

# Outputs from the Advanced Therapies Manufacturing Task-force (People, Skills and Training sub-team)

## Executive Summary

In order to ensure a sustainable supply of knowledge and skills necessary to fuel the growth of the sector, **the Task-Force recommends the creation and implementation of an end-to-end talent plan for the sector**. The plan will encompass integrated strategies to develop the talent pool at multiple entry-points. These range from Manufacturing Technicians through to Post-doctoral and Professional levels. Every effort has been made to leverage existing initiatives and the majority of funding will come from industry – either through direct subscription or through Apprenticeship Levy funds. Nevertheless, some central government funding is requested to ensure successful set-up and coordination of the plan. The impact is primarily measured in the creation of new highly-skilled jobs – which are estimated at several hundred per year on an on-going basis. The strategic objectives, recommendations and resource requests are summarised in Table 1

## Introduction/Context

The anticipated growth of the Advanced Therapies (AT) sector in the UK will critically rely on a commensurate growth in the available talent pool. A conservative estimate is for 400-600 additional skilled staff being required over the next two years <sup>(1)</sup>. The knowledge and skills sets companies will require will be varied – with employment opportunities ranging from relatively basic manufacturing operations progressing through to highly specialised tasks such as those carried out by Qualified Persons and Regulatory professionals. Furthermore, the balance of the skills and knowledge requirement will evolve as existing business models mature. Currently the AT manufacturing sector in the UK is in a nascent phase. Products are mostly in the experimental phase and manufacturing processes are largely under-developed and small-scale. Consequently, the skills and knowledge requirements currently associated with AT manufacturing are highly specialised (often post-doctoral) and multi-functional. As the industry matures and begins to commercialise products, the highest growth in skills and knowledge demand will not be in this highly expert group but increasingly in competent technicians or operators capable of reliably running routine manufacturing operations.

## Strengths, Opportunities and Existing Initiatives

The UK is fortunate to have many strengths that make it well-positioned to grow the necessary talent pool. Not least, the UK academic base is widely acknowledged as world-class. As well as a pipeline supplying high-quality graduates and post-graduates, the academic sector has consistently proven to be a strong source of innovation in the AT sector which has driven value through establishing intellectual property and spin-out companies.

The risk of an acute skills shortage is not unique to the AT sector. There are a number of science-based industry sectors that recognise a common need around themes such as attracting young people into STEM careers, promoting vocational training and linking academia to industry needs. The Science Industry Partnership (SIP), an industry-led group, recently published a report entitled Skills Strategy 2025 <sup>(2)</sup> which made a number of proposals regarding increasing the capability and capacity of the UK science talent pool to meet the identified needs of the industry over the next decade. The SIP report is therefore much broader in scope compared to the AT Manufacturing Task-force, nevertheless, there are a number of initiatives proposed within the SIP report that are relevant to the ATMT challenge. These include a proposed STEM Ambassador network, a system for facilitating placement of undergraduate work experience in the sector and mechanisms for promoting

continuing professional development within the workplace. The ATMT has aligned with the SIP where relevant and ensured that these broader initiatives are leveraged to suit ATM requirements. The focus of the ATMT proposals will be those that are unique to the AT industry.

### Summary of Identified Gaps (Risk Analysis)

#### Process

Over the course of six months, a dedicated sub-group of the ATMT gathered stakeholder feedback through a series of facilitated workshops and surveys designed to identify the likely manufacturing skills demand required to fuel the AT industry. Representation from industry was high (<75%), from both large pharma and SMEs, and all major companies in the sector contributed. The accumulated evidence suggests that the skills and knowledge requirements will be broad ranging. The team sought to assess the current capacity and demand, as well as the future (3-5 year) demand and anticipated capacity (assuming no new initiatives). The outputs of the evidence gathering are presented in Figure 1 in a simplified form.

