

# Intensification of RNA Therapeutics Manufacturing

A Workforce Foresighting Hub call to action report.





Authors: CPI, working with FUJIFILM Diosynth Biotechnologies. Date: June 2024



Attributions - The Workforce Foresighting process integrates data from the following international data sets:

IFATE – Institute for Apprenticeships and Technical Education, England

ESCO – European Skills, Competencies, Qualifications & Occupations, EU

ONet – Occupational Networks Online, USA

*In accordance with licence and publishing requirements of these organisations for the use of their data sets, the WFH team states that –* 

The IFATE data used contains public sector information licensed under the Open Government Licence v1.0.

The ESCO data is used in accordance with the EUROPEAN UNION PUBLIC LICENCE v. 1.2 EUPL © the European Union 2007, 2016

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Any errors, omissions and incorrect data are the responsibility of the WFH team and all queries should be addressed to <u>info@iuk.wf-hub.org</u>

The method and process used in the Workforce Foresighting process is under development and there may be errors and omissions in the data provided.

*This report was produced following workshops undertaken October – December 2023 using the data set and tools available at that time.* 



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# **0.0 Executive Summary**

# 0.0 Executive Summary

Section	Title
0.1	Summary of the challenge
0.2	Findings in summary
0.3	Recommended actions



# **Sponsor foreword**

It is with great pleasure that FUJIFILM Diosynth Biotechnologies introduce this comprehensive workforce foresighting report, which highlights the future capabilities and skills required to deliver the intensification of manufacturing of RNA therapeutics.

In the rapidly evolving landscape of medicines manufacturing, it is imperative that we equip our workforce with the necessary skills to enable industry to adopt and exploit innovative technologies in response to global, national and sector challenges. This report serves as a valuable tool in understanding the current skill sets within our sector and provides the insight and recommendations required to enable the UK to adopt to future skills needed for innovative technologies associated with the intensification of medicines manufacturing, including RNA therapeutics, to succeed in the dynamic global marketplace.

We encourage all stakeholders to carefully review the findings presented in this report, utilise the accompanying data sets to understand the impact on their organisation, the medicines manufacturing sector and join in our commitment to building a skilled and adaptable workforce that is prepared to meet the challenges of tomorrow.

We look forward to working with CPI, industry stakeholders and educators to support the implementation of the recommendations of this study. To create a workforce to drive innovation, ensure quality, and maintain the competitiveness of the UK in this sector.



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## 0.1 Summary of the challenge

RNA based therapies are an emerging technology that rose to prominence during the COVID pandemic but have vast potential beyond. These therapeutics have become increasingly important in recent years due to benefits identified around the speed of development, safety, and broad application. With the potential to treat a wide range of diseases including infectious diseases, cancer, genetic disorders, and autoimmune diseases.

For the UK to remain at the forefront of this technology and market opportunity, investment in the intensification of manufacturing of RNA therapeutics and the development of a skilled workforce is required. Through intensification of manufacturing, industry can deliver more sustainable medicines manufacturing, to progress towards NetZero. The capabilities associated with intensification of medicines manufacturing have applicability beyond RNA therapeutics. However, are an essential component of the future within this therapeutic domain. To enable the UK to be competitive in this market at a global level and maximise the market opportunities presented by this technology for future economic growth.

### **0.2 Findings in summary**

Some of the technologies and capabilities required within the supply chain to meet this challenge include:

- Intensification of manufacturing through the adoption of technologies such as continuous manufacturing, Process Analytical Technology (PAT), automation, real-time monitoring, and advanced process control
- Optimisation of the supply chain through the design and development of reagents, raw materials and single use consumables for increased productivity and reduced costs
- Process development to enable recovery of high value raw materials and repurposing and recycling of waste during the manufacturing process
- Equipment design for intensified and small-scale manufacturing with the development of unified communications protocols between equipment manufacturers
- Implementation of appropriate regulatory systems, validation specifications and data management

The workforce foresighting cycle identified 150 future capabilities relevant to the technologies required for the intensification of manufacturing of RNA therapeutics. Of these 45 were new capability statements developed by the project (Listed in section 4 of this report.) These capability statements were mapped against:

- Four sector job levels: Technical Operator; Manufacturing Engineer; Scientist / Engineer and Senior Scientist / Engineer / Tech Officer
- Three competence levels: Awareness; practitioner; expert.



This process identified future occupational profiles which will deliver these new capabilities including Technician Scientist, Process Leader, Automation Engineer, and Development Scientist within the supply chain. The data indicates that most of the workforce changes are required within Biopharmaceutical Manufacturers and Contract Development Manufacturing Organisations (CDMOs.) The existing education provision provides a solid foundation for the future skills, however further development is required to deliver an appropriately skilled workforce. For example, through the provision of short technical Continuing Professional Development (CPD) courses, or the adaptation of existing apprenticeship and Higher Education provision to include the new capabilities.

### 0.3 Recommended actions

This report was developed by CPI, in partnership with industry sponsor FUJIFILM Diosynth Biotechnologies. Consultation with stakeholders from industry, education and centres for innovation have taken place throughout the process and the recommendations of this report have been validated by industry. Through this consultation the capabilities required for intensification of manufacturing were highlighted as the most urgent in the medium-term and are likely to be in high demand across the workforce within the next 2-5 years.

It is recommended that employers review the identified Future Occupational Profiles (FOPs) and associated capabilities relevant to their organisation, to inform their workforce development plans. Then partner with Educators to develop appropriate provision. While educators should investigate the future capabilities identified, to match specific new capabilities with elements of existing provision to be found within a range of current occupational standards and relevant training provision. Whilst these elements will inform new course content in principle, context specific content will need to be generated to meet demand.

Without action there is a risk that a lack of an appropriately skilled workforce could deter inward investment. Potentially compromising the UK's competitive edge and hindering the market opportunities presented by this technology for future economic growth.



# **1.0 The Mission – Providing foresight for future change**

# 1.0 The Mission – Providing foresight for future change

Section	Title		
1.1	Addressing future workforce challenges		
1.2	The Skills Value Chain		
1.3	Workforce foresighting		
1.4	Approach used – principles and implementation		
1.5	Forecasting and foresighting		
1.6	Outcomes – insights and recommendations		



### **1.1 Addressing future workforce challenges**

The global marketplace is changing at a rapid pace and the continued development of innovative technologies is creating opportunities for growth in all sectors.

Whilst we are well placed to take advantage in the UK, the Government and industry have identified that we need a workforce able to adapt to new capabilities that require different and often higher skill sets. The 'Manufacturing the Future Workforce' <u>report</u>, published in 2020, states: "Failure to address the workforce development challenge will mean missing out on opportunities to build the UK's manufacturing base and to take market leading positions."

Developing this workforce and preventing a skills shortfall will provide future-thinking organisations with the capabilities to successfully adopt innovation and enable the UK to build a prosperous economy.

# 1.2 The Skills Value Chain

A Skills Value Chain (SVC) approach promotes connectivity between upstream UK innovation and downstream skills systems, as well as enabling better co-operation within education and training provider eco-systems. It aligns and integrates innovation and skills strategies with a common purpose.

The SVC approach was proposed in the 'Manufacturing the Future Workforce' <u>report</u>, which examined global best practice and convened UK pioneers to explore how the UK can develop skills to exploit innovative technologies.

And it starts with workforce foresighting.



Figure 1: The Skills Value Chain

# **1.3 Workforce foresighting**

Using the Skills Value Chain approach, the UK will start building the skilled workforce required by tomorrow's industries and employers, and understanding what these future needs will be is where workforce foresighting comes in.

Workforce foresighting is a systemic approach to identifying the organisational capabilities and workforce skills necessary to enable industry to adopt and exploit innovative technologies which respond to global, national and sector challenges.

The Workforce Foresighting Hub, initiated and funded by Innovate UK, and built in collaboration with the Catapult Network, provides the processes and data that inform insight and support the recommendations required for industry, policymakers, and educators to respond to continuing change.



**Our Vision:** To foster the organisational capabilities and workforce skills required to adapt to continuing change and enable adoption of innovative technologies to enable a prosperous UK industry.

**Our Mission:** To provide the process, insight and recommendations required to identify and address future skills demands to enable the UK to adopt innovation and succeed in the dynamic global marketplace.

### **Our Goals:**

**Define** future capabilities required across a sector in response to a challenge, or technology innovation and consequently define the skill sets of the workforce of the future.

**Understand** and explain gaps between technology adoption, organisational capability and workforce profiles that could hamper innovation.

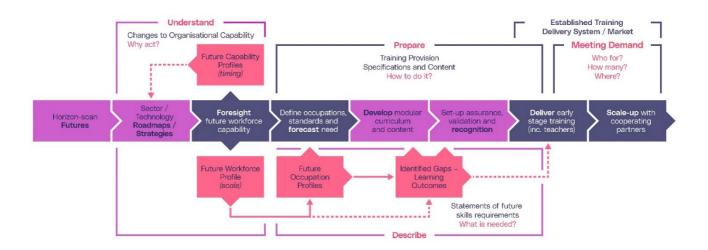
**Identify** and communicate insights, future requirements and the action required by industry and educators.

Enable and deliver a consistent approach to workforce foresighting.

### **Outcomes:**

The process integrates insight from experts in three categories – domain specialists/technologists, employers, and educators. Using a structured and facilitated series of collaborative information-gathering workshops, combined with data from open-source global data sets, the workforce foresighting process can produce a wealth of detailed quantitative data to inform action.

At the heart of the foresighting process are working groups consisting of the industry sponsor and centre of innovation, with support from the Workforce Foresighting Hub team, who undertake detailed analysis to report and summarise key data insights and recommendations for action. This report details future supply chain capabilities, prototype future occupational profiles and identifies changes required to current training provision for the sponsor to take forward and address skills challenges relating to the specific topic.







