineers	62	31
	Total Numbers	162	163
	As a % of all Employment Permits Issued	3%	2%

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

6.8 Conclusion

On the basis of assumptions made, the analysis indicates an estimated 810 graduates of various NFQ levels entered the Biopharma industry in 2014. Of these, it is estimated that 48% were from science and maths disciplines, with 24% coming from engineering, 12% from health and welfare, and 7% from business disciplines. The remaining 9% come from a combination of computer science, education, agriculture & veterinary, and arts/humanities disciplines. This inflow comprises a relatively modest proportion of the total annual outflow of graduates from science, technology, engineering and mathematics (STEM) discipline fields. There should be potential to increase the industry's share of recruitment from such disciplines. The quality of the graduate output is just as important to ensure that it is aligned and relevant to industry needs, especially for Biologics manufacturing. Biopharma roles requiring several years' experience are in demand, not only within Ireland but also globally.



Chapter 7: Demand for Biopharma Skills

7.1 Employment Trends

Employment in the Biopharma industry²⁰ fell from 28,140 in 2009 to 26,240 in 2012 and has increased since then to 28,200 in 2015. This employment trend profile is presented in Figure 9. It is estimated that, within this number, employment in Biologics manufacturing has risen from 4,000 in 2010 to 6,700 in 2015. The majority of Biopharma employment is within foreign-owned companies, with Irish owned firms mainly being engaged in sub-supply and support services for the industry.

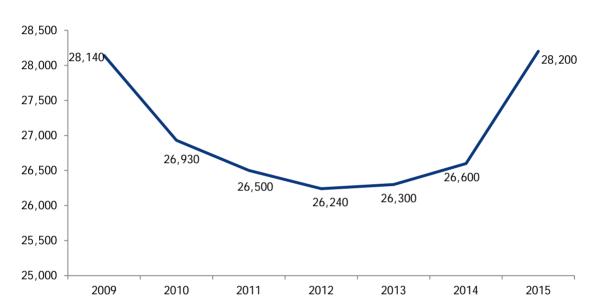


Figure 9: Biopharma industry Employment Trends

Source: Years 2009-2012 CSO Business Demography, Chemicals and Pharmaceuticals (Revs 20, 21) and Scientific Research and Development Services (Rev 72). Years 2013-2015 estimates by EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

7.2 Biopharma Investment Plans

Given recent investment plan announcements as well as feedback from the research consultations undertaken, it is anticipated that an additional 5,000 staff will be employed in Biologics manufacturing by 2020, increasing Biologics employment to 11,700, with Pharmaceutical and related services employment remaining stable at around 21,500.

²⁰ This includes the manufacturing of Chemical and Pharmaceutical products NACE Rev 2 20, and also 2 21 and also Scientific Research & Development Rev 2 72.



Of this anticipated increase of 5,000 positions in Biologics manufacturing, around 1,000 will be for roles such as facility maintenance, supply chain/logistics, human resources, finance and legal²¹. These are roles which, although they will require Biopharma domain knowledge, are also employed across other sectors. Biopharma companies will be competing for such skills sets in terms of their offerings of remuneration, conditions of work, career progression opportunities, etc. The remaining 4,000 roles will require specific Biologics related science and engineering skillsets. While many persons with such skillsets are employed within the Biopharma industry, other sectors, such as the Health sector, are also employers of these skillsets.

7.3 Replacement Demand

The number of potential job openings arising in any year includes both net jobs that have to be filled due to any expansion demand as well as existing jobs that need to be filled due to net replacement demand (arising from retirement and net movements between other sectors, full time study, unemployment, family care, and emigration).

From the research work undertaken it is estimated that the annual net replacement demand for the Biopharma industry is approx. 2.4%. This rate would be higher for the Pharmacheutical sector (which has a relatively older age profile) than that for newer Biologics manufacturing activities. This replacement demand rate results in a current average 670 potential job openings per annum.



Source: IDA

²¹ An indicative breakdown of the anticipated increase in Biologics positions by roles, numbers, NFQ levels and amount of hands on in depth training required is given in Appendix 2 - Source: Biopharma Skills Forum.



7.4 Skill Demand Scenarios

As previously stated, it is estimated that 28,200 people were employed in the Biopharma industry in Ireland in 2015, of which 21,500 were engaged in Pharmaceutical production and related services and 6,700 within Biologics manufacturing.

In assessing future skills demand, two Scenarios have been considered. Scenario 1 is based on the assumption that Biologics manufacturing employment will grow from 6,700 in 2015 to 11,700 by 2020, whilst Pharmaceutical and related services employment will remain stable at 21,500 (although the nature of the activities and roles within Pharma manufacturing will continue to change). Under this Scenario, total employment in the Biopharma industry will reach 33,200 in 2020.

Scenario 2 is also based on the assumption that there will be a growth in Biologics manufacturing from 6,700 in 2015 to 11,700 in 2020. However, in this scenario, Pharma and services related employment would reduce by 5% to 20,500 as some Pharma companies reconfigure their activities towards Biologics. The nature of activities and roles will also continue to change. Total employment under Scenario 2 would reach 32,200. Figure 10 outlines the two employment trend scenarios for the Biopharma industry.

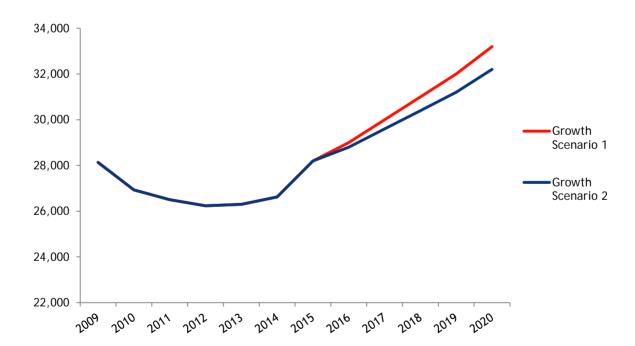


Figure 10: Biopharma industry Employment Trend Scenarios 2015-2020

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

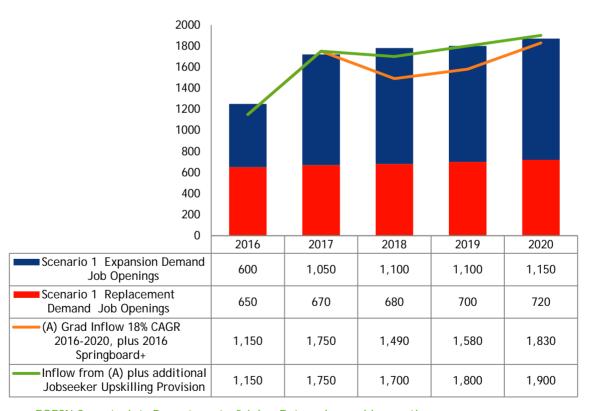


7.5 Biopharma Future Demand and Supply Scenarios

Scenario 1 is based on the assumption that there will be an increase in Biologics manufacturing from 6,700 in 2015 to 11,700 in 2020. This expansion demand is then added to an average estimated replacement demand of 680 per annum over the period to provide the total number of job openings that will arise in the industry. In total this would result in 8,400 potential job openings in the industry over the next five years, as shown on Figure 11 below.