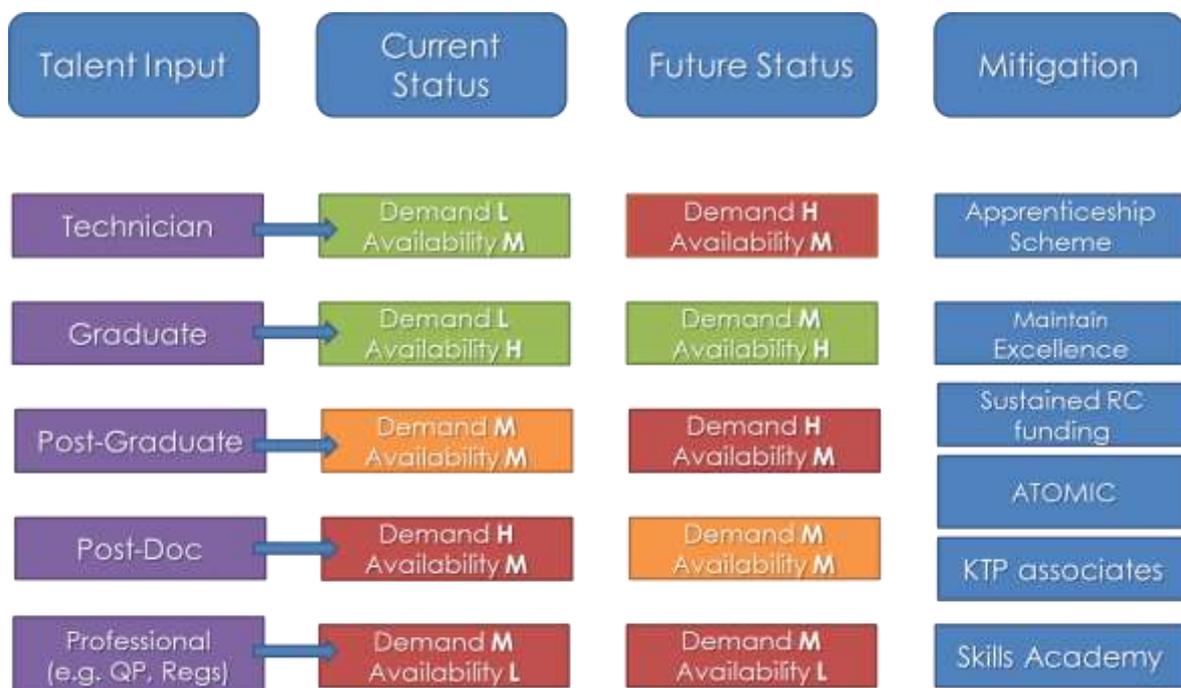


Figure 1: Summary Talent Plan for the AT industry illustrating current Demand/Capacity and anticipated future Demand bottle-necks if no strategies are employed.

The strategies proposed to remediate each gap are summarised below in Table 1 and described in detail in Appendix 1.

### Resource Requirement

The delivery of a successful Talent Plan will involve multiple stakeholders including industry, academia and funding bodies such as the science Research Councils and Innovate UK. If it is to truly meet industry-need then it should be industry-led and industry-funded. Nevertheless, there is a minimal level of ‘activation energy’ to launch specific initiatives and it is here that central funding can be critical to catalyse future growth and sustainability. The resource requirements and proposed sources are summarised below in Table 1.