# **1.4 Approach used - principles and implementation**

The core of workforce foresighting is convening three groups of relevant specialists to conduct structured, Delphi-style, facilitated workshops to capture and discuss the set of organisational capabilities that will be required to respond to and exploit technology innovation. Lists of workshop participants are provided in Appendix 5.1

Organisational capabilities are captured using a bespoke classification that has been developed by the Workforce Foresighting Hub. The classification uses a structured common language to enable cross sector and cross centre collaboration and integration of data. Additionally, the classification enables data from a number of other national and international open-source workforce datasets to be integrated through the same common language. This data is held in a cloud based "data-cube" that is dynamically growing as each workforce foresighting cycle adds to the shared data relating to future workforce capabilities.

Using cutting edge AI and Large Language Model data tools, the data-cube is used to undertake detailed analysis to 'map' future workforce capability requirements against the current education and training provision to identify where existing provision can be used and where new provision, CPD or qualifications are required.

As an agile development project, the WFH team are constantly evolving and improving the detailed workshop process and workshop approach, but essentially always consists of the following stages:

- **Considering** Clarifying the Challenge to be met (the 'what' and the 'when') and collating solutions (the 'how') as foresighting topic suggestions align with strategic priorities
- **Identifying** Gain clarity and consensus about the solutions to be put forward make the case for foresighting
- Preparing The convening of specialists and scheduling of workshops
   Carrying out Run foresighting workshops with experts, collate and analyse data
   Communicating Insights, findings and recommendations gathered from all research in an actionable report
- **Causing action** The driving of action based on the recommendations (promoting progress down the rest of the skills value chain) built on the findings and recommendations of foresighting



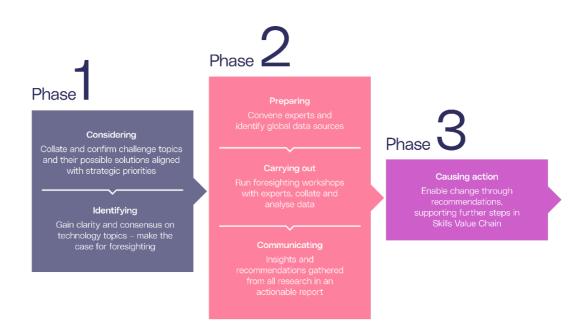


Figure 3 - The workforce foresighting process

## **1.5 Forecasting and Foresighting**

The result of workforce foresighting is understanding why skills requirements will need to change to enable the adoption of innovative technologies, and to define what this change is likely to be in terms of future occupations and shorter-term skills gaps. Forecasting of demand can then take these future focused findings and work with industry and government stakeholders to estimate the quantity of workers necessary for an industry to fulfil emerging skill demands at a given time and place. The two approaches are linked in that workforce foresighting identifies the requirements and forecasting can then determine the quantity needed, the people needing the skills and therefore prepare programmes to deliver them.

## **1.6 Outcomes - insights and recommendations**

Workforce foresighting is a data intensive approach that can provide sponsors, stakeholders, and participants with detailed insight about future workforce requirements. A dynamic data set is provided for each cycle to allow all stakeholders and participants to freely access and interrogate the data. Additionally, the WFH team will support the production of a report that provides targeted recommendations that require action to address gaps in training and education provision relevant to the challenge and planned technology solution.

The dynamic data portal provides a range of standard data sets and visualisations. Additionally, users can download data to undertake their own more detailed interrogation of data to guide and inform subsequent actions.

The key aspect is to provide insight about gaps – which capabilities required in the future are not addressed by aspects of current provision – apprenticeship standards, qualifications, or other provision. Gaps represent:

- Short term CPD topics required across the workforce to upskill members of current workforce
- **Medium term** topics to be included as current provision / standards are reviewed and updated
- Longer term new qualifications and standards that may be needed to equip new entrants

The insight produced by a workforce foresighting cycle (project) provides:

- **Technologists** and technical leads with insight of the organisational capability sets required across future supply chain partners in response to the identified challenge.
- **Employers** with insight about possible future roles and occupations that may be required across the whole workforce, operators to researchers, to ensure they are equipped and ready.
- **Educators** with details of the gaps to be addressed by short-course training to upskill the existing workforce and also insight about qualifications and provision that will be required to support new entrants in the future.



# 2.0 Aligning the Challenge and Solutions with national priorities

# 2.0 Aligning the Challenge and Solutions with national priorities

Section	Title
2.1	Positioning and context of challenges
2.2	Workforce foresighting for chosen prioritised technology solution



# 2.1 Positioning and context of national challenge

The landscape of medicine manufacturing in the UK is continually evolving, influenced by technological advancements, regulatory changes, and global market dynamics. With Life Sciences in the UK identified as "among the most valuable and strategically important in the UK economy, and critical to the country's health, wealth, and resilience" [Life Sciences Vision, UK Gov 2021] it becomes imperative to understand the skills required to drive innovation, ensure quality, and maintain competitiveness in this sector.

### **National Strategy**

RNA based therapies are an emerging technology that rose to prominence during the COVID pandemic but have vast potential beyond. The <u>mRNA Revolution report</u> produced by the BIA reveals how the UK is poised to become a global leader in mRNA medicine. Identifying the need for a "robust workforce trained to support this pipeline of new products." <u>The Cell</u> and <u>Gene Therapy UK Skills Demand report 2023</u> anticipates employment in the total Bioprocessing industry will grow by "63% over the next five years" and identifies "need to continue to prioritise and deliver an end-to-end skills provision in the UK to ensure that growth is not restricted by the size of the skilled workforce."

### **Developing Solutions**

RNA therapeutics are a type of medical technology that exploits RNA molecules to produce proteins within the body, with the goal of treating or preventing diseases. They have become increasingly important in recent years for several reasons:

- 1. Speed of development: RNA-based vaccines and therapeutics can be rapidly developed and manufactured in response to emerging infectious diseases or other health threats. This was demonstrated by the development and deployment of mRNA-based COVID-19 vaccines in record time.
- **2.** Safety: RNA therapeutics are generally considered safe because they do not integrate into the patient's genome and are rapidly degraded by the body.
- **3.** Potential for broad applicability: RNA therapeutics have the potential to treat a wide range of diseases beyond infectious diseases, including cancer, genetic disorders, and autoimmune diseases.



# 2.2 Workforce foresighting for chosen prioritised technology solution

For the UK to remain at forefront of this technology and market opportunity, we must upskill the existing scientific workforce and develop the future talent pipeline to provide the skilled workforce for this industry to grow and thrive in the UK. Enabling the UK to be competitive in this market at a global level.

A lack of an appropriately skilled workforce poses the risk of deterring inward investment. Potentially compromising the UK's competitive edge and hindering the maximisation of market opportunities presented by this technology for future economic growth. These challenges could be exacerbated due to the potential departure of key academics and innovators abroad given the mobile nature of this workforce. Given the typical co-location of manufacturing and R&D activities, such a trend could significantly impact the UK.

This report aims to provide a comprehensive analysis of the skills needs within the UK medicine manufacturing sector, with focus on the manufacturing of RNA therapeutics. By exploring current trends, challenges, and demands of this opportunity, stakeholders can better anticipate future skill requirements, strategize workforce development initiatives, and foster a resilient ecosystem for continued growth and excellence.



3.0 Results – Findings, Data and Insight

# 3.0 Results – Findings, Data and Insight

Section	Title
3.1	Findings, methodology and presentation
3.2	Insight into organisational changes
3.3	Occupational change insight
3.4	Summary of findings



# 3.1 Findings, methodology and presentation

This section describes the future organisational capabilities that will be required to meet the Challenge using the proposed Solution (technology) and which occupations are likely to change to deliver these capabilities.

Summary information is provided with a narrative based on the underlying data which is also provided using bespoke visualisations to enable greater insight and access to detail. This section of the report is aligned to the needs of those responsible for workforce planning – employers, educators, and skills providers.

The two parts interpret the data findings and contain links to the relevant visualisation elements.

Actions necessary to meet the skills and training requirements for the changed occupations are considered in Section 4 with recommendations to be considered by the foresighting Sponsor, Convenor, and others on behalf of the stakeholder and participant groups.

### **Organisational changes**

Providing insight into Organisational Changes – this indicates how organisations will need to adapt their current capabilities in order to implement the Solutions that respond to the Challenge addressed by this foresighting project.

Typically, this will also require the adoption of new capabilities and a change in the distribution of these capabilities across value chain partners. This change in capabilities within an organisation as well as their value chain partners will determine the changes knowledge and skill changes required by the role families within the workforce of each supply chain partner.

### **Occupational changes**

A set of 'Future Occupational Profiles' (FOPs) is produced by the foresighting process that demonstrate how current occupations may need to change in the future. FOPs are generated using a combination of attributes from the underlying capability classification and from data collected in the workshops. The FOP generation algorithm works to group capabilities into logical sets reflecting role families, function, proficiency, and capability similarity. As part of the foresight process the generated FOPS are reviewed, revised, and distilled by the Employer group. This agreed set of FOPs are then compared with selected current education provision; the default reference is the set of Institute for Apprenticeships and Technical Education (IFATE) occupational standards; to assess which current training and education provision could be used in the future. Two bespoke metrics, match and surplus are used to evaluate the alignment of current provision with the set of FOPs proposed. Summaries are presented of the key findings related to each supply chain partner.

Findings are aimed at both Employers and Education and Training Providers and identify matches and gaps in future training needs compared with current provision to guide further detailed investigation.



### **Recommended actions for future provision**

The outputs from Workforce Foresighting identify recommended changes to education and training provision – principally occupational standards that will deliver the knowledge, skills and behaviours required by future occupations. In some cases, this will include the development of short courses and continued professional development (CPD) to upskill the current workforce to meet future needs. Additionally, foresighting outputs can be used to develop programmes, qualifications, and occupational standards for new entrants to the workforce joining via apprenticeship, taught qualification, or other training programme.