The analysis in Figure 11 also presents how this demand can be met through increased graduate recruitment inflow, approved 2016 Springboard+ provision²², and the additional upskilling of jobseekers in years 2017/18 through Springboard+ type training provision. Skillnets programme provision will also continue to add to the supply through the upskilling of jobseekers to fill available positions/and the upskilling of those within the workforce. The Biopharma industry can also continue to draw upon available experienced international talent including expatriates. It should be noted that the industry will need to attract an 18% compound annual growth rate (CAGR) 2016-2020 increase in graduates across relevant fields of studies to meet this demand, but as outlined in Chapter 5, (along with additional jobseeker upskilling provision) this should be achievable.

Figure 11: Scenario 1- Indicative Skills Demand and Supply Biopharma industry 2016-2020



Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

²² Assumes that 65% of total Springboard + participants are employed on completion,



Scenario 2 is based on the assumption that Biologics manufacturing employment will also grow from 6,700 in 2015 to 11,700 in 2020, whilst Pharma and related services employment would reduce by 5% to 20,500 as some Pharma companies reconfigure their activities more towards Biologics manufacturing. The net expansion demand is then added to an estimated average replacement demand of 670 per annum over the period to provide the total number of job openings that would arise in the Biopharma industry over the period 2016-2020.

2000 1800 1600 1400 1200 1000 800 600 400 200 0 2,016 2.017 2.018 2,019 2,020 Scenario 2 Net Expansion 500 900 800 850 1,000 **Demand Job Openings** Scenario 2 Replacement 650 660 670 680 690 **Demand Job Openings** Grad Inflow 18% CAGR 2016-1,150 1,750 1,490 1,580 1,830 2020, plus 2016 Springboard+

Figure 12: Scenario 2- Indicative Skills Demand and Supply Biopharma industry 2016-2020

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

The analysis in Figure 12 outlines how this demand can be met through increased graduate recruitment inflow, and approved 2016 Springboard+ provision. There will continue to be a valuable role for Springboard+ and Skillnets programme provision for the upskilling of jobseekers to fill available positions/and the upskilling of those within the workforce. The industry can also continue to draw upon available experienced international talent - including expatriate talent.

7.6 Nature of Future Skills Demand

Over the next five years, it is anticipated that the Biopharma industry will create a diverse range of roles requiring specific scientific engineering and technical skills across NFQ levels 6-10. As well as technical skills, soft skills including communications, teamworking, problem solving and environmental health and safety are essential across all of these roles. Table 10 provides an outline of the nature of skills needs for Biologics Manufacturing.



Table 10: Nature of Skills needs for Biologics Manufacturing

Roles	Skills	Typical NFQ Levels
Manufacturing Engineers and Operators	Good Manufacturing Practice (GMP), aseptic and sterile manufacturing, upstream processing, cell culture, bioreactor control, downstream	Engineers: NFQ levels 8/9
	processing, chromatography, filtration, viral clearance, media and buffer preparation, validation.	Operators: NFQ level 7 - and those at NFQ level 6 with craft experience
Manufacturing Science and Technology Scientists	Good Manufacturing Practice, aseptic and sterile manufacturing, upstream processing downstream processing, molecular biology, protein characterisation, bioanalytics.	NFQ levels 7/8
Bioprocess Engineers and Technicians	Good Manufacturing Practice, aseptic and sterile manufacturing, facility management, clean utilities, calibration, automation, equipment maintenance, environmental health and safety, continuous improvement, Lean Six Sigma, project management, validation, technology transfer.	Bioprocess Engineers: NFQ levels 8/9 Technicians NFQ level 7+
Quality Assurance and Quality Control staff	Good Lab Practice, biochemistry, protein chemistry, glycan analysis, microbiology, bioassays, mass spectrometry, documentation management, quality person duties, batch release, regulatory filings.	NFQ levels 8/9
Research & Development	Clinical trial skills, Health Informatics, New product improvement and modifications, production technologies and applications.	NFQ levels 8/9/10
Supply Chain Management	Good Manufacturing Practice, production planning, procurement, stock management, distribution.	NFQ level 7+
Marketing/HR /Finance/Legal	Specific technical knowledge and domain knowledge of the Biopharma industry.	NFQ level 7+

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.



7.7 Conclusions

This section highlights how both expansion demand and replacement demand must be taken into account in estimating the total number of job openings likely to arise within the Biopharma industry up to 2020.

The presentation of the two Scenarios outlines how the levels of total job openings can be met through a combination of increased graduate inflow and through job seekers upskilling provision on Springboard+/Skillnets training programmes. This increased inflow is considered feasible given the relative scale of science, engineering, health, computing and business disciplines that the industry currently draws upon to fill available roles. This can also be set against the background of the stated objective of "Irelands National Skills Strategy 2025" for participation in STEM disciplines to grow.

It is essential that the quality of this inflow is aligned to the specific skill needs of the Biopharma industry and recommendations on this are made in the report. There is a need for the industry to be better at selling the attractive careers it has on offer to students and job seekers as well as putting graduate entrant programmes in place. There is also a sizeable cohort of job seekers' with relevant qualifications that can be drawn upon for upskilling. The industry can also continue to draw upon available experienced international talent.

The pace of change in Biopharma markets, technology and processes means that workforce skills need to be continually updated. This highlights the need for continuing professional development within the workforce to maintain global standards of product and process compliance, and deliver on the specific skills requirements for both Pharma as well as Biologics drugs manufacturing.



Chapter 8: Conclusions and Recommendations

8.1 Conclusions

The Biopharma industry in Ireland is a major employer and contributor to export growth.

Biopharma manufacturing is knowledge-intensive and requires a highly skilled workforce. Skills and talent availability is seen by companies as a key prerequisite in terms of their future competitiveness, investment and employment. Biopharma companies have responded in a positive way to the post patent-cliff environment by focusing on increasing productivity and competitiveness through operational excellence, process R&D and diversification into new areas. The impact of patent expiry on drugs produced has eased significantly since 2012 although it continues to feature as a challenge, albeit to a lesser extent, as drugs that have expired since then have been of less value.

There is a strong pipeline of Biologics Manufacturing Plant capital investments amounting to around €4bn. Biologics manufacturing activity is the fastest growing sector of the Biopharma industry. There are also opportunities arising in key services/support function activities as a result of consolidation and mergers.

Ireland is developing into an important supply chain hub for the Biopharma industry. As the number of Biopharma products rises and new process technologies such as continuous manufacturing are introduced, the complexity of Biopharma operations and the need to ensure the consistency and security of the Biopharma supply chain will increase²³.

Ireland has an international reputation based on process development and manufacturing excellence. There is a strong collaboration in the research field between the Biopharma industry and State supported research centres. The development of academic/industry Biopharma research capability is supported by Science Foundation Ireland, IDA Ireland, Enterprise Ireland and the Higher Education Authority (HEA).

Ireland has invested in NIBRT as a centre of process research and training for the Biopharma industry on par or better than other competitor locations in the world. The facility has been cited as a key factor in the attraction of several recent major investments. In this regard the investment made by Government in NIBRT has proven to be impactful.

Ireland's Biopharma industry has an excellent track record in terms of compliance with statutory and quality regulations. This is a key competence and advantage in Ireland's proposition to sustain and attract investment.