	Strategic Objective	Recommendation	Resource required	Approximate value	Proposed Funder
1.0	Describe and deliver an End-to-End Talent Plan for the AT Manufacturing sector	<ul style="list-style-type: none"> <li>Plan will include components at multiple levels (Technician to Experienced Professional)</li> <li>Administered by a dedicated Training and Skills Manager</li> </ul>	<ul style="list-style-type: none"> <li>a. 1xFTE for Training and Skills Manager (TSM)</li> <li>b. Associated budget for catalysing Talent Plan</li> </ul>	<ul style="list-style-type: none"> <li>a. 75K pa for 3 yrs</li> <li>b. 200K pa for 3 yrs</li> </ul>	Centrally funded (G)
1.1	Create a technician workforce with the specialised skills necessary to serve the emerging AT industry	<ul style="list-style-type: none"> <li>Create and implement a Life Sciences Apprenticeship scheme that includes practical and theoretical modules on AT manufacturing</li> </ul>	<ul style="list-style-type: none"> <li>a. Curriculum content development</li> <li>b. Funding for apprenticeships</li> </ul>	<ul style="list-style-type: none"> <li>a. Approx. £50K contained within TSM budget</li> <li>b. According to need</li> </ul>	Levy funds from larger employers (I)
1.2	Accredited professional training for pre-existing talent within the Pharma/Biotech industry who wish to specialise in AT	<ul style="list-style-type: none"> <li>Create an accredited curricula of courses with specific emphasis on Qualified Persons, Regulatory Affairs and Clinicians</li> </ul>	<ul style="list-style-type: none"> <li>a. Curriculum content development</li> <li>b. Funding for professional training</li> </ul>	<ul style="list-style-type: none"> <li>a. Approx. £50K contained within TSM budget</li> <li>b. According to need</li> </ul>	Levy funds from larger employers (I)
1.3	A 'Skills Academy' for the sector that provides a venue for technical training	<ul style="list-style-type: none"> <li>A fully equipped, simulated production environment for practical training in AT manufacturing skills</li> </ul>	<ul style="list-style-type: none"> <li>a. Laboratory set-up costs</li> <li>b. Equipment</li> <li>c. Course delivery (Apprenticeship)</li> <li>d. Course delivery (Specialised courses)</li> </ul>	<ul style="list-style-type: none"> <li>a. £400K centre set-up costs. Still being discussed</li> <li>b. Equipment up to £400K</li> <li>c. According to need</li> <li>d. TBD</li> </ul>	<ul style="list-style-type: none"> <li>a. LEP secured funding (N Herts College) (G)</li> <li>b. Industry donation (I)</li> <li>c. Levy funds (I)</li> <li>d. Industry subscription (I)</li> </ul>
1.4	Ensure adequate supply of industry-ready PhD and post-doctoral researchers	<ul style="list-style-type: none"> <li>Sustained Research Council funding for existing initiatives such as Centres for Doctoral Training</li> </ul>	<ul style="list-style-type: none"> <li>a. Sustained RC funding for students</li> </ul>	<ul style="list-style-type: none"> <li>a. At 2016 budget level minimum</li> </ul>	<ul style="list-style-type: none"> <li>a. Research Councils (G)</li> </ul>
1.5	Improve the co-ordination and translation of AT bioprocessing research	<ul style="list-style-type: none"> <li>ATOMIC – an AT manufacturing industry club. A networking initiative to co-ordinate AT bioprocessing research and engage PhD students in the UK</li> </ul>	<ul style="list-style-type: none"> <li>a. Funding for ATOMIC</li> <li>b. Funding for KTP cohort</li> </ul>	<ul style="list-style-type: none"> <li>a. According to need</li> <li>b. Approx. £500K</li> </ul>	<ul style="list-style-type: none"> <li>a. Industry subscription (I)</li> <li>b. Innovate UK (G)</li> </ul>

Table 1: Summary of Strategic Objectives, associated proposals, resource required and proposed sources to meet anticipated skills shortages in the UK AT manufacturing sector

## Conclusions

Due to its excellent scientific capabilities, the UK currently enjoys a leading role in the nascent AT industry. This positions it very favourably to reap the rewards, both from a public health and economic perspective, that this sector is anticipated to deliver. However, without an adequate and sustained supply of appropriately-skilled and knowledgeable talent, the UK AT manufacturing sector will lose out to European and other overseas competitors. Considering the strengths and existing advantages present within the UK, this would be an enormous missed opportunity and damaging to the home grown development of new and innovative treatments. Currently, the strong UK academic science base attracts significant numbers of high-quality talent from other EU nations, who often come to the UK to study but subsequently move into the UK industry. For the UK to maintain its global position it would be risky to rely on the continued availability of external talent. It is imperative that the UK invests in and delivers a Talent Plan for the sector that ensures there is no over-reliance on external supply, but builds in a strategic and sustainable way on the lead that the UK currently enjoys.

## References

1. Cell and Gene Therapy Catapult, Skills and Training Consortium, February 2016
2. [http://www.scienceindustrypartnership.com/media/529053/5202fd\\_sip\\_skills\\_strategy\\_2015\\_final\\_low.pdf](http://www.scienceindustrypartnership.com/media/529053/5202fd_sip_skills_strategy_2015_final_low.pdf)

## Contributors

Particular thanks go to Paul Lewis of Kings College London and Ivan Wall of UCL for their excellent support on apprenticeships and UK academic base respectively.

Other contributing organisations include:

EPSRC, Autolus, KTN, BIA, Innovate UK, MHRA, GSK, Oxford BioMedica, AstraZeneca, Pfizer, GE, Cell & Gene Therapy Catapult, NBMC, UCL, Kings College London, Loughborough University, FUJIFILM Diosynth Biotechnologies, Eisai, Cobra Biologics, Synpromics, NightstaRx, Convatec, Roslin Cells, Fisher BioServices, Cellular Therapeutics, NHSBT, amc, eXmoor pharma concepts, MMIP skills, The Automation Partnership, Clinical Biomanufacturing Facility, Cognate, Aggio Sergeant, Science Industry Partnership, Apprenticeship Trailblazer Group, Scottish Enterprise, Skills Development Scotland, MeiraGTx

