

DEVELOPING TECHNICIAN SKILLS FOR EMERGING INDUSTRIES: LESSONS FROM THE ADVANCED THERAPIES SECTOR IN THE UK

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EXECUTIVE SUMMARY

The Gatsby Charitable Foundation funded a short piece of work, conducted between February and April 2017, to determine barriers to apprenticeship uptake in the Advanced Therapy Medicinal Products (ATMP) sector and building on a previous assessment by Paul Lewis (Lewis 2016a). This recent work was initiated as part of a recommendation contained in a wider skills assessment for the ATMP sector conducted by the Advanced Therapies Manufacturing Taskforce, led by industry and chaired by Jim Faulkner at Autolus – a leading ATMP company

Fourteen companies (Appendix 1) were interviewed, including core ATMP organisations and others with similar skills needs. Many of the core ATMP companies are growing rapidly, with a forecast doubling of numbers in the next twenty-four months. The output was presented to The Gatsby Charitable Foundation, Innovate UK and BEIS on the 26th April 2017. In summary, organisations are not used to taking on apprentices and support is required to embed apprenticeship thinking in the sector through a partnership between the relevant employers, thereby enabling them to amalgamate demand and coordinate activity. Increasing the number of apprenticeships in the sector, as it moves into a manufacturing phase, should reduce staff turnover, increase human resource capacity and contribute to anchoring investment in the UK.¹ There are currently a small number of levy paying companies in the ATMP sector. However, we anticipate that the 'non-levy paying' part of the community may take on apprentices when they recognize the value of doing so, and procedures are clarified and simplified.

¹ Investors will be less inclined to invest if there is no national commitment to an integrated skills development platform

1. INTRODUCTION

This report, which builds on previous analysis (Lewis 2016a), sets out the challenges faced in ensuring that emerging industries in advanced manufacturing in the UK possess the technician skills they need. It also offers suggestions about how those challenges can be met and overcome. The analysis draws on studies of one emerging sector in particular, namely the Advanced Therapy Medicinal Products (ATMP) sector of the UK pharmaceutical industry (i.e. cell, gene and regenerative medicine). However, the challenges described, and the lessons learned, are applicable to other parts of UK advanced manufacturing, where developments in science and engineering are — as in the case of ATMPs — leading to the commercialisation of new technologies and products. Hence, the ideas outlined below should be useful, not only for those interested in the ATMP sector, but also for policy-makers seeking to support other parts of advanced manufacturing where firms need to acquire skilled technicians in order to operate and maintain new manufacturing technologies.

The conclusion to which the analysis leads is that policy-makers should facilitate a partnership between the relevant employers to enable them to amalgamate demand and coordinate activity with other relevant parties such as the catapult centres.

2. THE ADVANCED THERAPIES MEDICAL PRODUCTS (ATMP) SECTOR

Advanced Therapy Medicinal Products (ATMPs) are medicinal products that involve the use of cell therapies, tissue engineering, and gene therapy techniques to stimulate the replacement or regeneration of human cells, tissues or organs, in order to restore or establish normal bodily functioning. Regenerative medicine, as it is also known, holds out the prospect of developing improved treatments and even cures for a variety of illnesses. It is also widely regarded as an important, emerging part of the UK life sciences sector, with the potential to generate significant economic benefits. The value of the world regenerative medicine market passed \$1 billion in 2012, and is predicted to grow strongly, reaching an estimated value of \$10 billion by 2025. Therefore, the economic benefits to be had from capturing a sizeable share of the global market are significant (Regenerative Medicine Expert Group 2015: 3; House of Commons Science and Technology Select Committee 2017: 13). It is for that reason that policy-makers have identified cell, gene and regenerative medicines as one of the “eight great technologies” that will help to “propel the UK to future growth” (Willetts, 2013; House of Commons Science and Technology Select Committee 2017: 5).