The insight and data in this part of the report are primarily aimed at educators training providers, occupational standards bodies, and awarding organisations. Combined with insight arising from the supply chain capability changes, the provision insight offers an effective way for employers to identify training opportunities that align to their future needs.

### Method

The Workforce Foresighting process uses a series of structured workshops and surveys to capture and summarise input from relevant sector experts – covering technology, workforce development and education. At a number of points in the workshop and analysis sequence the foresighting process utilises large language models (LLM) and artificial intelligence (AI) tools to parse and assist in the analysis of the content generated by workshop participants. For example, the AI model can compare capability statements with existing occupational standards more thoroughly and rapidly than human comparison. All AI derived outputs are reviewed and validated by the participant groups through the workshops and the integral quality assurance reviews of the foresight process.

## 3.2 Insight into organisational changes

Organisational insight indicates how diverse types of organisations in the value chain will need to make functional changes to align their future capabilities to those required to respond to the Challenge being addressed. This provides useful insight for these organisations and in turn, provides a data rich and well-founded basis to understand how future occupations and their skillsets may need to change to meet that challenge. This is developed in section 3.3 of this report.

### **Organisation functions**

The Workforce Foresighting process uses an information architecture built on five functional areas which are common to any business:



Design	The function of an organisation that focuses on activities relating to product, service, or solution design.			
Implement	The function of an organisation that focuses on activities relating to producing / making / providing its products or services.			
LogisticsThe function of an organisation that focuses on activities relation procurement, delivery, materials, or services necessary for operative service / manufacturing, etc.				
Support	The function of an organisation that focuses on activities relating to users, in-service support, repair / maintenance, recycling, end of life disposal.			
Enterprise	Core functions of an organisation - e.g., strategic planning, leadership and management, human resources. Digital backbone and data systems. Integration of relevant statutory / regulatory requirements and compliance.			

This functional structure is developed to levels of detail that enable the foresight process to reference external data sets including ONET (US) Occupational Information Network [<sup>1</sup>], ESCO – European Skills, Competences, Qualifications and Occupations[<sup>2</sup>], IFATE – (UK) Institute for Apprenticeships and Technical Education[<sup>3</sup>].

The five root functions comprise ~ 40 Domains which are broken down to ~ 140 Functional Areas. This architecture is used to position ~ 25,000 capability statements which are the building blocks used in the workforce foresight process. Each capability statement has several attributes. Some are static and reflect the position of the capability statement in the architecture, others are dynamic and are assigned values through a cycle and set of workshops.

The data-architecture is implemented in a bespoke 'data-cube' which underpins the foresight process, workshops, and enables extensive use of LLM and AI tools. Additionally, a key feature of the data-cube is that the data from each foresight topic cycle is added into the data set and can then be used, where relevant, in future cycles. This ensures that the capabilities of the system are dynamic and up to date.

 <sup>&</sup>lt;sup>2</sup> ESCO - European Skills, Competences, Qualifications and Occupations - <u>https://esco.ec.europa.eu/en</u>
 <sup>3</sup> IfATE - Institute for Apprenticeships and Technical Education - <u>https://www.instituteforapprenticeships.org/</u>



<sup>&</sup>lt;sup>1</sup> ONET - Occupational Information Network - <u>https://www.onetcenter.org/</u>

### Identifying the Future Supply Chain Capabilities.

The following charts and graphs summarise the changes in the set of capabilities that will be required by the supply chain in the future. The pie-charts reflect the distribution of capabilities across the five functions. The future state data is captured in three Technologists workshops and the current state data is generated using information collected about current occupational standards used across the existing supply chain. This latter information is not as detailed as that produced by the workshops and is indicative and used to provide a point of comparison.

These initial pie charts illustrate the changing proportions of the five functions between the current and future. This indicates an overall relative:

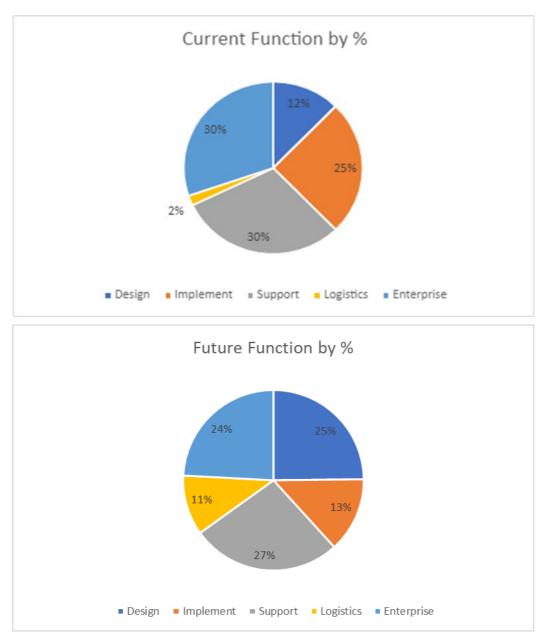


Figure 3: Current and Future Supply Chain - Capability Functions summary by %



Please note the current state has been built by proxy using a review of the existing commonly used apprenticeships standards in the industry, while the future state is dependent on data captured through the workshops which may have omissions, so this information is to be used to provide context to trends rather than specific analysis.

To gain further insights the Future functions have been analysed to provide detail on the distribution of future capabilities required within specific functional domains of an organisation such as technical research and regulatory compliance.

The charts below are sorted by future capability requirement and provide insight into the likely relative importance of each functional domain within the future organisation.

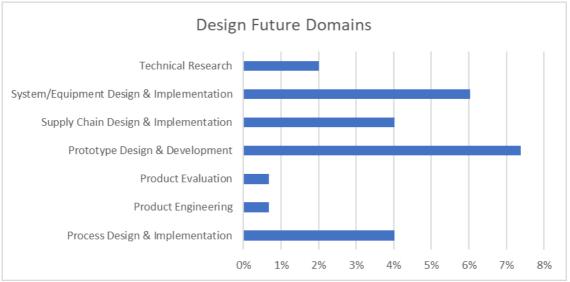


Figure 4: Design Future Domains

The future capabilities required with Design function reflects the foresighted transition to an increase in new consumables, equipment, and reagents to increase efficiencies within RNA therapeutics manufacturing and reduce costs associated with raw materials and consumables.



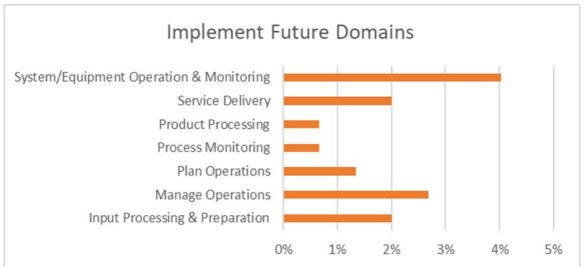


Figure 5: Implementation Future Domain

Within the future organisation Implement function there is a requirement for capabilities to implement unified communication protocols for automated equipment, adoption of AI techniques, and use of machine learning algorithms for system and facility operation and maintenance.

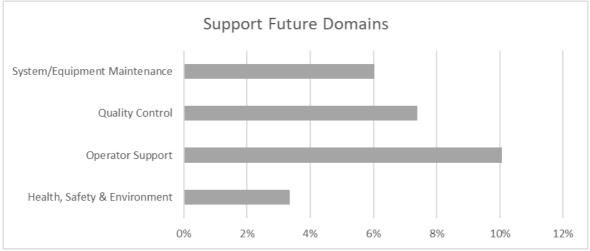


Figure 6: Support Future Domain

A significant proportion of the future organisational capabilities sit within the support function. The characteristics of RNA, regulatory requirements for the manufacturing environment, and implementation of new systems and technologies to deliver continuous and automated manufacturing, impact the capabilities required within this functional domain.



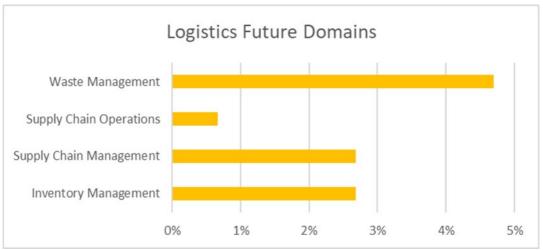


Figure 7: Logistics Future Domain

Development and implementation of waste reduction strategies, recovery of high value raw materials during the manufacturing process, and use of Life Cycle Assessment methodologies were identified as key capabilities required within the future Logistics functional domain.

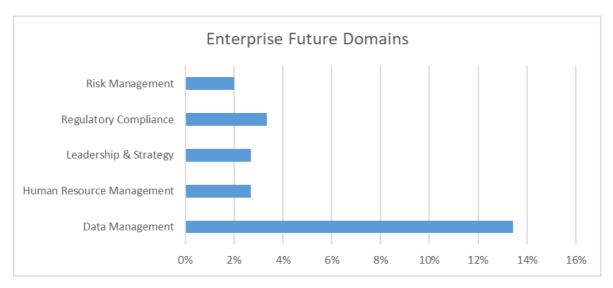


Figure 8: Enterprise Future Domain

Management of data, data analytics, data security and transfer protocols are key to the future organisational capabilities to deliver intensification of RNA therapeutics manufacturing.

Further detail on the capabilities which fit into these functional domains can be found within the output data visualisation tool, which can be accessed using the link below.



### **Visualisation Instructions**

Visualisation Data Link	What is it and what can it be used for?
Organisational Capabilities	Generally, the data presented here can provide an indication of how well served the sector is. This page provides a high-level summary of each capability statement generated in the cycle. The capability statement describes the depth and nature of each capability within an Organisation against a defined reference. The page also provides a way of reviewing the capabilities through the lens of the Capability Classification Framework (Design/Implement/Logistics/Support/Enterprise). This information can be used to provide insight about the types of capabilities and their distribution across the classification framework. This can be used to identify which capabilities may be supported by existing provision, and where there may be gaps that require new development to support.