## Appendix

### Detailed Summary of Strategic Objectives

#### 1.0 An End-to-End Talent Plan for the Sector

<b>Strategic Objective</b>	Describe, validate and deliver an End-to-End Talent Plan for the AT Manufacturing sector
<b>Recommendation</b>	The plan will include components at multiple levels (Technician to experienced professional) and encompasses delivery of Strategic Objectives 1.1-1.5. A dedicated Training and Skills Manager (TSM), with associated budget, can monitor and adjust the plan to ensure effective delivery to stakeholders
<b>Implementation Plan</b>	TSM will be recruited by and associated with the existing Cell and Gene Therapy Catapult (CGTC). Their objectives and performance will be encompassed within the CGTC operation
<b>Owner</b>	Industry via CGTC
<b>Impact/Metrics</b>	An initial 3-year post should enable the delivery of Strategic Objectives 1.1-1.5
<b>Resource and funding required</b>	1xFTE for Training and Skills Manager - £75K pa for 3 yrs (G) Assoc. budget for catalysing Talent Plan - £200K pa for 3 yrs (G)

#### 1.1 Create a suitably-skilled technician workforce

<b>Strategic Objective</b>	Create a suitably-skilled technician workforce with the specialised skills necessary to secure the emerging AT manufacturing need
<b>Recommendation</b>	Create and implement a Life Sciences Apprenticeship scheme that includes practical and theoretical modules on cell therapy and regenerative medicine.
<b>Implementation Plan</b>	In order to reduce costs and ensure a 'critical mass' of apprentices, it is important to exploit as much as possible the commonalities between the training required by apprentices in cell therapy and other, closely related fields (e.g. biologics). Curriculum content will be developed and curated by a dedicated TSM (see SO 1.0). Content will include online modules to facilitate remote/regional delivery. Hands-on and F2F training will be delivered through the proposed Skills Academy (SO 1.3)
<b>Owner</b>	Industry to administer scheme, potentially through an external training organisation. Oversight via TSM
<b>Impact/Metrics</b>	Pilot Scheme in place Oct 2017. Up to 50 pa enrolled Apprentices from 2018 onwards
<b>Resource and funding required</b>	Curriculum content development - approx £50K contained within TSM budget Funding for apprenticeships according to need via Levy funds from larger employers (I)

#### 1.2 Accredited professional training for pre-existing talent

<b>Strategic Objective</b>	Accredited professional training for pre-existing talent within the
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	Pharma/Biotech industry who wish to specialise in AT. Specific emphasis on Qualified Persons, Regulatory Affairs and Clinicians
<b>Recommendation</b>	Create an accredited curricula of courses aimed at refocusing pharma professionals into key areas of need for AT manufacturing.
<b>Implementation Plan</b>	Professional training in this sector could be accredited as an Advanced Apprenticeship (Level 7), which will allow employers to utilise Apprenticeship Levy to fund or part-fund training. MHRA (Quality), TOPRA (Regulatory) and NIHR (Clinical) are all examples of organisations who have offered to help with curriculum development and delivery
<b>Owner</b>	Industry via Training and Skills Manager oversight
<b>Impact/Metrics</b>	Pilot Scheme in place Oct 2017. Up to 20 pa enrolled Advanced Apprentices from 2018 onwards
<b>Resource and funding required</b>	Curriculum content development - approx £50K contained within TSM budget Funding for apprenticeships according to need via Levy funds from larger employers (I)

### 1.3 A Skills Academy for the sector

<b>Strategic Objective</b>	A 'Skills Academy' for the sector that provides a resourced venue for accredited training. This can serve SO-2 (Technician Training) and also host specialised industry-tailored courses
<b>Recommendation</b>	A fully equipped, simulated production environment for practical training in AT manufacturing skills
<b>Implementation Plan</b>	North Hertfordshire College is located close to the CGTC. It has been awarded an initial £400K LEP grant to host a new engineering design and innovation centre. Initial discussions have strongly suggested that they would be willing to host the AT simulator laboratory within this facility. NHSBT also engaged to provide training facilities in additional geographical locations, along with the proposed National Horizons Centre Industry suppliers have offered to donate key equipment for free or at cost. As well as Apprentice training (paid by the Levy), the centres could host specific, tailored industry-led practical short courses. These would be subscription-based and self-funded. Possible models include Ireland's 'NIBRT' (see <a href="http://www.nibr.ie/">http://www.nibr.ie/</a> ) and the AMRC training centre, based in Sheffield (see <a href="http://www.amrc.co.uk/about/amrc-training-centre/">http://www.amrc.co.uk/about/amrc-training-centre/</a> )
<b>Owner</b>	North Herts College with oversight from Training and Skills Manager
<b>Impact/Metrics</b>	A unique training centre for multiple industry needs. Operational from 2018.
<b>Resource and funding required</b>	Laboratory set-up costs - £400k, LEP secured funding at N Herts College (G) Additional £150K 'activation' money and then £50Kpa for 5 years to operate the clean room facility at N Herts College (G) Equipment – up to £400k, industry donation (I) Course delivery (Apprenticeship) –according to need via Levy funds (I) Course delivery (specialised courses) – TBD, Industry subscription (I)