²³ In this regard, the recommendation made in the EGFSN Key Skills for Enterprise to Trade Internationally report (2012), for companies to build up their global supply chain management skills is very relevant.



Companies in the industry have traditionally been engaged in Pharma production, but in recent years the relative growth has been in Biologics manufacturing. There is a significant investment pipeline in Biologics manufacturing. Several Biologics manufacturing plants are at a start-up stage, moving over a 2 to 3 year period towards a full production state. This is putting an immediate requirement on companies' skills demand needs.

For Biologics manufacturing there is a strong commonality with traditional Pharma in relation to Good Manufacturing Practice, Quality Risk Management and operational excellence and knowledge. There is an additional requirement in Biologics for knowledge of the biotechnological process. All staff must have knowledge of contamination, sterile processing, and cleanroom and operations. Data analytics is a key emerging skills area. There is a demand for staff who can also understand the manufacturing process and the drug and medicines life cycle. There is significant demand for experienced people, especially in Process Engineering and for Quality Assurance/Validation. Within "small molecule" production there is a continuing need for upskilling with a move from volume to technology-continuous manufacturing.

Over the next five years, it is anticipated that the Biopharma industry (including sub-supply companies) will create a diverse range of roles requiring specific science, engineering, technology and business skills across NFQ levels 6-9. As well as technical skills, soft skills such as communications (written and oral), teamworking, problem solving, and environmental health and safety awareness are essential across all of these roles.

A main reason for companies' concerns is around the availability of skills supply to meet the anticipated growth in "large molecule" Biologics manufacturing. Companies also cite a lack of "soft skills" among graduates. Some companies only hire persons with a Third Level qualification for all available roles while others take in recruits at NFQ Level 6 and skill them up as well as providing experience in different functional areas.

There is a view that many science graduates do not see the industry as an attractive career and are not aware of the roles on offer or its operations. This lack of awareness goes back to second level education. There needs to be a coordinated effort by the Biopharma industry to get the message across to students and job seekers on the range of rewarding career opportunities available within the industry. This should include information on the range of drugs and medicines produced and the benefits that people receive from them.

The 'cultural fit' of an individual within an organisation is also important. In many cases this revolves around the "soft skills" competences that companies are looking, for such as showing initiative, taking responsibility, collaborating with others, communication skills, adaptability, and showing a positive attitude. A person with the required technical qualifications also needs to be able to demonstrate the above qualities.



There is need for closer engagement between companies and education/training providers to ensure an improved alignment of the design and delivery of programmes. Regular reviews of the programmes in Third Level Institutions should be held to ensure that they are market-informed and relevant. To do this, companies themselves need to engage in more forward-looking manpower planning.

The findings of this study are that the quantity of skills required from various discipline areas for anticipated Biopharma job openings up to 2020 should be available - taking into account domestic graduate output, the potential for upskilling of existing employees and jobseekers with the relevant qualifications and aptitude, and where necessary the inward migration of experienced staff, including expatriates. The challenge for the Biopharma industry, working in collaboration with education and training providers, will be to utilise all measures to enhance skills and talent capability, particularly for Biologics manufacturing. These measures include:

- The industry communicating the nature and benefits of the drugs/medicines it produces.
- Promoting the attractiveness of careers in the industry to Secondary and Third Level students.
- Attracting a bigger share of the available supply of graduates with Biopharma related skillsets.
- Utilising the significant pool of job seekers with relevant Biopharma skills and experience.
- Continuing Professional Development of staff for both "small molecule" and "large molecule" production, especially where there is a move in activities from one to the other.
- Optimising the attraction of experienced international talent.



Figure 13 below provides a SWOT Analysis of the sector.

Figure 13: SWOT Analysis of the Biopharma industry in Ireland

Weaknesses
 There is limited general awareness of the success and scale of the Biopharma industry in Ireland. Students and Parents are not fully aware of the attractive careers on offer within the industry. The level of engagement between companies and academics has weakened over recent years (although there is recognition of the need to improve this). Many students do not receive structured work place training which would be helpful in developing both their technical and "soft" skills such as communications, teamworking and problem solving. Academia requires access to the facilities and funding resources to provide experiential training for students.
Threats
 There might not be a sufficient skills supply to fully support potential Biologics employment and business growth. This is against the background of a strong global demand for Biopharma skills, especially for those with several years' experience. The cost base of the industry could dis-improve due to a shortage of skills and resultant wage inflation.

Source: EGFSN Secretariat, Department of Jobs, Enterprise and Innovation.

Future Skills Needs of the Biopharma Industry in Ireland 51

the national network of five Clinical Research

Facilities.

²⁴ The aim of the Hub is to drive collaboration between the health system and enterprise in order to facilitate enterprise develop and commercialise new healthcare technologies, products and services; facilitate the health service to find efficiencies and improvements; and to support innovative development s emerging from within the health system.

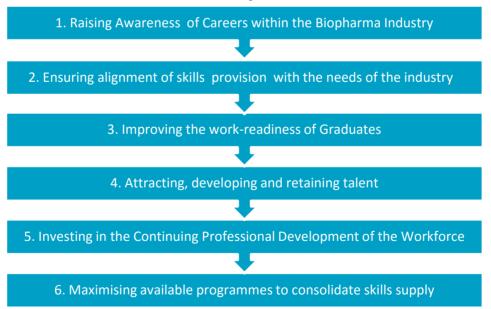


8.2 Recommendations

The following set of recommendations can serve as an Action Plan for addressing the skills and talent needs of the Biopharma industry up to 2020. They are made in the context of this study's findings that the quantity of skills supply required to meet the needs of the industry up to 2020 should be available, taking into account relevant domestic graduate output, the potential for upskilling of jobseekers with the relevant qualifications, the continuing professional development of those at work, and where necessary the inward migration of experienced staff, including expatriates. The challenge for the industry, working in collaboration with education and training providers and relevant stakeholders, will be to:

- Attract a greater number of available graduates with the right balance of skills from the fields of science, engineering, health, computing and business studies (set against the objective in Ireland's National Skills Strategy 2025 that participation in STEM will grow).
- Ensure the improved alignment and ongoing relevance of Biopharma related education and training programme content and delivery, particularly for Biologics manufacturing;
- Continue support for the upskilling of jobseekers with the necessary qualifications and aptitude to fill available job opportunity positions;
- Support the continuing professional development of those at work in both Pharma and Biologics manufacturing;
- Optimise the attraction and retention of experienced international talent.

Recommendations are made within six main headings:



The Lead Body for driving the delivery of each recommendation is identified, along with other partners who need to be involved in ensuring effective delivery. Industry members (i.e. companies) have an important role to play in ensuring that many of the recommendations are progressed.



Recommendations which could be delivered within the next twelve months and have an immediate impact are:

- Develop a set of Communications tools to promote the sector (Rec. 1.1).
- Increase industry presence at Career Fairs, Open Days, etc. (Rec.1.2).
- Continue development and utilisation of the Biopharma Skills Forum which has been established by BPCI (Rec. 2.1).
- Finalise the Biopharma Skill Forums Action Plan for Skills (Rec. 2.2).
- Engagement with the Regional Skills Fora to highlight skills requirements and career opportunities in the industry (Rec. 2.3).
- Carry out a survey to determine the capacity of companies to provide work placements on a regional basis (Rec. 3.2).
- Companies to continue to increase the scale of their Graduate Entry Development Programmes (Rec 4.1).
- Maximise use of the Springboard+ and Skillnets programmes to upskill suitable jobseekers and increase the skills supply for the Biopharma industry - with 935 Springboard+ Biopharma training places approved for 2016. (Rec 5.2, 6.2, 6.3).
- Assess the possibility of developing a new Biopharma Apprenticeship (Rec. 6.5).