# 3.3 Occupational change insight

This insight into occupational change uses the understanding of how capabilities will change across business functions (section 3.2) to inform proposals for how occupations and their associated skills sets for each supply chain partner may need be revised to reflect change for each role family within that Partner.

#### Supply chain partner organisation types

The workforce foresighting process recognises that different partners in a supply chain will require appropriate capabilities and these are determined and agreed in the initial workshops.

In this cycle, the following Supply Chain Partners were identified and then used during participant workshops and data analysis to determine the organisational needs:

- 1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA
- 2. EQUIPMENT MANUFACTURERS
- 3. CONSUMABLE AND RAW MATERIAL PROVIDERS
- 4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMOs)

This categorisation enables the analysis and reporting of the major areas of occupational change by business function for each partner, recognising that each will have distinctive characteristics and requirements. Using the data set held in the WF-Hub data cube, these changes are expressed as capabilities – i.e. something that an organisation can do.

The prioritisation and capabilities in the report have been selected by the Sponsor, Technical and Educator Leads. However, the Visualisation data provides all the capabilities from the entire cycle.

The first chart below shows the distribution across organisational functions of the total future capabilities required within the workforce, to deliver intensification of RNA therapeutics manufacturing, including those capabilities which may already exist within the workforce.



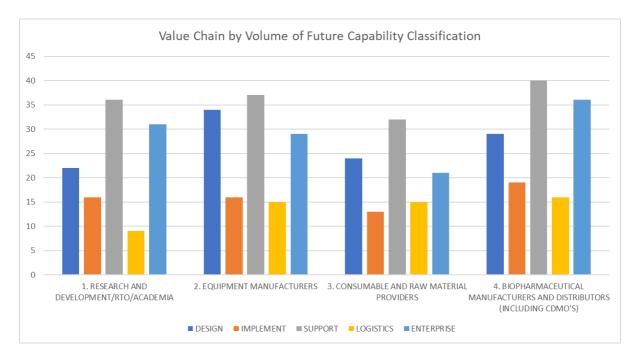


Figure 9: Value Chain by Volume of Future Capability Classification

While the chart below shows specifically the new workforce capabilities identified through this foresighting cycle required by the future workforce for RNA therapeutics manufacturing.

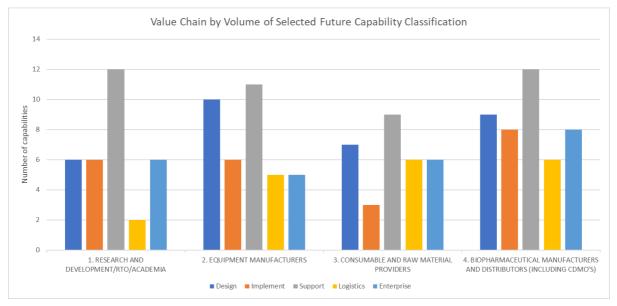


Figure 10 – Value Chain by Volume of Selected Future Capability Classification

This graph illustrates the distribution of capabilities by function across the Value Chain Partners. These capabilities form the basis of Future Occupational Profiles within each Role Family, detailed in the next section. Details of the new challenge-specific future workforce capabilities defined through this foresighting cycle, can be found within section 4 of this report.



### **Visualisation Instructions**

Visualisation Data Link	What is it and what can it be used for?
<u>Value Chain</u> Capabilities	This page provides an overview of the identified capabilities at a Supply Chain / Workflow Partner level.
	By selecting/deselecting each Supply Chain / Workflow Partner you can review the capabilities identified as required in that area of the Supply Chain / Workflow.
	This can be used to generate organisational capability profiles for each area of the workflow /supply chain to help prioritise and focus the acquisition of new capabilities that will be required in the future.
	It can also be used to generate combined organisational profiles, where an organisation may be involved in more than one area of the supply chain.

#### **Role Families**

The foresighting process uses the concept of Role Families to represent future occupations. This approach acknowledges that the workforce is not homogeneous, there will be varying levels of proficiency required across a workforce and qualifications and training may be aligned/require different types of vocational or academic qualifications. Additionally, the role family approach seeks to avoid presuming that the future workforce will be "current state plus."

#### For this cycle, the following Role Families were determined through the workshops:

- **1.** Technical Operator (RNA)
- **2.** Manufacturing Engineer (RNA)
- 3. Scientist / Engineer (RNA)
- 4. Senior Scientist / Engineer / Tech Officer

#### **Proficiencies**

Each of these role families will require proficiency that reflects their role and the needs of each Supply Chain Partner. The foresight process uses a three-point scale to capture and differentiate the proficiency required. This information is used in the generation of the Future Occupational Profiles and to assist the definition of training needs identified. Within the workforce foresight process Proficiency is defined as:

**Awareness (A)** - Has a foundational knowledge of tools, technology, techniques relevant to sector, industry, and company. Sufficient comprehension to know where to seek further information/details as necessary for a particular issue.

**Practitioner (P)** - Has the ability to apply and use independently a tool, system, or process. Understands the implications, consequences, and impact for their role/function. Knows what key actions are required and in what context.



**Expert (E)** - Has detailed knowledge of process, system, tool, or technology. Can support others and identify improvements required for a process, system, or tool. Can implement improvements personally or direct and guide others.

In the workshops participants apply their insight to assign proficiency for each role family to each capability. Individual responses are aggregated by the system to arrive at a consensus.

A summary of the distribution of required proficiency for the role families in this cycle are:

	Technical Operator (RNA)	Manufacturing Engineer (RNA)	Scientist / Engineer (RNA)	Senior Scientist / Engineer / Tech Officer
Awareness	38%	13%	11%	12%
Practitioner	62%	63%	76%	16%
Expert	0%	25%	13%	72%

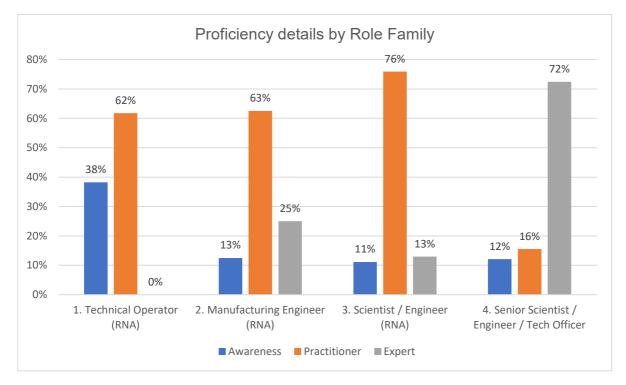


Figure 11: Proficiency details by Role Family



### **Future Occupational Profiles**

The FOPs (Future Occupational Profiles) are a construct created and used during workforce foresighting workshops and analysis to capture future skills needs in a form that may be compared with current occupation definitions – typically occupational standards.

The familiar nature and structure of 'FOP's assists with their evaluation and validation by employers and educators and enables the analytical comparison that results in useful indications of matches, surplus and gaps of future skills needs compared with current state. This then allows recommendations for action to be made based on future need and current fit to those needs.

FOPs are used to describe and suggest occupations, or roles, that may be required in the future and provide a framework to indicate capabilities and related duties. They can be used to review the impact on current roles and the adaptation that may be required in the future.

**Educators** can review current occupational standards against the requirements of the FOPs and interpret which need to be changed to fill the gaps between the current and future state.

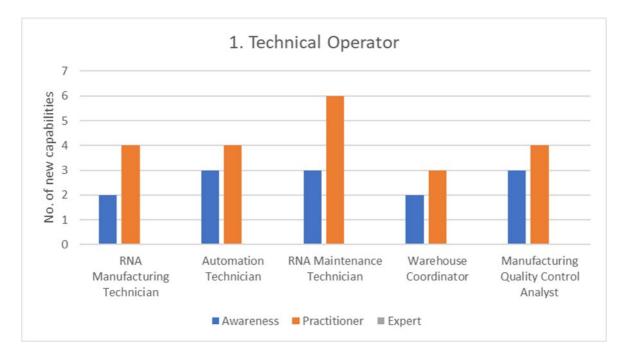
**Employers** can consider existing apprenticeship standards and make a judgement on adapting an existing apprenticeship standard to upskill their workforce to meet the requirements of a particular FOP.

**Educators** may react to these specified skill requirements from Industry by editing, adapting, or creating new content.

#### FOPs and indicative skills need

Combining proficiency with the identified FOPs, the following graphs indicate the priority needs across the supply value chain for each Role Family to deliver future capabilities.





### Technician / Operator Role Family FOPs:

Figure 12: Technician / Operator Role Family

Within the Technical and Operator role family, the Future Occupational Profile most affected by the change in workforce capabilities required is Maintenance Technician. There are nine new capabilities required to be delivered through this role, to enable the adoption of technologies to deliver the intensification of manufacturing for RNA therapeutics. Six of these capabilities at practitioner and three at awareness proficiency level. Therefore, this could be a priority for employers to focus their workforce development activities.





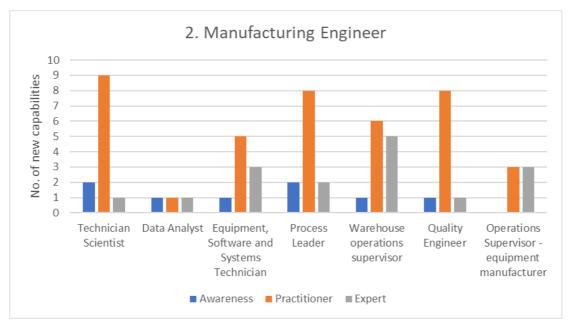


Figure 13: Manufacturing Engineer Role Family

Among the Future Occupational Profiles in the Manufacturing Engineer role family, the majority of capability change at this skill level is delivered through Technician Scientist, Process Leader, Warehouse Operations Supervisor and Quality Engineer roles. Future required capabilities relating to these roles include those associated with recycling of waste, sustainability, regulatory monitoring, and cold-chain and aseptic conditions. Further details on the specific capabilities required, can be found within the data visualisation tool, which can be accessed through the link in appendix 5.5 of this report.





