

House of Commons Science and Technology Select Committee inquiry: Closing the STEM skills gap

BioIndustry Association submission – January 2017

Key points:

- **STEM skills are essential for innovation-led industries in the UK, such as life sciences.** These skills are necessary to support every stage of the innovation pathway, from discovery through translation, manufacturing and market delivery
- This submission addresses the current skills deficit identified for manufacturing of Advanced Therapies (AT) – a specialised area of the life sciences industry focused on the development of new gene and cell-based medicines – as the BIA has recently been part of a taskforce looking at this issue in-depth. The BIA refers the Committee to the submission of the Science Industry Partnership for a broader perspective on the STEM skills requirements of the sector
- Due to its strong research base, the UK is well-placed to secure a world-leading position in the Advanced Therapies manufacturing market, which is expected to grow to be **worth between \$14-21 billion globally per year by 2025**
- In order to ensure a sustainable supply of knowledge and skills necessary to fuel the growth of AT manufacturing in the UK, **the creation and implementation of an end-to-end talent plan for the sector is required.** This must support the development of a range of skills from Manufacturing Technicians through to Post-doctoral and Professional levels
- The strategic objectives, recommendations and resource requests of the plan are summarised in Table 1 of this submission. These include:
 - **Creating specialised Apprenticeship Training Schemes** for AT Manufacturing Technicians
 - **Providing an accredited curricula** of courses with specific emphasis on Qualified Persons, Regulatory Affairs and Clinicians
 - Ensuring **continued funding for AT bioprocessing PhD studentships** through the Research Councils
 - Establishing a **networking initiative to co-ordinate AT bioprocessing research and engage PhD students** in the UK

Background

Early in 2016 the Medicines Manufacturing Industry Partnership (MMIP), supported by BIA, ABPI and KTN, launched a joint Industry/ Ministerial Advanced Therapies Manufacturing Taskforce (ATMT) to make the UK the go to destination for international investment in Advanced Therapies (AT) manufacturing, which is expected to grow to be worth between \$14-21 billion globally per year by 2025. The Taskforce is co-chaired by Ian McCubbin of GSK and Jo Johnson MP, with Mark Bustard of KTN leading the secretariat, and has representation from industry, academia, government departments and associated bodies, including funders and regulators. The resulting Action Plan¹, which outlines the key actions the UK must take to capture advanced therapies manufacturing investment, was launched to industry at the bioProcessUK conference on 23 November and simultaneously presented to government. The recommended actions were endorsed by the Government, recognising regenerative medicine as one of the Eight Great Technologies². The paper below details the people, skills and training component of the Action Plan.

¹ MMIP (2016), Outputs from the Advanced Therapies Manufacturing Task-force (People, Skills and Training sub-team): <http://bia.me/ATMTskills>

² These were launched by the Coalition Government in 2013 as part of an industrial strategy. See <https://www.gov.uk/government/speeches/eight-great-technologies> for more information.

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 2025³ 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 ATMT, 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 AT manufacturing requirements. The focus of the ATMT people, skills and training proposal outlined below will be those that are unique to the AT industry.

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

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 years⁴. 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.

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

³ Science Industry Partnership (2016), Skills Strategy 2025: <https://goo.gl/dVHVfA>

⁴ Cell and Gene Therapy Catapult, Skills and Training Consortium, February 2016

manufacturing skills demand required to fuel the AT industry. 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.

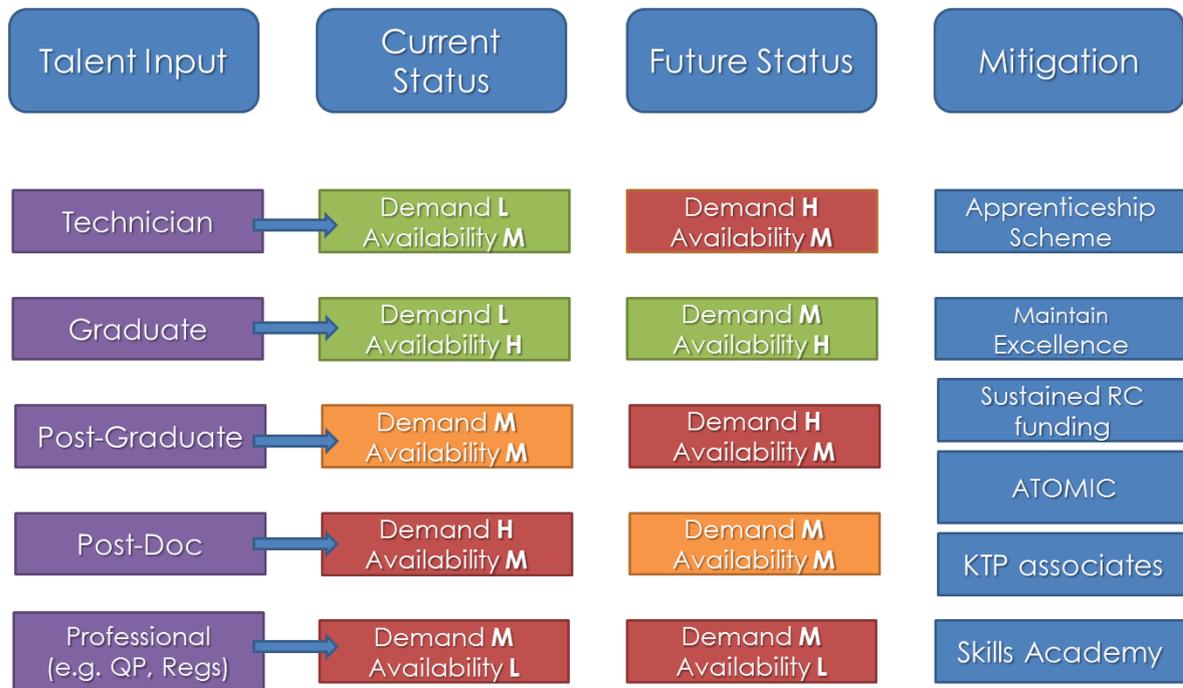


Figure 1: Summary Talent Plan for the AT industry illustrating current Demand/Capacity and anticipated future Demand bottle-necks if no strategies are employed. L = low; M = medium; H = high.