The implementation of the recommendations requires a sustained effort and collaboration between all the main stakeholders. This is feasible given the strong representative body that the industry has and the relatively small number of firms that make up the sector. There is also a strong desire from industry at this time to address the skills needs of the sector.

The Biopharma Skills Forum, chaired by BioPharmaChem Ireland offers an ideal platform for many of the stakeholders to work together to drive forward the recommendations made in this report.

Recommendations are denoted by their time-period for their implementation: Short-term (within the next 12 months) and Medium-term (1-2 years).



1. Raising Awareness of Careers within the Biopharma industry

A key challenge for the Biopharma industry is to attract more graduates from relevant disciplines to work in the industry. It is competing against other sectors of the economy, and from Biopharma companies abroad, for many of the graduates who have the skills sets required for Biopharma manufacturing.

The products manufactured by the Biopharma industry are highly innovative and have a huge impact on the health and wellbeing of millions of people worldwide. However, the industry is not presenting this message clearly enough in lay-terms to students, parents, Career Guidance professional and the general public. Led by BioPharmaChem Ireland, the industry needs to develop a set of communications tools to explain what Biopharma is, the practical use of its products in the world of medicine, their impact on health and well-being and the interesting and challenging roles that people working in the sector in Ireland play in that process. There are several examples of company promotional material that could usefully be built upon.

The process of attracting students begins at Secondary school level. Amgen²⁵ and Biomarin are examples of just two companies who currently engage with teachers and Transition Year students in local Secondary schools to create awareness of the range of career opportunities available in the Biopharma Industry. There is scope to build on these initiatives by more companies reaching out to their local Secondary schools. BPCI could play a central role by promoting the approach amongst its members and tracking progress to enable a sharing of best-practice amongst its members.

Communications tools should be prepared for, and targeted at, Second Level and Third Level students, teachers, Career Guidance professionals and parents. Such tools could include printed material, videos, radio, and should use social media platforms and relevant websites. The terminology used in these materials should be standardised and should avoid industry jargon. A good example of promotional material for the sector, supported by BioPharmChem Ireland, is available on the Careers Portal website²⁶.

Communications materials will also be beneficial for use at Careers Fairs, Third Level Open Days, etc. Industry representatives have been increasing their presence at these types of events and should continue to build on this.

The following recommendations are made to raise awareness of the range of rewarding careers within the Biopharma industry:

See http://www.abeireland.com/#!programme/c14p0.
 See http://www.careersportal.ie/sectors/profile.php?client_id=40#.V0guI2dwXct.



No.	Recommendation	Timeline	Lead body	Partners in delivery
1.1	Develop a set of Communications tools to better promote the sector. These should include printed material, videos and use of	Short- Term	BioPharmaChem Ireland (BPCI)	Industry members
	social media and relevant websites targeted at Second Level and Third Level students, teachers, Career Guidance professionals and parents.			Career Guidance professionals
	The tools should explain in non-technical terms: the role of Biopharma in the field of medicine,			SFI (Smart Futures programme)
	 their impact on health and well-being, the range and nature of the work carried out in Biopharma processing, and the career progression opportunities available. 			HEIs providing relevant courses
1.2	Increase industry representation at Career Fairs, Third-Level Open Days, etc, to promote the sector and speak to students about available career opportunities.	Short- term	BPCI	Industry members
	The industry should use the opportunity of engaging with students to organise site visits to allow students to view the work undertaken by companies in the sector.			
1.3	Building on initiatives currently run by several companies in the sector, increase industry engagement with local Secondary Schools to create awareness at Transition Year stage, in particular, of the range of rewarding careers in Biopharma.	Short to Medium term	Industry members	BPCI, Local Secondary Schools
	This can be done on an incremental basis at local level by companies. However, as the industry representative body, BPCI should promote the approach amongst its members and track progress centrally, to enable a sharing of best-practice.			



2. Ensuring alignment of education and training provision with the skills needs of the Biopharma industry

Given the dynamic and changing nature of the Biopharma industry, it is essential that there is close and on-going engagement between the industry and education and training providers to ensure the relevance of programme content and delivery, particularly for Biologics manufacturing. A closer engagement will also facilitate the adaptation of programmes, where necessary, to meet emerging skills, knowledge and competency requirements of companies. The consultation process for this review suggests that the degree of engagement between companies and education and training providers can be inconsistent, with some providers responding better than others to industry requests for engagement. It was suggested that a more structured framework to support improved engagement is required.

BioPharmaChem Ireland has established a Biopharma Skills Forum to ensure that there is sufficient quantity and quality of employees to meet industry demands. The Forum includes stakeholders from industry, education and training providers, and State agencies and provides a platform for closer engagement on the skills agenda for the sector. The Forum is developing a Biopharma Skills Action Plan to quantify skills demand, increase the supply of potential skilled employees and to drive the Continuous Professional Development of existing workers. There is scope to continue to develop the Skills Forum and to ensure that the full range of providers and relevant State agencies are included on the group to support improved and structured engagement. This does not, of course, preclude individual companies from collaborating directly with education and training providers.

The new Regional Skills Fora also provide a vehicle for engagement between the industry and providers. While these Fora are at an early stage of development, in view of the regional spread of Biopharma companies, the industry should seek to ensure that its skills requirements and career opportunities are represented on these Fora, either through direct participation by companies, or through BioPharmaChem Ireland or an associated industry representative body such as IBEC.

Given the rapid growth of Biologics manufacturing, education and training providers would benefit from a structured programme of placement opportunities for relevant academic staff in Biopharma companies to ensure they are fully au fait with the latest processes, procedures and technologies in the sector. This could potentially be arranged in the early Summer period and might last for a period of 1-3 weeks. Company staff can also add value to programmes in education and training institutions by providing staff to give lectures on particular course modules. This exchange programme (whether two-way or one-way depending on the particular institution/company) should be piloted with one or two Higher Education Institutions, and rolled out more widely, based on the learnings from the initial pilot.

Given the pace at which increased investment in the industry has taken place in recent years, there is a risk that the focus of the planning of provision - from both an industry perspective and an education/training provider perspective - could become overly focused on shorter term skills demands. It is important also that the sector continues to be forward-looking and identify new emerging skills trends. For example, the demand for PhD graduates is expected to grow between now and 2020, particularly where companies increase their R&D activities.



The following recommendations are made to help ensure Biopharma education and training provision meets the skills, knowledge and competency needs of the industry.