#### 1.4 Continued Supply of industry-ready PhD and post-doctoral researchers

<b>Strategic Objective</b>	Ensure an adequate supply of industry-ready PhD and post-doctoral researchers
<b>Recommendation</b>	Sustained Research Council funding for existing initiatives such as Centres for Doctoral Training
<b>Implementation Plan</b>	Continued funding and support at least at 2016 levels
<b>Owner</b>	Research Councils
<b>Impact/Metrics</b>	> 30 PhDs annually across relevant Doctoral Training Centres
<b>Resource and funding required</b>	Sustained RC funding for students at 2016 budget level min, RCs (G)

#### 1.5 ATOMIC – an ATM industry club

<b>Strategic Objective</b>	A networking initiative to co-ordinate ATMP Bioprocessing research
<b>Recommendation</b>	A mechanism for engaging PhD students from throughout the UK, enabling national collaboration, maximising opportunity for innovation and facilitating competitive applications for research funding.
<b>Implementation Plan</b>	Take learnings from successful BRIC (Bioprocessing Research Industry Club) and apply to ATOMIC. Use existing successful dissemination and show-casing forums such as bioProcessUK meetings, amc and summer schools. Establish a cohort (up to 10 pa) of Knowledge Transfer Partners (KTP) for the sector as part of existing Innovate UK scheme at 1 <sup>st</sup> post-doc level to translate technology into industry and produce industry-ready independent researchers and AT manufacturing sector leaders.
<b>Owner</b>	Industry-led through company subscription. KTP initiative led by Innovate UK
<b>Impact/Metrics</b>	Dynamic community of early-career scientists Increase academic-industry collaboration through networking events Facilitate recruitment into industry Dedicated KTP associates to translate innovation
<b>Resource and funding required</b>	Funding for ATOMIC - according to need via industry subscription (I) Funding for KTP cohort – approx. £500k, Innovate UK (G)

#### Landscape of ATMP Training Initiatives

<b>Training Provider</b>
EPSRC & MRC CDT Loughborough
EPSRC & MRC CDT Manchester
EPSRC CDT Leeds
EPSRC CDT UCL
EPSRC CDT Nottingham
EPSRC Doctoral Training Partnership
EPSRC Fellowships

EPSRC/BBSRC/MRC CASE awards
EPSRC Impact Acceleration Accounts
UCL MBI courses
UCL Vision Leadership Programme
UCL IDTC in Bioprocess Engineering Leadership
UCL Manufacturing the Future: Regenerative Medicines
UCL Undergraduate courses
Cell Therapy Manufacturing: Getting it Right From the Start
Apprenticeships - Foundation Degree in Applied Bioscience Technology
eXmoor pharma concepts
Apprenticeships - HNC and HND Applied Biological Sciences
MMIP Skills Workstream
BIA MAC
BIA PAC
Regener8 Early Career Researcher network
Future Investigators in Regen Med (FIRM)
ESACT
IChemE
BSCGT
BBSRC BRIC
BBSRC Modular Training Partnerships (MTP)
BBSRC Flexible Interchange Programme (FLIP)
BBSRC Professional Internship for PhD students (PIPS)
BioProNET
SIP
NBMC - National Horizons Centre
CGTC
NHS BT
MRC Doctoral Training Partnership
MRC Biotechnology YES competition
MRC Career Development Award (CDA)
Senior Non-Clinical Fellowship (SNCF)
Royal Society of Biology
Cogent
Innovate UK KTPs
BBSRC STARS - UoM
MHRA - QP
Scottish Centre for Regenerative Medicine (SCRM)
Centre for Tissue Regeneration and Repair (CTRR)