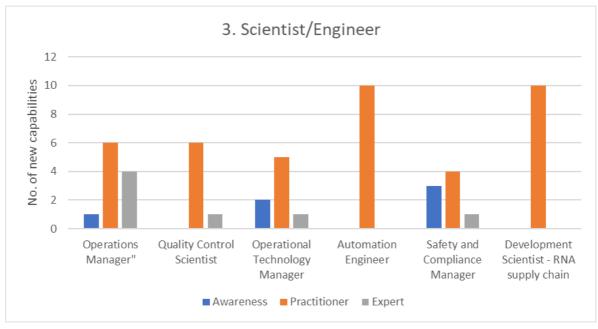
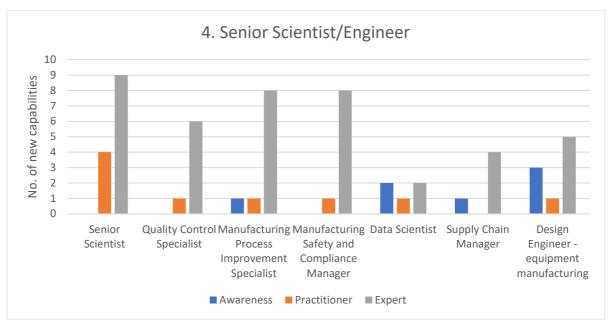


Figure 24: Scientist / Engineer Role Family

In the Scientist / Engineer level Future Occupational Profiles, the bulk of new capabilities in this role family are delivered through the Automation Engineer and Development Scientists within the supply chain. Which perhaps is to be expected given the identified need for development of new technologies, reagents, and consumables.



## Senior Scientist / Engineer Role Family FOPs:

Figure 35: Senior Scientist / Engineer / Tech Officer Role Family



Within the senior technical and specialist level roles, delivery of new capabilities is incumbent on the Senior Scientist, Manufacturing Process Improvement Specialist and Manufacturing Safety and Compliance Manager Future Occupational Profiles.

Details of the specific new capabilities required within each of these Future Occupational profiles can be found within the workforce foresighting cycle output data visualisation tool, which can be accessed using the link in the visualisation instructions below. This detail could be helpful to employers to build workforce development plans and to understand the level of training intervention necessary, based upon the required proficiency level of capability for that role.

## **Visualisation Instructions**

Visualisation Data Link	What is it and what can it be used for?
Prototype Occupational Profiles (PFOP Matrix)	This page provides a detailed breakdown of future occupational profiles that could be required in the future workforce. These were generated using a combination of attributes collected through the workshops and an algorithm. These suggested profiles were then reviewed and ratified by small groups of employers who were able to add/remove capabilities and uprate/downrate proficiency levels required. You can view all the P-FOPs in a role family by selecting one (or more) of these from the drop down. This will then allow you to select the P-FOPs aligned to that role family.
	The populated table allows you review and compare different P-FOPs within or across role families. You can view the capabilities in each P-FOP and the assigned proficiency levels.
	You can also toggle 'Hide Empty Capabilities' on/off to reduce the view down to only those capabilities included in the role family you are reviewing.

## Comparison with current state

The Workforce Foresighting process has developed two metrics to quantify the alignment between a FOP and a current standard or qualification:

**Fit** – expressed as a %, it is a measure of the proportion of a FOP that is covered by an existing standard or qualification.

**Surplus** – expressed as a %, it is a measure of the not relevant material in an existing standard that is not required for a FOP.

An ideal existing qualification or standard would have a high fit and low surplus – this implies good coverage of the FOP but with little material that is not relevant to the FOP. Conversely a poor candidate would have a low fit and high surplus. Using these two metrics it is possible to quantitively evaluate, rank, and compare a range of existing provisions against a set of FOPs describing future needs.



By looking at how current occupational standards fit the Future Occupational Profiles, the most suitable and efficient route for change can be determined, e.g. a fit factor of less than 33% probably indicates that the current standard is unlikely to a good candidate for change, however a fit factor of 66% suggests that less adaptation will be necessary to meet future needs.

This interpretation is represented by a simple nine-box model to position the suitability of a given current occupational standard to a future occupational profile:

Fit Factor	Fit score	Surplus Factor	Surplus score
0 - 32%	1	81-100%	1
33-65%	2	51-80%	2
66-100%	3	0 - 50%	3

## **Factor scores**

(Multiplying the Fit score by the Surplus score gives a Suitability Grid score of 1-9 as below)



## Suitability Grid

Figure 4: Fit Factor scores and Suitability Grid

For this foresighting cycle, it was found that a higher threshold on surplus factor is more useful in filtering out the less relevant IFATE standards, whilst a slightly lower threshold on fit factor is useful to ensure relevant standards might be included.



#### Using this score and indicated 'RAG status' the following interpretation can be made:

#### Good Suitability – 7,8,9 – for standards that have good coverage of FOPs

Represents good candidates from current occupational standards used as the basis of development to meet FOP requirements and inform elements of short course and CPD provision.

**Some Suitability– 4,5,6 – for standards that have only partial coverage of FOPs** These are likely to require extended work to meet FOP requirements, further review of the data may be necessary. They are likely to contain some useful information to inform elements of short course and CPD provision.

Low Suitability – 1,2,3 – for standards that have poor coverage of FOPs These are unlikely to be adaptable to meet future needs but may contain some useful information to inform elements of short course and CPD provision. This can be assessed using the data visualisation tools.

#### FOP findings compared with current standards

Using the approach described above and applying the 'RAG' scores to each FOP indicating the suitability of current occupational standards selected from the IFATE set, the following table begins to identify areas of action and concern for the provision of future skills for each Supply Chain Partner to respond to the Challenge. It is recognised that while a primary Value Chain Partner is highlighted in this analysis, it is likely that some FOPs will existing within the workforce of multiple parts of the value chain.

Using Equipment Manufacturers as an example, all four role families are represented, and using the data extracted we can identify that there is good coverage of the future capabilities required for the Future Occupational Profile of 'Automation Technician' within the existing IFATE standards. While the capabilities required for Future Occupational Profile of 'Equipment, Software and Systems Technician' are only partially delivered through the existing IFATE standards relevant to this role.

As expected, the IFATE standards provision is stronger for the Technical Operator role families than for Manufacturing Engineer, Scientist/Engineer, Senior Scientist / Engineer / Tech Officer.

Role Family	Primary Value Chain / Workflow Partner	Selected Future Occupational Profiles	Overall Suitability RAG
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Senior Scientist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Quality Control Specialist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Data Scientist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Manufacturing Process Improvement Specialist"	

## Research and Development / RTO / Academia



## **Detailed breakdown:**

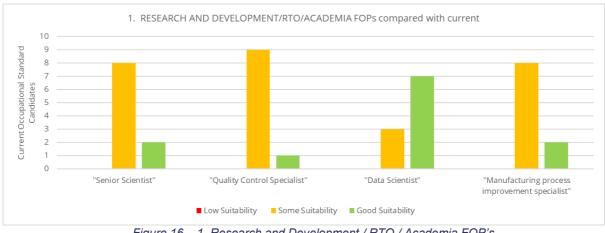


Figure 16 – 1. Research and Development / RTO / Academia FOP's

## **Equipment Manufacturers**

Role Family	Primary Value Chain / Workflow Partner	Selected Future Occupational Profiles	Overall Suitability RAG
1. Technical Operator (RNA)	2. EQUIPMENT MANUFACTURERS	"Automation Technician"	
2. Manufacturing Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Equipment, Software and Systems Technician"	
2. Manufacturing Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Operations Supervisor - equipment manufacturing"	
3. Scientist / Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Automation Engineer"	
4. Senior Scientist / Engineer / Tech Officer	2. EQUIPMENT MANUFACTURERS	"Design Engineer - equipment manufacturing"	

## **Detailed breakdown:**

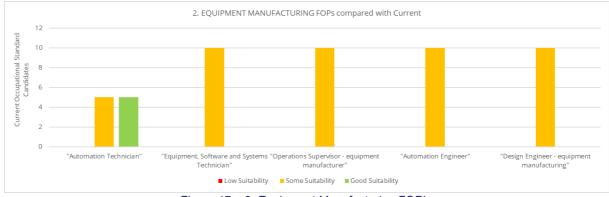


Figure 17 – 2. Equipment Manufacturing FOP's



## **Consumable and Raw Material Providers**

Role Family	Primary Value Chain / Workflow Partner	Selected Future Occupational Profiles	Overall Suitability RAG
2. Manufacturing Engineer (RNA)	3. CONSUMABLE AND RAW MATERIAL PROVIDERS	"Quality Technician"	
3. Scientist / Engineer (RNA)	3. CONSUMABLE AND RAW MATERIAL PROVIDERS	"Development Scientist - RNA supply chain"	

## Detailed breakdown:

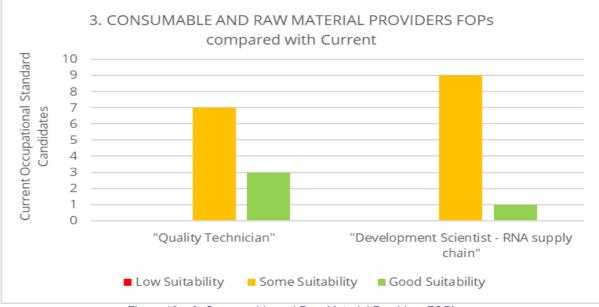


Figure 18 – 3. Consumable and Raw Material Providers FOP's



## Biopharmaceutical manufacturers and distributors

		Selected Future Occupational	Overall Suitability
Role Family	Primary Value Chain / Workflow Partner	Profiles	RAG
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"RNA Manufacturing Technician"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Manufacturing Quality Control Analyst"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Warehouse Coordinator"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"RNA Maintenance Technician"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Technician Scientist"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Warehouse operations supervisor"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Data Analyst"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Process Leader"	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Operations Manager"	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	Operational Technology Manager	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Quality Control Scientist"	
4. Senior Scientist / Engineer / Tech Officer	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Manufacturing Safety and Compliance Manager"	
4. Senior Scientist / Engineer / Tech Officer	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Supply Chain Manager"	

## Detailed breakdown:

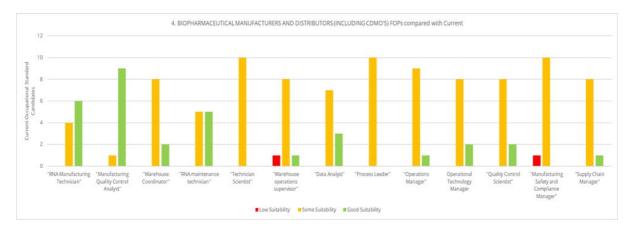


Figure 19 – 4. Biopharmaceutical Manufacturers and Distributors FOPs



## 3.4 Summary of findings

## Top Fits

From a FOP perspective and utilising the suitability grid it can be determined which of the groups of standards are more appropriate than others.