No.	Recommendation	Timeline	Lead body	Partners in delivery
2.1	Continue to develop the Biopharma Skills Forum, to include representation from both the Further Education and Higher Education sector (e.g. HEA, SOLAS).	Short- term	BPCI	Biopharma Skills Forum members
2.2	The Biopharma Skills Forum to finalise its Action Plan for Biopharma Skills, taking account of the recommendations made in this EGFSN report. The measures in the Action Plan need to be specific in terms of how actions are to be delivered and by whom. The Plan should be updated on an on-going basis, to allow for additional actions to be added, and underpinned by a regular monitoring and reporting system.	Short- term	BPCI	Biopharma Skills Forum members
2.3	Given the regional spread of Biopharma companies and employment in Ireland, to ensure that the skills requirements of the industry - as well as career opportunities - are reflected in the new Regional Skills Fora, through direct participation on the Fora by companies or through an industry representative body.	Short- term	BPCI (to coordinate)	Regional Skills Fora managers, Industry members
2.4	Education and Training providers to carry out more regular reviews of Biopharma in collaboration with industry, to ensure the alignment of programmes with the skills, knowledge and competency needs of industry. This should include consideration of the development and delivery of elective modules for both small and large molecule manufacturing processes.	Medium- term	Relevant HEIs and ETBs	Local Biopharma- companies, HEA, QQI
2.5	Identify participant partners, and pilot exchange opportunities of 1 to 3 weeks' duration for academic staff and staff in Biopharma companies. Roll out the initiative more widely, based on the learnings from the initial pilot.	Medium- term	Biopharma Skills Forum	Selected Higher Education Institutions and companies
2.6	Engage in greater forward-planning of manpower requirements within companies in order to identify emerging skills demand, and communicate these to education and training providers.	Medium- term	Industry members	Relevant education and training institutions



3. Improving the work-readiness of Graduates

The research consultation process for this study indicated that companies in the Biopharma industry value graduates with a balance of both "soft" and technical skills. Embedding the development of "soft skills" such as interpersonal, communications and problem solving skills and relevant business skills into programmes and through work experience would help produce more balanced skillsets.

The research also highlighted the need for structured student work placements of at least 6-9 months duration as being key to improving the employability of graduates (as did the 2010 EGFSN report on the Skills needs of the Biopharma-Pharmachem industry). They can be a transformative experience in supporting graduates to be more "job ready".

While work placements and experiential learning are currently provided on some courses, they need to become an integral part of all Biopharma related programme provision. Including work placements in all relevant courses will require companies to make opportunities available for undergraduates. It may be helpful for BioPharmaChem Ireland to carry out a survey to determine the capacity of its members to offer such placements on a regional basis. This would provide a useful starting point for engagement with education and training providers on formalising a structured work experience module for undergraduates on Biopharma courses.

The delivery of online learning modules to students during work placements should be examined, to ensure a blend of continued academic learning in parallel with practical in-company work experience. The potential for undertaking academic supervised tasks such as credited placement modules and credited research projects, should also be considered.

No.	Recommendation	Timeline	Lead body	Partners in delivery
3.1	Industry should identify core skills and competencies required for roles within the main functional areas of the industry, particularly for Biologics manufacturing. These need to be communicated to education and training providers and students, by using channels such as the Biopharma Skills Forum, Career Guidance professionals, and programme reviews by the Higher Education	Short to Medium term	BPCI (to coordinate)	HEIs, Career Guidance professionals
3.2	Institutions (see Rec. 2.4). BioPharmaChem Ireland to carry out a survey to determine the capacity of its members to offer work placements on a regional basis.	Short- term	BPCI	Industry members
3.3	Education and training providers to provide accredited practical work placements of 6-9 months duration on all Biopharma related courses in collaboration with companies in the industry.	Medium- term	HEIs	HEA, Industry members



3.4	In relation to relevant ETB provision, strengthen the work place training element in collaboration with companies in the industry.	Medium term	ETBs	SOLAS, Industry members
3.5	Provide Third Level graduates studying Biopharma related subjects with opportunities for experiential learning in their final years of study - with co-ordinated use made of training in NIBRT and other relevant institution facilities.	Medium- term	HEIs providing relevant courses	HEA, BPCI
3.6	Explore the potential for a dedicated funding stream to support this experiential learning through the Biopharma Skills Forum.	Short to Medium term	Biopharma Skills Forum	HEA
3.7	Deliver online modules to students during placements, to ensure a blend of continued academic learning in parallel with practical incompany work experience.	Medium- term	HEIs & ETBs providing relevant courses	HEA, SOLAS



4. Attracting, developing and retaining talent

Biopharma companies have a central role to play in putting best practices in place for the attraction, development and retention of talent. This is closely linked with increasing awareness of the work of the industry and its career potential. Differentiated strategies should be adopted for attracting different cohorts to the industry - e.g. new graduates, professionals with several years' experience, levels 5/6 entrants, overseas talent, etc.

Structured Graduate Entry programmes are successful in helping to better integrate new graduates into a company and supporting their career progression. They ensure a cadre of highly skilled recruits. Consultations carried for this review suggests that there is considerable scope for companies to expand their Graduate Entry programmes. The selection of suitable candidates for such programmes would be assisted by the introduction of work experience modules for undergraduates referred to above, ensuring that graduate recruits have already had some engagement with the complex and highly regulated manufacturing processes in the industry.

While the supply of graduates with the relevant education and training (including the upskilling of job seekers with the right qualifications and aptitude) should be available to meet the skills demand needs of the Biopharma Industry over the next five years, there is also merit in continuing to attract experienced international talent, including expatriates, to add necessary experience and diversity to the sector in Ireland.

Nine of the world's Top Ten Pharmaceutical companies are based in Ireland and the country is emerging as a leading location for Biopharma, with a strong pipeline of investments. This presents an opportunity to develop an information/media campaign to promote Ireland as a location of choice for experienced overseas workers with Biopharma skills. This campaign can complement the IDA's on-going efforts to attract investment into Ireland.

No.	Recommendation	Timeline	Lead body	Partners in delivery
4.1	Companies to increase the scale of their Graduate Entry Developmental Programmes. These should be sustained over time.	Short to Medium term	Industry members	
4.2	Develop an international information campaign to increase awareness of Ireland as a location of choice for experienced workers with Biopharma skills.	Medium term	BPCI	IDA Ireland



5. Investing in the Continuing Professional Development of the Workforce

The pace of change in Biopharma markets, technology and processes means that workforce skills need to be continually updated. This includes the general challenge of achieving innovation and operational excellence, maintaining global standards of product and process compliance, and delivering on the specific skills required for both Pharma as well as Biologics manufacturing.

No.	Recommendation	Timeline	Lead body	Partners in delivery
5.1	Companies to optimise use of their own inhouse training, along with NIBRT and other relevant training facilities, to bring their workforce through successive lifecycle stages of a start-up operation - commissioning, validation and manufacturing. This approach could be done in partnership with professional bodies which support Continuous Professional Development of members ²⁷ .	Short to Medium Term	Industry members	NIBRT & other relevant education/ training providers, Relevant professional bodies
5.2	Companies to maximise use of the Skillnets training networks model to upskill their staff.	Short Term	BPCI (to coordinate)	Industry members, Skillnets
5.3	Improve the understanding by key staff working in "small molecule" operations of the "large molecule" manufacturing process through Continuous Professional Development.	Short to Medium Term	Industry members	Relevant education/ training providers
5.4	Provide Biopharma-Leadership Training Programmes for middle and senior level managers, for the development of the strategic leadership skills, technical knowledge and business acumen to drive global Biopharma business growth.	Medium Term	Industry members	Relevant education/ training providers
5.5	Explore with education and training providers the potential to increase the provision and use of flexible, part-time, accredited online programmes for those at work and those seeking employment in the industry. This provision could be blended with workshop activities in education institutes/training centres ²⁸ .	Medium Term	BPCI	Industry members, Relevant education/ training providers

Such as Engineers Ireland.