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

Resource Requirement

To address the challenges identified, the ATMT proposes a Talent Plan. The delivery of a successful 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 from Government can be critical to catalyse future growth and sustainability. The key components of the plan and proposed funders are summarised below in Table 1.

	Strategic Objective	Recommendation	Proposed Funder
1.0	Describe and deliver an End-to-End Talent Plan for the AT Manufacturing sector	<ul style="list-style-type: none"> Plan will include components at multiple levels (Technician to Experienced Professional) Administered by a dedicated Training and Skills Manager 	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"> Create and implement a Life Sciences Apprenticeship scheme that includes practical and theoretical modules on AT manufacturing 	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"> Create an accredited curricula of courses with specific emphasis on Qualified Persons, Regulatory Affairs and Clinicians 	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"> A fully equipped, simulated production environment for practical training in AT manufacturing skills 	a. LEP secured funding (N Herts College) (G) b. Industry donation (I) c. Levy funds (I) d. Industry subscription (I)
1.4	Ensure adequate supply of industry-ready PhD and post-doctoral researchers	<ul style="list-style-type: none"> Sustained Research Council funding for existing initiatives such as Centres for Doctoral Training 	a. Research Councils (G)
1.5	Improve the co-ordination and translation of AT bioprocessing research	<ul style="list-style-type: none"> ATOMIC – an AT manufacturing industry club. A networking initiative to co-ordinate AT bioprocessing research and engage PhD students in the UK 	a. Industry subscription (I) b. Innovate UK (G)

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. 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.

About the BIA

Established in 1989, the BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises. BIA members include emerging and more established bioscience companies, pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector.

Our members are responsible for over ninety per cent of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

For a full list of organisations that contributed to this work, please see the Advanced Therapies Action Plan⁵

For additional information or clarification on any of the points raised please contact Martin Turner, Policy and Projects Manager, at mturner@bioindustry.org or on 020 7630 2192.

⁵ MMIP (2016), Outputs from the Advanced Therapies Manufacturing Task-force (People, Skills and Training sub-team): <http://bia.me/ATMTskills>

Appendix

Detailed Summary of Strategic Objectives

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

Strategic Objective	Describe, validate and deliver an End-to-End Talent Plan for the AT Manufacturing sector
Recommendation	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
Implementation Plan	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
Owner	Industry via CGTC
Impact/Metrics	An initial 3-year post should enable the delivery of Strategic Objectives 1.1-1.5
Resource and funding required	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

Strategic Objective	Create a suitably-skilled technician workforce with the specialised skills necessary to secure the emerging AT manufacturing need
Recommendation	Create and implement a Life Sciences Apprenticeship scheme that includes practical and theoretical modules on cell therapy and regenerative medicine.
Implementation Plan	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)
Owner	Industry to administer scheme, potentially through an external training organisation. Oversight via TSM
Impact/Metrics	Pilot Scheme in place Oct 2017. Up to 50 pa enrolled Apprentices from 2018 onwards
Resource and funding required	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

Strategic Objective	Accredited professional training for pre-existing talent within the Pharma/Biotech industry who wish to specialise in AT. Specific emphasis on Qualified Persons, Regulatory Affairs and Clinicians
Recommendation	Create an accredited curricula of courses aimed at refocusing pharma professionals into key areas of need for AT manufacturing.
Implementation Plan	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
Owner	Industry via Training and Skills Manager oversight
Impact/Metrics	Pilot Scheme in place Oct 2017. Up to 20 pa enrolled Advanced Apprentices from 2018 onwards
Resource and funding required	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

Strategic Objective	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
Recommendation	A fully equipped, simulated production environment for practical training in AT manufacturing skills
Implementation Plan	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 http://www.nibr.ie/) and the AMRC training centre, based in Sheffield (see http://www.amrc.co.uk/about/amrc-training-centre/)
Owner	North Herts College with oversight from Training and Skills Manager
Impact/Metrics	A unique training centre for multiple industry needs. Operational from 2018.
Resource and funding required	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

Strategic Objective	Ensure an adequate supply of industry-ready PhD and post-doctoral researchers
Recommendation	Sustained Research Council funding for existing initiatives such as Centres for Doctoral Training
Implementation Plan	Continued funding and support at least at 2016 levels
Owner	Research Councils

Impact/Metrics	> 30 PhDs annually across relevant Doctoral Training Centres
Resource and funding required	Sustained RC funding for students at 2016 budget level min, RCs (G)

1.5 ATOMIC – an ATM industry club

Strategic Objective	A networking initiative to co-ordinate ATMP Bioprocessing research
Recommendation	A mechanism for engaging PhD students from throughout the UK, enabling national collaboration, maximising opportunity for innovation and facilitating competitive applications for research funding.
Implementation Plan	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 st post-doc level to translate technology into industry and produce industry-ready independent researchers and AT manufacturing sector leaders.
Owner	Industry-led through company subscription. KTP initiative led by Innovate UK
Impact/Metrics	Dynamic community of early-career scientists Increase academic-industry collaboration through networking events Facilitate recruitment into industry Dedicated KTP associates to translate innovation
Resource and funding required	Funding for ATOMIC - according to need via industry subscription (I) Funding for KTP cohort – approx. £500k, Innovate UK (G)

Landscape of ATMP Training Initiatives

Training Provider
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)