**Note:** It is recommended that the data visualisation tool is used to access the next layer of detail and review the specific standards that have been identified as having Good Suitability / Some Suitability or Low Suitability.

The FOPs with a good suitability score resulting from their comparison with current IFATE standards and provision are:

- RNA Manufacturing Technician
- Manufacturing Quality Control Analyst
- Automation Technician
- RNA maintenance technician
- Data Analyst
- Quality Technician
- Data Scientist

Eurther breakdown	of the fit and cu	rolue analysis is	detailed in the table below.
	of the fit and su	i pius analysis is	

Selected Future Occupational Profiles	Low Suitability	Some Suitability	Good Suitability	Overall Suitability RAG
"RNA Manufacturing Technician"	0	4	6	
"Manufacturing Quality Control Analyst"	0	1	9	
"Automation Technician"	0	5	5	
"RNA maintenance technician"	0	5	5	
"Data Analyst"	0	7	3	
"Quality Technician"	0	7	3	
"Data Scientist"	0	3	7	

As a comparison the FOPs which have no standards recognised with good suitability to deliver the required capabilities can be identified. This suggests that some intervention is required to support these Future Role Profiles as the existing IFATE standards deliver only some of the capabilities required. The FOPs identified through this comparison are:

- Technician Scientist
- Equipment, Software and Systems Technician
- Process Leader
- Operations Supervisor equipment manufacturer
- Automation Engineer
- Manufacturing Safety and Compliance Manager
- Design Engineer equipment manufacturing



Selected Future Occupational Profiles	Low Suitability	Some Suitability	Good Suitability	Overall Suitability RAG
"Technician Scientist"	0	10	0	
"Equipment, Software and Systems Technician"	0	10	0	
"Process Leader"	0	10	0	
"Operations Supervisor - equipment manufacturer"	0	10	0	
"Automation Engineer"	0	10	0	
"Manufacturing Safety and Compliance Manager"	1	10	0	
"Design Engineer - equipment manufacturing"	0	10	0	

## Further breakdown of this fit and surplus analysis is detailed in the table

## **Visualisation Instructions**

Visualisation Data Link	What is it and what can it be used for?
<u>P-FOP Detail</u>	This page allows you to review a specific Occupational Profile, including the capabilities contained within it and the Knowledge, Skills & Behaviour (KSB) tags associated with the capability. You can select an individual Role Family and linked P-FOP in the two available dropdowns. The table in the lower section of the page will then be populated with all relevant capabilities. The search control above the table allows you to filter content of any of the columns of data. A key piece of functionality in this table is the presence of the KSB tags associated with the capabilities.
<u>Future KSBs</u> <u>Summary</u>	<ul> <li>This page provides a view of the complete set of capabilities within the cycle along with all of the associated KSB tags which are linked to them. It is, essentially, the superset of all details displayed on the P-FOP detail page.</li> <li>This is used to: <ul> <li>To review the identified Knowledge, Skill and Behaviour tags for a given capability, to support development of future education and learning material.</li> <li>To review the requirements from a capability level, rather than a role family/occupational profile grouping.</li> </ul> </li> </ul>
<u>P-FOP</u> <u>Distribution</u>	<ul> <li>This page allows provides a breakdown of the Capabilities within the selected Cycle and how they are distributed across the P-FOPs with the addition of a distribution chart showing the required proficiency across those P-FOPs.</li> <li>Clicking the "View P-FOPs" button alongside each capability will provide a list of the proficiencies (EPA) with the P-FOPs that fall into them.</li> <li>The exported version of this data will include a full breakdown of the FOP IDs which contain the capability within a specific proficiency.</li> <li>This is used to.</li> <li>understand the levels/volumes of common/crossover Capabilities, to support prioritisation of Capability Development</li> <li>identify which Occupational Profiles contain these common/crossover capabilities, and so which may be prioritised for development activity</li> </ul>



<u>Capabilities</u> <u>Matched to</u> <u>Current</u> <u>Provision</u>	<ul> <li>This page allows you to review and compare individual capabilities against 'Duty' statements in an Apprenticeship / Occupational Standard.</li> <li>You can select individual capabilities to review their specific matches. These matches are shown in the bottom panel, including the Standard, the Level and the Duty Statement this is matched to.</li> <li>You can filter in several ways to focus your review: <ul> <li>By the Capability Classification Framework (left-hand panel).</li> <li>By capabilities that <b>are</b> served by the reference mapping framework – the default is Institute for Apprenticeships and Technical Education (IFATE) provision.</li> <li>By capabilities that <b>are not</b> served by the reference mapping framework, e.g., IFATE provision – these are capabilities required in the future that may require new/bespoke training and CPD materials to be developed to upskill/re-skill the workforce.</li> </ul> </li> <li>This page can be used to identify where existing provision may exist across the broad spectrum of Occupational Standards, and not just within a narrow range of sector-specific Standards.</li> <li>The data also allows you to identify where provision may already exist to support specific capabilities.</li> </ul>
	This page allows you to review the 'Fit' and 'Surplus' of Prototype Future
Fit & Surplus	Occupation Profiles (P-FOP) against existing training provision e.g. Institute for Apprenticeships and Technical Education (IFATE).
<u>Factors</u>	It is possible for the 'Fit' and 'Surplus' comparison to total over 100%, as they are two separate calculations based on a two-way comparison.
<u>Fit &amp; Surplus</u> <u>Matrix</u>	This page is a visual representation of the 'Fit and Surplus Factor' insight. You can visually review 'Fit' and 'Surplus' of Prototype Future Occupation Profiles (P-FOP) against existing training provision e.g. Institute for Apprenticeships and Technical Education (IFATE).
	This can help you identify which provision may align strongest, or which may require adaptation, to provide the suitable provision fit for each future role. It will help you focus in on which provision to focus your attention for analysis.
<u>P-FOP</u> <u>Capability</u> <u>Matches</u>	This page allows you to view the matches between Capabilities and Institute for Apprenticeships and Technical Education (IFATE) Duty Statements. Clicking the arrow next to a number in the 'Matches' column will open a popup with more detail for each Capability.
	Each capability also includes Knowledge, Skill and Behaviour Tags, to support with scaffolding future education provision.
	You can review individual Prototype Future Occupational Profiles (P-FOPS) or review all P-FOPs under a Role Family, to give a more holistic view of Capabilities and Matches
	Where a future capability has been matched to existing provision (currently, by default, IFATE apprenticeship standards) it is possible to interrogate the data and identify specific statements in standards that align to enable identification of existing training materials and activities that could be used or adapted to meet future requirements.
	This can be used to review the capability requirements for Role Families and P-FOPs, from Job / Occupation level through to Knowledge, Skill and Behaviour level



# 4.0 Recommendations

## 4.0 Recommendations

Section	Title
4.1	Use of the findings
4.2	Future vs current state
4.3	Recommended actions



## 4.1 Use of the findings

Whilst some of the FOPS (Future Occupational Profiles) are generic, some are more specific to the intensification of medicines manufacturing and to RNA therapeutics. Building on this initial highlighting of opportunities and issues, further direction from Employers is required regarding workforce development plans and the level of demand for specific roles. This feedback shared with Educators can enable the development of the education and training provision for the future. Using the analysis of current IFATE occupational standards to inform the content, level, and delivery of this provision. This deeper investigation will be supported by the data sets and visualisation tools accompanying this report.

Within an organisation a job role might incorporate several occupational profiles or only parts of one depending on the size and scope of the employer. Similarly, a college course might be designed to address one or several occupational profiles alongside or independent of other pre-existing course material. The Future Occupational Profiles and the associated capability sets provide employers with building blocks to help in the design of future roles and inform workforce planning. Similarly, the findings and data provide educators with building blocks to guide the development of course modules and content to prepare the future workforce.

## In summary, FOPs can be used to:

- Highlight where roles related to a current occupational standard require updating. For incumbent or transferring workers this could be met by short course and CPD events
- Influence and inform changes to occupational standards used to define the education and training of new entrants to the future workforce

## 4.2 Future State vs Current State

## 752 IFATE standards across all 6 academic levels were used for comparison with the derived FOPs.

By using the Suitability Grid in section 3.3, Educators can focus on the most suitable IFATE standards to investigate in further detail using the visualisation tools to access the underlying data. This does not result in automatically produced requirement statements or fully defined curriculum but provides access to a coherent and consistent skills data related to employers' future needs. Therefore, enabling productive and effective education and training development to deliver a workforce for the future.