28 Examples of this include IT Sligo online Pharmaceutical and Biopharmaceutical Courses at different NFQ levels run by the School of Science which may also incorporate laboratory practical days in the NIBRT training facility.



6. Maximising available programmes to consolidate skills supply

Upskilling/Conversion Programmes for job seekers and returnees should be developed through collaboration between education/training providers and enterprises. This should include a period of structured practical work placement experience within companies. Under the Springboard+ skills conversion programme, 935 Biopharma training places have been approved for 2016.

The Skillnets training programme has also proven to be valuable for upskilling of job seekers in the Biopharma sector. While a number of large companies have participated in the programme, the model could potentially also be used by a wider network of smaller companies. As part of the process, the Department of Social Protection (DSP) identifies job seekers who had previously worked in Biopharma or related roles and who would be interested in upskilling for available opportunities. Training is then provided by companies, in collaboration with Skillnets.

The Cork ETB Biopharma Training Facility located in Carrigaline provides NFQ Level 5 course certification in Lifescience manufacturing operations which helps learners enter the industry and progress to a higher level.

A new Apprenticeship model was introduced in 2015 by the Minister for Education and Skills. The model extends Apprenticeships beyond the traditional sectors, to provide new opportunities for structured training to meet the needs of the modern economy. The first call for proposals under the Apprenticeship model closed at the end of March 2015.

A new Apprenticeship for the Biopharma industry would open up a vocational route into careers within the industry. The industry should assess the possibility of developing new Biopharma Apprenticeship(s) in advance of any future call for new Apprenticeship proposals. This option might be best coordinated through the Biopharma Skills Forum. The Apprenticeship programme(s) would require a combination of formal learning and industry placement, with progression pathways facilitated between levels 6/7 and levels 8/9.

Prior to the call for any new Apprenticeship proposals, the industry itself could develop and pilot a "National Biopharma Career Traineeship" as a precursor initiative.



No.	Recommendation	Timeline	Lead body	Partners in delivery
6.1	Continue to provide adequate funding for competitive programmes such as Springboard+ and Skillnets to offer the opportunity for the Biopharma industry to build on the success of these programmes in addressing skills supply for the industry.	Short term to Medium term	DSP HEA	
6.2	Maximise use of the annual Springboard skills conversion programme to upskill suitable candidates to work in the Biopharma industry.	Short term	Education and training providers	Industry companies, DES
6.3	Build on the experience of programmes run with companies in the Biopharma sector to identify and upskill suitable jobseekers through a collaborative approach involving companies, the Department of Social Protection and Skillnets.	Short term to Medium term	Industry companies	DSP, Skillnets, NIBRT and other training providers
6.4	Utilise valuable ETB Carrigaline Co. Cork facility for Level 5/6 training.	Short term to Medium term	ETB Carrigaline	SOLAS
6.5	Assess the possibility of developing a new Biopharma Apprenticeship(s) in advance of any future call for new Apprenticeships proposals, building upon the criteria announced by the Apprenticeship Council in 2015 for the new Apprenticeships programmes.	Short term	Biopharma Skills Forum	Industry companies
6.6	Prior to the call for any new Apprenticeship proposals, develop and pilot a Biopharma Career Traineeship (which could be entitled a "National Biopharma Training Scholarship"), as a precursor initiative.	Short term	BPCI	Selected education/ training providers, QQI



Appendix 1: Terms of Reference

Biopharma Skills Study Ireland 2016-2020

Objectives

This study forms part of the work programme of the Expert Group on Future Skills Needs for 2016 and is included as an action within the Action Plan for Jobs 2016. The objective of the study is to review the demand for and supply of skills required to address the skill needs of the Biopharma industry in Ireland up to 2020. There is a specific focus on Biologics manufacturing which is a growing sector of the industry with its own specific skill needs. The aim is to ensure that the right skills (to meet both expansion and replacement demand) are available to drive business and employment growth and help graduates and job seekers fill potential job openings. The most recent study in this area was carried out in 2010.

The intended outcome is a report assessing the current and future skills needs of the industry and how any identified skills gaps (in terms of quantity, quality and diversity) may be addressed, including through:

- raising awareness of the interesting and rewarding career opportunities in the sector;
- further education and training, and higher education provision;
- continuing professional development;
- talent recruitment and retention practices;
- retraining of jobseekers; and
- inward migration of experienced talent including expatriates.

Background

There has been a significant level of investment announcements within the Biopharma industry in recent years with much of this being within Biologics manufacturing. An increasing proportion of new medicines are "large molecule" Biologics based, rather than chemically - processed "small molecule" medicines. The skills needed for the research, development, manufacturing and commercialisation of large molecule biologics medicines are very specific and key to the ability of the industry to deliver innovative medicines to patients.

It is estimated that there were 28,200 people employed within the Biopharma industry in 2015, and that within this total, employment in Biologics manufacturing has increased to around 6,000. The need for a collaborative approach to ensure the adequacy of the supply of Biopharma skills and talent has been raised by the industry. Skills and talent availability is seen as a key prerequisite in terms of future competitiveness, investment and employment. It is recognised that industry, training and employment providers and other stakeholders all have a key role in developing the skills and talent pipeline.



Methodology for Study

The methodology comprises several integrated elements. These are outlined as follows:

- Review the main trends and drivers of change impacting on the industry's current and future skills and competency requirements.
- Determine the 2016 baseline workforce profile of the industry.
- Undertake a structured Survey of Key Informants enterprises and organisations on skill demand needs and how to address them.
- Hold two workshops (Cork and Dublin) on Biopharma skill needs and supply provision with selected Biopharma companies, employer organisations, training and education providers, research bodies and State Agencies, including IDA Ireland, Enterprise Ireland and Science Foundation Ireland (SFI).
- Profile the current supply of relevant skills from training and education provision.
- Consider the scope for the upskilling of jobseekers to fill potential job openings.
- Consider how any identified gaps in skill provision quantity, quality and diversity may be addressed, particularly within Biologics manufacturing.
- Review actions taken by other countries to develop a supply of relevant talent.
- Recommend responses to address any identified gaps in skills provision.

Outputs

The output will be a report reflecting the current position with regard to the skills needs of the Biopharma Industry, with a particular focus on the needs of Biologics manufacturing. It will include recommendations on measures to build up the domestic supply of skills and talent over the period 2014-2020, including through (a) the higher education and further education systems; (b) upskilling /reskilling; (c) continuing professional development; (d) talent retention initiatives; (e) upskilling of job seekers; and (f) inward migration including expatriate supply. Recommendations made will advise on optimising the use of existing resources - by both Government and the private industry.

Project Time Line

A Draft Final Report will be presented to the Expert Group on Future Skills Needs for consideration in June 2016 and will be published following approval.