The table below lists the new challenge-specific future workforce capability statements defined through this foresighting cycle reviewed by the Challenge Industry Sponsor and leads:

Capability ID within visualisation tool	Organisational Function	Capability Statement	
194434	Design	Utilise predictive modelling for process monitoring and control	
196969	Design	Apply innovative processing techniques using Advanced Robotics	
196972	Design	Create detailed product specifications for manufacturing equipment and disposables using industry-standard documentation tools i.e., Product Requirement documents (PRDs) and Functional Requirement Documents (FRDs)	
196973	Design	Incorporate Virtual Reality (VR) and Augmented Reality (AR) tools for immersive design visualization and user experience testing.	
196975	Design	Design equipment for continuous manufacturing processes using Core engineering principles including mathematics and science and their application to relevant area of specialism.	
196976	Design	Select equipment based on compatibility with RNA therapeutics manufacturing requirements.	
197002	Design	Develop new techniques for RNA manufacture with academic partners	
197004	Design	Design raw materials such as enzymes for increased productivity and reduced cost	
197008	Design	Gather equipment manufacturers to identify unified communications protocols.	
197010	Design	Specify sampling technology and procedures for raw materials and consumables e.g. using Raman Spectroscopy	
197011	Design	Maintain and track equipment configuration for traceability and regulatory requirements.	
196995	Enterprise	Apply machine learning algorithms to identify emerging risks in the manufacturing process and supply chain	
196996	Enterprise	Implement sustainable practices by incorporating renewable energy sources and minimising waste in manufacturing processes	
197000	Enterprise	Analyse supplier performance metrics using Data Analytics tools.	
197032	Enterprise	Identify Good Manufacturing Practice (GMP) job descriptions and competencies.	
197033	Enterprise	Implement Good Manufacturing Practice (GMP) training records and systems.	
197036	Enterprise	Apply machine learning and other analytics tools to predict product and raw quality.	
201319	Enterprise	Maintain consistent and document compliance with all relevant Safety, Health and Environmental (SHE), Good Manufacturing Practice (GMP), Data Integrity (DI), quality and best practice requirements.	



201320	Enterprise	Validate equipment and process to ensure compliance with regulatory requirements.	
196979	Implement	Analyse facility operations data using SPC and Advanced and predictive analytics, machine learning and artificial intelligence techniques, simulations, optimisation, and automation.	
196984	Implement	Monitor equipment performance using Data Analytics	
197014	Implement	Implement a unified communications protocol for automated equipment e.g. using BPOG Protocol	
197015	Implement	Prepare and pick bill of materials for RNA manufacture process.	
197016	Implement	Adopt a digital method for labelling and tracking of RNA product.	
197017	Implement	Adopt AI techniques for QA review of batch documentation and facility / equipment operating parameters.	
201327	Implement	Implement the technical transfer of development projects to GMP scale manufacture, ensuring compliance with regulatory requirements.	
201328	Implement	Implement facility validation plans in line with validation standards and standard operating procedures.	
197019	Logistics	Develop new Quality Control methods for raw material and ingredients.	
197020	Logistics	Ensure cold chain capacity for supply of raw materials into the manufacturing process and drug product produced.	
197021	Logistics	Develop traceability systems that satisfy GMP regulations.	
197022	Logistics	Develop processes that enable recovery of high value raw materials during the manufacturing process.	
197023	Logistics	Develop processes to reduce cost of raw materials.	
197024	Logistics	Develop ways to repurpose and recycle waste to improve cost efficiencies in manufacturing process.	
189787	Support	Implement predictive maintenance techniques to optimize equipment performance and prevent breakdowns.	
189970	Support	Develop customized virtual reality training programs to enhance operators' skills and knowledge.	
196989	Support	Train others to use equipment for process operation using Immersion (Virtual Reality)	
196992	Support	Implement secure real-time monitoring systems using IoT technologies to ensure continuous quality control in RNA therapeutics manufacturing	
196993	Support	Implement real-time monitoring systems to continuously assess product characteristics and quality during manufacturing process	
196994	Support	Implement real-time environmental monitoring systems to ensure compliance with safety standards and promptly detect any deviation	
197029	Support	Implement in-process analysis during manufacture.	
201322	Support	Implement, monitor, and maintain GMP environmental monitoring and quality management systems procedures to support GMP manufacturing facilities.	



201323	Support	Contribute to customer and regulatory bodies Audits & inspections.
201324	Support	Ensure critical clean room consumables, gowning garment are replenished regularly and GMP cleaning schedules are followed.
201325	Support	Take responsibility for the maintenance and calibration of equipment to ensure it operates in a safe and efficient manner and maintain documentation in line with regulatory requirements.
201326	Support	Evaluate product characteristics and quality using appropriate RNA analytical techniques

## **Visualisation Instructions**

Visualisation	What is it and what can it be used for?		
Data Link			
	This page allows you to compare P-FOPs against existing IFATE Standards.		
P-FOP vs Provision	The information here allows you to prioritise effort or action over the short, medium or long-term. This is displayed as a Matched/Not Matched Capability, comparing the Capability in a P-FOP to the Duties in a Standard.		
	The left-hand side allows you to select the Role Family and P-FOP, while the righ hand modal allows you to compare against the top 10 matched IFATE Standards for that Occupational Profile.		
	Where a future capability has been matched to existing provision (currently, by default, IFATE apprenticeship standards) it is possible to interrogate the data and identify specific statements in standards that align to enable identification of existing training materials and activities that could be used or adapted to meet future requirements.		
	This page provides a list of all the P-FOPs within the selected cycle with details of		
P-FOP	their fit and surplus factors.		
Priorities	The information here allows you to prioritise effort or action over the short, medium or long-term.		



## 4.3 Recommended actions

These recommendations summarise the short and mid-term actions required by both Industry and Education, working in collaboration to ensure the necessary future skills are in place to enable the implementation of innovative technologies as solutions to the challenge to deliver the intensification of RNA therapeutics manufacturing.

A future shortage of correctly skilled Technical Operators, Scientists and Engineers will have a serious impact on the UK ambition to drive growth in the Life Sciences sector through the opportunity presented by RNA therapeutics and the intensification of medicines manufacturing.

#### A. Review of Findings

The findings of Section 3 should be reviewed by those involved in the process. Whilst the data acquisition and analysis were quality assured during the workshops and reporting, review and feedback will secure the validity of the following recommendations.

The Future Occupational Profiles are the major output of the process and are used to evaluate the need for action. Further work to adapt combinations of FOPs to better fit emerging roles is anticipated as employers plan for future needs.

What	Review of findings
Who	Stakeholders, Sponsor, Leads, Participants
When	Before formal publication
Result	Robust actions

#### **B.** Dissemination of Findings

These findings indicate where there are likely to be future gaps in skills which if not addressed will cause delays in:

#### Technology development and deployment

- Lack of capacity and capability in the sector will hinder early lifecycle technology design and development work.
- Delays in testing and proving will impede innovative technology uptake in a risk-averse sector.

#### Scaling-up production

- Scaling up production of innovative technologies requires time.
- Process involves developing at-scale production methodologies, investing in, and installing capital equipment, and recruiting and training the workforce.

## **Project delivery**

- Shortage of skilled workers will act as a major supply chain bottleneck
- Increased costs and future delivery inefficiency

Current (as listed in Appendix 5.1) and future stakeholders in both aspects should be made fully aware of the foresighted gaps and the actions and the workforce skills and training actions necessary to mitigate the risk. The Sponsor can play a key role in this.

The findings should also be reviewed by WF-Hub Steering Board members to identify scope for departmental support for actions.

What	Dissemination of Findings
Who	Stakeholders, Industry and Sector groups, Government and Regions
When	Following publication
Result	Web hosted reports and traffic

## C. Short term actions

The understanding of changing occupations captured by the FOPs provides a basis for short term re-skilling and upskilling of the current workforce to meet the demands of emerging technologies as they are introduced by employers. This is especially important for those involved in early life-cycle activities such as design.

Educators should investigate the future capabilities identified within the design function data, to match specific new capabilities with elements of existing provision to be found within a range of current occupational standards. Whilst these elements will inform new course content in principle, context specific content will need to be generated to meet demand.

The volume of demand for some roles may exceed the opportunities to develop the skills of the current workforce leading to recruitment from industries with transferrable skills. As an example, the 'Brewer' apprenticeship standard scores well for suitability for several FOPs. Given the transferrable skills around cleaning and sanitation processes, control and safe operation of plant equipment, quality and safety control checks, and maintenance of accurate records, there are opportunities for Employers to reskill recruits with RNA therapeutics manufacturing specific training indicated by the FOPs.

Findings suggest that whereas upskilling / reskilling those in the Operator / Technician role family appears feasible, further investigation will be required for the less well-matched Engineer / Senior Engineer future roles.

What	Short term action
Who	Educators, Awarding Bodies, Employers
When	Prepare ahead of scale-up need
Result	Timely availability of short-term training for current workforce



## D. Mid-term actions

Short-term developments to address the needs of the incumbent workforce become available for use after a period of analysis and preparation within some one to two years. Formal changes to occupational standards and the apprenticeships and qualifications to deliver new entrants to the workforce with the required future skills have a considerably longer lead time.

The Future Occupational Profiles (FOPs) identified as without IFATE standards with good suitability sit predominantly within the Equipment Manufacturer and Biopharmaceutical Manufacturer (including CDMO) part of the Value Chain. Therefore, Employers within these parts of the Value Chain would benefit from reviewing the capabilities within these FOPs to inform their workforce development plans, then partner with Educators to develop appropriate provision.

Typically, such structural changes require a period of review and programme development of some years followed by individuals undertaking the revised or new programmes over several years. Preparation time should be reduced by integrating efforts with the outputs of the short-term work aimed at the current workforce since both are intended to meet the same future needs as defined by the FOPs.

This long lead-time for new entrants to become effective in the workforce highlights the need to include skills for future needs in their training programmes from the outset.

What	Mid-term actions
Who	Educators, Awarding Bodies, Employers
When	As soon as possible for prioritised FOPs to update current standards
Result	Take up of programmes meeting future skills needs as well as current

## E. General action for Educators to support Employers' demand for future skills

A modular approach to change is feasible within the timescales, compared to re-designing entire courses to meet FOPs requirements.

Educators can help Employers determine their training needs by assessing gaps.

- Short-term CPD: Topics to upskill current workforce members across all role families.
- Medium-term program updates: Topics to integrate into existing occupational standards through review and incorporation.
- Longer-term changes: New qualifications and standards required to prepare new entrants.

#### For the short term CPD solutions, Educators should:

- Review IFATE standards and relevant qualifications for roles described by the FOPs with Employers.
- Assess FOPs data against selected Standards and Qualifications, providing feedback to employers



- Evaluate existing CPD provision for possible incorporation.
- Commission new CPD courses if none are available.
- Facilitate collaboration to identify core education needs, maintaining a joined-up approach.

## F. Identify further workforce foresighting

Further cycles of foresighting solutions that respond to intensification of manufacturing of therapeutics and RNA therapeutics should be identified as technology challenges become clear. Focussing on those technology innovations within the horizon 2 timeframe of 2-5 years where this workforce foresighting methodology is most effective.

What	Identify Further workforce foresighting
Who	Stakeholders – Bioprocessing industry and industry organisations
When	3 months after publication
Result	Further FOPs and data uncovering new and common skills needs

## G. Lessons learnt

This foresighting study has been the pilot study within CPI and one of the first to use the Workforce Foresighting Hub online Data Visualisation Tool. Working with the Foresighting Hub, the foresighting process is continually updated and improved for future cycles. Some areas for further consideration include:

- Capturing the "Current state" in terms of existing workforce capabilities at the outset would enable helpful comparisons and remove the need to develop a "proxy" current state as for this cycle.
- Additional consultation with stakeholders during the 'Identify' and 'Prepare' phase of the Foresighting Cycle to 'seed' the process with capability sets and existing workforce occupational profiles could reduce the need for level of quality assurance and prevent potential data omissions.
- Allowing sufficient time, 2 weeks has been suggested, for Technologists to quality assure the 'Data-Cube' future capability outputs in between the early workshops in the 'Carry-out' phase of the foresighting cycle, would remove a need for further data cleansing later in the process.

The above points will be drawn into future CPI workforce foresighting projects.

## H. Recommendations to Workforce Foresighting Steering Board

- Maintain collaboration: Ensure the group progresses effectively to deliver benefits. Without concerted efforts to develop the right skills, we risk being unprepared for the Future.
- Ensure alignment between existing skills and new demands while focusing on skill development.



# **5.0 Appendices**

## 5.0 Appendices

Section	Title
5.1	List of Participants
5.2	References
5.3	Cycle timeline
5.4	Summary of FOP findings compared with current standards
5.5	Access to output data - link and authorisation
5.6	Glossary - common language



## 5.1 List of Participants

Technologists	Employers	Educators
CPI	FUJIFILM Diosynth	University College London
Cytiva	Biotechnologies	Cogent Skills
Cell and Gene Therapy	Aldevron LLC	East Durham College
Catapult	Astra Zeneca	Education Partnership NE
CEPI (Coalition of Epidemic	Bioindustry Association	Imperial College
Preparedness Innovations)	Biopharm services	Education Training Collective
Imperial College	Croda Europe Ltd	National Horizon Centre
Labman Automation	eXmoor Pharma Concepts Ltd	North East Institute of
Office for Life Sciences	Labcorp Drug Development	Technology
Sheffield University	Moderna	Teesside University
Sartorius	New England Biolabs	
University College London	NeoVac Ltd	
42T	Quotient Sciences Ltd	

The following organisations participated in the project:

## **5.2 References**

Collier, I., Shakspeare, P., & Sandford Smith, D. (2020). Manufacturing the Future Workforce. High Value Manufacturing Catapult, The Gatsby Charitable Foundation <a href="https://www.gatsby.org.uk/uploads/education/reports/pdf/manufacturing-the-future-workforce.pdf">https://www.gatsby.org.uk/uploads/education/reports/pdf/manufacturing-the-future-workforce.pdf</a>

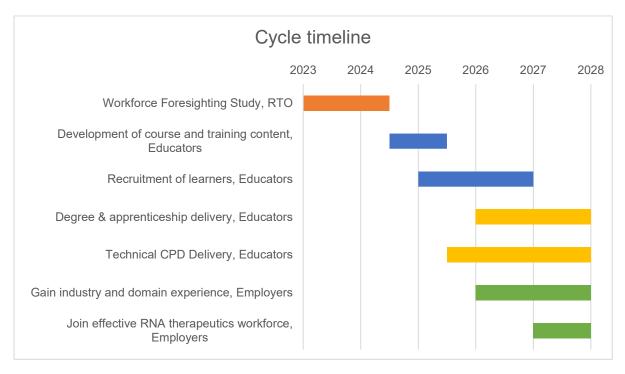
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## **5.3 Cycle timeline**





# **5.4 Summary of FOP findings compared with current standards**

The following table provides an overview of the data shared in section 3 of this report, showing the overall suitability RAG rating for Future Occupational Profiles when compared with current standards.

		Selected Future	Overall Suitability
Role Family	Primary Value Chain / Workflow Partner	Occupational Profiles	RAG
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"RNA Manufacturing Technician"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Manufacturing Quality Control Analyst"	
1. Technical Operator (RNA)	2. EQUIPMENT MANUFACTURERS	"Automation Technician"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Warehouse Coordinator"	
1. Technical Operator (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"RNA maintenance technician"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Technician Scientist"	
2. Manufacturing Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Equipment, Software and Systems Technician"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Warehouse operations supervisor"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Data Analyst"	
2. Manufacturing Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Process Leader"	
2. Manufacturing Engineer (RNA)	3. CONSUMABLE AND RAW MATERIAL PROVIDERS	"Quality Technician"	
2. Manufacturing Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Operations Supervisor - equipment manufacturer"	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Operations Manager"	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	Operational Technology Manager	
3. Scientist / Engineer (RNA)	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Quality Control Scientist"	
3. Scientist / Engineer (RNA)	2. EQUIPMENT MANUFACTURERS	"Automation Engineer"	
3. Scientist / Engineer (RNA)	3. CONSUMABLE AND RAW MATERIAL PROVIDERS	"Development Scientist - RNA supply chain"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Senior Scientist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Quality Control Specialist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Data Scientist"	
4. Senior Scientist / Engineer / Tech Officer	1. RESEARCH AND DEVELOPMENT/RTO/ACADEMIA	"Manufacturing process improvement specialist"	
4. Senior Scientist / Engineer / Tech Officer	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Manufacturing Safety and Compliance Manager"	
4. Senior Scientist / Engineer / Tech Officer	4. BIOPHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS (INCLUDING CDMO'S)	"Supply Chain Manager"	
4. Senior Scientist / Engineer / Tech Officer	2. EQUIPMENT MANUFACTURERS	"Design Engineer - equipment manufacturing"	



## 5.5 Access to output data - link and authorisation

Link to Visualisation Data

## 5.6 Glossary - common language

## Additional glossary terms for this cycle:

RNA – Ribonucleic acid CDMO – Contract Development Manufacturing Organisation RTO – Research & Technology Organisation

#### WF Hub Glossary

Term	Definition
Impact Domains	Innovate UK domains used as Strategic Categories to assist setting and monitoring priorities
National Challenge (Industry / Sector / Region)	A recognised technological or socio-political threat or opportunity for which there is consensus that workforce action is necessary
Challenge Response	Specific intervention aimed at the challenge
Capability (Organisation)	The collective abilities, and expertise of an organisation to carry out a function, because provision and preparation have been made by the organisation
Capability Classification	Classification provides a common, structured vocabulary to define capability
Capability Statements	Description of the depth and nature of each capability within an organisation
Capability Syntax	Common language to describe each capability application within organisation type
Competencies (Workforce / Individual)	<sup>'</sup> Proficiency, aptitude, capacity, skill, technique, experience, expertise, facility, fitness related to capability
Competency definition 'KSBs' (Knowledge, Skills and Behaviours)	Knowledge, Skills, and Behaviours are the elements used to express the required competencies for each Role Family
Competency Domain	Used during foresighting analysis to provide focus on existing and emerging competency needs
Delphi Process	Foresighting takes a Delphi approach which has come to represent consulting expert opinion. (Harking back to the Delphic Oracle of ancient Greece)
Foresight Cycle	Set of workshops, analysis and reporting that implements the Foresight Process for each subject
Foresight Process	A series of activities which are convened to understand future competence needs, the opportunities available and actions required to deliver the right skills at the right time and place
	An individual nominated within a new user organisation of foresighting to facilitate and lead the use of foresighting processes and tools with the support of the Project Team
Foresighting Subject	The application of specific technologies in the context of a given challenge and which are candidates for foresighting
Future Competency Set	The KBS output from the Educator workshop for each Role Family
Map and Gap Analysis	A combined expert and automated process that maps the Future Competency Set against a selected reference framework



Organisation Type	Simple description of nature of organisation for which capability is required
Proficiencies	Proficiencies differentiate the degree of competencies required from differing Role Families to support capabilities
Project Sponsor	Typically, a stakeholder in the challenge being successfully met who requires information to under-write plans to act
Role Family	Role families are a collective of roles that exist in a typical manufacturing business / industrial sector
Syntax	The way in which a statement is phrased to ensure reliable, repeatable and meaningful interpretation
Technologies	The technology that could be used to address the challenge
Working Scenario	To provide further context in relation to the subjects and used to position participants thinking during the detailed identification of future capabilities
Workshops	Online sessions used to undertake each step in the foresight process
Roadmaps	Sector, Industry, Regional view of emerging opportunities and their market entry
Participants	Technologists, Educators, Employers