Appendix 2: Estimated Breakdown of Forecast Biologics Manufacturing Jobs²⁹

Department	Projected Employment Requirement	Likely Educational Level	Intensity of training ³⁰
Manufacturing			
Upstream Processing	369	seven/eight	10
Downstream Processing	369	seven/eight	10
Support Manufacturing	387	seven/eight	10
Process Engineering	165	eight/nine	8
Lean improvements.	55	eight/nine	7
New product Introduction	138	eight/nine	7
Process improvement	82	eight/nine	6
Technical support	82	eight/nine	7
Programme management	46	eight/nine	5
Facilities maintenance	276	six/seven	9
Utilities operation	82	six/seven	7
Calibration	110	six/seven	10
Automation	82	six/seven	10
Quality Assurance	276	eight/nine	5
Quality Control	442	eight/nine	5
Quality Systems	55	eight/nine	5
Validation	138	eight/nine	6
Microbiology	111	seven/eight	5
Regulatory	55	eight/nine	6
Fill Finish/Packaging et	850	seven/eight	10
Supply Chain/Logistics	331	eight/nine	6
Human Resources	180	eight/nine	6
Finance	193	eight/nine	5
TOTAL	4874		

Source: Biopharma Skills Forum.

Intensity refers to amount of hands on in depth training required - or that knowledge that cannot be just taught in a classroom environment.



Appendix 3: Members of the Validation Group

Name	Organisation	
Brendan Murphy	Cork Institute of Technology	
Matt Moran	BioPharmaChem Ireland	
Louise Prendergast	Bristol Myers Squibb	
Dominic Carolan	NIBRT	
Tommy Fanning	IDA Ireland	
Ray Bowe	IDA Ireland	
Rory Mullan	IDA Ireland	
Cepta Duffy	Enterprise Ireland	
Peter Clifford	Science Foundation Ireland	
Vivienne Patterson	Higher Education Authority	
William Parnell (Chair)	Department of Jobs, Enterprise and Innovation	
Gerard Walker (Project Manager) Department of Jobs, Enterprise and Inno		



Appendix 4: Questionnaire: Future Skills Demand within the Biopharma industry

Company Profile

Size of Company - Number of Employees

Under 100 Please Tick (√)

100-500

500-1000

1.000 +

Type of activities engaged in Biologics-large molecules

Pharmachem-small molecules

Bio-Pharma related Services

Ownership Foreign-Owned Company

(please tick relevant ownership) Irish-Owned Company

Current Skills Needs

- Q1 What are the key drivers of change impacting on skills demand in your company at present?
- 02 In what way are these skills demands impacting on different roles within your company?
- 03 What skillsets, qualifications and levels of experience are needed for Biologics?
- Q4 In what ways do these skills requirements differ from small molecules production?
- 05 Are there any critical skills needs that are not currently being met for Biologics Manufacturing, and if so, what are they?
- Q6 More generally, are there any specific roles /disciplines where you are seeing a skills need for which there is a supply shortage (including admin, supply chain functions, etc)?

Emerging and Future skills needs

- 07 Over the next 2-5 years what % change (+or-) do you anticipate in the level of employment within your company - and which roles will be in greatest demand?
- **Q8** What do you believe are the key skills challenges facing the Biopharma Industry and specifically Biologics manufacturing over the next 3-5 years?
- Q9 Views on the reasons for any skills gaps that are evident or expected?
- Q9 Is staff turnover/churn a problem in your company - if so why and for which roles?
- Q10 Is replacement demand (retirements) a problem for your company - if so for why, and for which roles?



Views on the Quantity and Quality of available skills supply

- Q11 What are your views on Biopharma-related education/training provision?
- Q12 In your view, does anything need to be done to improve the quantity and/or quality of provision, and if so in what way?
- Q13 Does education/training provision for Biologics manufacturing specifically need to be improved? If so, please indicate in what way?
- Q14 Are new graduates' skills profiles aligned to your company needs? If they need to be improved, in what way?
- Q15 What level of engagement does your company have with education/training providers?
- Q16 What can be done by either by your company, the industry as a whole, or education & training providers to improve the quality of this engagement?
- Q17 What are your views about the effectiveness of current initiatives (including workplacement programmes, experiential learning, etc.) in helping to ensure that the skills profiles of graduates are aligned to the needs of enterprises?
- Q18 What role does in-house CPD provision play in upskilling/reskilling staff in your company?

Proposals to address Skills Demand and Supply

Imagine an ideal scenario where the skills demand and supply for Biopharma manufacturing and specifically for Biologics manufacturing is in balance in 3 years' time - what proposals would you make to achieve this? (Areas you may wish to consider include career advice and promotion; alignment of education and training provision; engagement between enterprise and education; continuing professional development; attraction and recruitment practice; graduate placement/experiential learning; retraining of job seekers; inward migration, etc.).

Proposal 1

What is the Proposal?

How could this be done?

Who would be responsible for its implementation?

Proposal 2

What is the Proposal?

How could this be done?

Who would be responsible for its implementation?

Proposal 3

What is the Proposal?

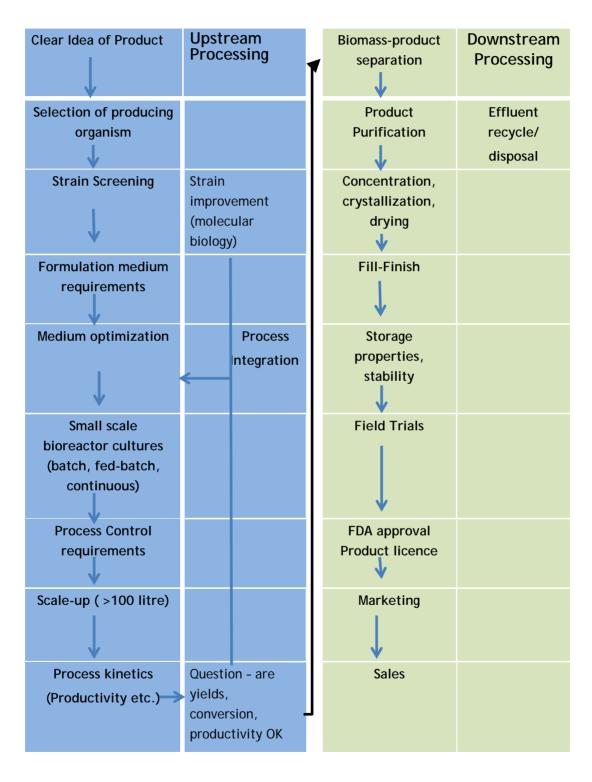
How could this be done?

Who would be responsible for its implementation?

Q20 Would you like to offer any other comments which have not been addressed above?



Appendix 5: Overview of Upstream and Downstream Processing of Biopharmaceuticals



Source: Presentation by Ian Marison, Professor of Bioprocess Engineering, DCU.



Appendix 6: Glossary of Terms used in the report

Antibody	An infection fighting protein molecule that tags, neutralizes, and helps destroy foreign microorganisms or toxins.
Antibody Drug Conjugate	Biotherapeutics that combine the antigen-specific selectivity and antitumor activity of monoclonal antibodies with the potency of cytotoxic molecules.
Aseptic	Sterile, free from bacteria, viruses, and other pathogenic contaminants.
Batch	A quantity of a drug substance or drug product with uniform character and quality, within specified limits, produced according to a single manufacturing run during the same cycle of manufacturing.
Bioanalytics	The quantitative measurement of drugs and biological molecules in unnatural locations or concentrations and biotics in biological systems.
Bioassay	Inoculation of an infectious substance into an animal to see if it develops the same disease as a control animal; other analytical methods that use living cells, tissues, or organisms as test subjects.
Biobetter	A follow-on biologic that implies some improvement on an existing biologic.
Bioinformatics	Use of computers for searching and analysis of electronic databases of genomes and protein sequences, and computer modelling of biologic systems.
Biopharmaceuticals A therapeutic product created through the genetic manipulation of	
Biosimilar	A biopharmaceutical that is produced using a different cell line and/or different process yet meets criteria for comparability in clinical activity.
Bioreactor	A vessel capable of supporting a cell culture in which a biological transformation takes place (also called a fermenter or reactor).
Buffer (buffering agent)	A solution containing a weak acid and a conjugate base of acid; it resists change in pH near a specific value when an acid or a base is added to it.
Cell Culture	Cells taken from a living organism and grown in a lab ("in culture").
Chromatography	A technique used to separate molecules based on how they tend to bind to various solids, liquids and gases.
Downstream Processing	Bioprocessing steps following fermentation and/or cell culture, a sequence of separation and purification activities needed to obtain the drug product at the necessary level of purity.
Fill and Finish	The final filling of the formulated vaccine into containers, e.g. vials, pre-filled syringes.
Filtration	Separation of solid particles from a fluid by passing the mixture through a porous, fibrous or granular substance.
Formulation	The method and process of selecting the components of a mixture; the product of such a process; the form in which a drug is given to patients (tablets or injections) developed in concert with a drug delivery system and targeting mechanism needed to get the active ingredient to its site of action.



Glycan	Refers to polysaccharide or oligosaccharide that can be found attached to proteins.
Good Manufacturing Practices	Good Manufacturing Practices influences the manner in which biopharmaceuticals and other drugs and medical devices are produced. Standard operating procedures must be followed, processes must be validated, equipment qualified, and properly trained staff must maintain a clean/sterile environment.
Lean Six Sigma	A team effort to improve performance, combining lean manufacturing/lean enterprise and Six Sigma to eliminate eight kinds of waste: time, inventory, motion, waiting, over production, over processing, defects, and skills.
Mass Spectrometry	An analytical technique to measure the mass-to-charge ratio of charged particles.
Media	Plural form of medium - A usually sterile preparation made for the growth, storage, maintenance or transport of micro-organisms or other cells.
Protein	Complex organic macromolecules whose structures are coded in an organism's DNA. Each protein has a unique, genetically defined amino acid sequence that determines its specific shape and function.
Purification	A central part of downstream processing that takes a crude fermentation or cell homogenate and isolates the product from it in a fairly pure form.
Process Analytical Technology	A system for designing, analysing, and controlling manufacturing through measurements of critical quality and performance attributes of raw and inprocess materials and processes to ensure final product quality.
Quality Assurance	The quality systems and processes used to control every manufacturing step to ensure that the product meets all of its specifications.
Quality Control	The system of testing that confirms and measures the quality of raw materials, process intermediates, final product and environmental samples, during ongoing production as well as during start up and validation.
Sterile	Absolutely free of any microbiological contamination.
Upstream Processing	The cell-culture or fermentation process used to express proteins. The output of upstream processing is an aqueous solution containing, recombinant protein, dells, amino acids, buffer salts, nutrients and other additives.
Vaccines	Preparations that elicit an immune response (production of antibodies) to protect a person or animal from a disease causing agent.
Validation	Documented evidence that shows that a process, when operating within specified critical parameters, has a high probability of meeting specifications.
Viral clearance	Process step which separates a given class of virus, if any are present, from the desired product.
Virus	The simplest form of life. They cannot reproduce on their own but require the aid of a host (bacteria, plant or animal). The host cells synthesis is often inhibited by the infecting virus, which may or may not result in disease.



Appendix 7: Members of the Expert Group on Future Skills Needs

Name	Organisation	
Una Halligan	Chairperson	
William Parnell	Head of Secretariat and Principal Officer, Skills & Education Unit, Department of Jobs, Enterprise and Innovation	
Inez Bailey	Director, National Adult Literacy Agency	
Peter Baldwin	Assistant Secretary, Department of Education and Skills	
Ray Bowe	IDA Ireland	
John Burke	Department of Public Expenditure and Reform	
Liz Carroll	Training and Development Manager, ISME	
Ned Costello	Chief Executive, Irish Universities Association	
Margaret Cox	Managing Director, I.C.E. Group	
Mark Christal	Manager CMD and Client Skills, Enterprise Ireland	
Bill Doherty	Executive Vice President, EMEA, Cook Medical	
Tony Donohoe	Head of Education, Social and Innovation Policy, IBEC	
Bryan Fields	Director, Strategy, Research and Evaluation, SOLAS	
Paul Healy	CEO, Skillnets	
Joe Hogan	Founder, Chief Technology Officer & VP Openet Labs & IP Management	
Declan Hughes	Assistant Secretary, Department of Jobs, Enterprise and Innovation	
Brendan Murphy	President, Cork Institute of Technology	
Vivienne Patterson	Higher Education Authority	
Peter Rigney	Industrial Officer, ICTU	



Appendix 8: Recent Publications by the Expert Group on Future Skills Needs

Report	Date of Publication
The Expert Group on Future Skills Needs Statement of Activity 2015	May 2016
Vacancy Overview 2015	May 2016
Guidance for Higher Education Providers on Current and Future Skills Needs of Enterprise: Springboard+ 2016	February 2016
Assessment of Future Skills Requirements in the Hospitality Sector in Ireland, 2015-2020	November 2015
Regional Labour Markets Bulletin 2015	October 2015
Monitoring Ireland's Skills Supply: Trends in Education and Training Outputs 2015	August 2015
National Skills Bulletin 2015	July 2015
Vacancy Overview 2014	May 2015
Lifelong Learning among Adults in Ireland, Quarter 4 2014	May 2015
A Study of the Current and Future Skills Requirements of the Marine/Maritime Economy to 2020	April 2015
The Expert Group on Future Skills Needs Statement of Activity 2014	April 2015
Addressing the Demand for Skills in the Freight Transport, Distribution and Logistics Sector in Ireland 2015 - 2020	February 2015
Guidance for Higher Education Providers on Current and Future Skills Needs of Enterprise: Springboard 2015	January 2015
Regional Labour Markets Bulletin 2014	September 2014
Monitoring Ireland's Skills Supply: Trends in Education and Training Outputs 2014	August 2014
National Skills Bulletin 2014	July 2014
Vacancy Overview 2013	May 2014
Assessing the Demand for Big Data and Analytics Skills, 2013 - 2020	May 2014
The Expert Group on Future Skills Needs Statement of Activity 2013	March 2014
Regional Labour Markets Bulletin 2013	March 2014
Guidance for Higher Education Providers on Current and Future Skills Needs of Enterprise: Springboard 2014	February 2014



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Expert Group on Future Skills Needs

c/o Department of Jobs, Enterprise and Innovation Kildare Street Dublin 2

Tel: 631 2881

Email: info@skillsireland.ie Website: www.skillsireland.ie