The UK has a strong research base in this field, but a key challenge lies in ensuring that the research in question is translated into commercially-viable manufacturing based in the UK. As one industry expert recently explained in testimony to the House of Commons Science and Technology Select Committee,

The nature of these products is that they are moving quickly and within one or two years, they will be much more common ... SMEs are growing, but they will hit a tipping point quite quickly where they have to make their mind up about whether they invest in manufacturing capability here or go somewhere else. We have to make sure that, when they reach that point, they do it here and the mechanisms are in place. (Quoted in House of Commons 2017: 12.)

To that end, the government established in March 2016 an Advanced Therapies Manufacturing Taskforce, with the goal of helping to “identify opportunities and actions to anchor advanced therapy manufacturing and the associated supply chain in the UK and to identify any gaps in the manufacturing landscape that need to be tackled” (Medicines Manufacturing Industry Partnership 2016). This report focuses on one of the requirements for attracting ATMP manufacturing to the UK, namely the existence of an institutional mechanism that will ensure that manufacturers enjoy an adequate supply of skilled technicians.

3. TECHNICIANS

Technicians are skilled people who deploy their knowledge and practical skills in the fields of science, engineering, mathematics, and technology in order to identify and solve practical problems. Technician roles require level 3-5 skills and knowledge and thus encompass both ‘craft roles’, such as those of maintenance engineer and laboratory technician, and also ‘associate professional/technical roles’ such as those of an engineering maintenance manager and laboratory manager. Examples of technician roles in the life sciences include the following: laboratory and quality control technician; engineering maintenance technician; manufacturing technician; and logistics technician.²

4. RESEARCH FINDINGS

4.1. First research project

The research that informs this report was carried out in two stages. The first piece of work was carried out in 2015-16, and involved interviews with twelve employers in the ATMP sector (Lewis 2016a). The project’s key findings can be summarised as follows:

- Several of the organisations are expanding, or planning to do so, moving either from R&D to process development, or from process development to manufacturing. This will create more work of the kind carried out by technicians, making it worthwhile to create specialist technician roles (e.g., manufacturing technician). Consequently, one would expect both the absolute number of technician roles, and also the share of such roles in the workforce, to increase.
- However, where they already exist, laboratory and manufacturing roles are usually filled, not by people with level 3-5 skills—that is, by genuine technicians—but by graduates. This is an instance of *over-qualification*; the highest level of formal qualification possessed by the workers exceeds that required to do their job well.³ The widespread incidence of over-qualification reflects the way in which the abundance of bio-science graduates produced by UK universities, and the paucity of suitable apprenticeship training programmes, means that advertisements for technician positions typically elicit large numbers of graduate applicants and few if any from people qualified only to technician level.

² More detailed descriptions of the first three of these roles can be found in Lewis (2016a: 6-7, 11-12) and Lewis (2016b: 14-29).

³ Other examples of over-qualification graduates being used to fill laboratory technician and manufacturing roles can be found in the chemical industry and in industrial biotechnology (Lewis 2013a: 16-18; Lewis 2016b: 17-19). Recent analysis suggests that the extent of over-qualification is greater in the UK than in most other European nations (CIPD 2015).

- The use of over-qualified, but under-skilled, graduates is problematic, for two reasons: graduates usually lack the practical skills required to apply their theoretical knowledge effectively in the workplace (i.e., they are over-qualified but under-skilled); and they often become dissatisfied with the work and pay associated with technician roles, leading to high and costly rates of labour turnover.
- As a result both of organisations' plans to expand the scale and scope of their activities, and also of their increasing awareness of the shortcomings of using graduates to fill technician roles, employers in the ATMP sector are becoming increasingly interested in the possibility of training apprentices to fill technician roles.⁴ However, evidence from several other emerging industries indicates that ATMP employers are likely to have difficulties in finding appropriate training providers, both for the off-the-job technical education required by apprentices (e.g., courses in cell biology and in QA procedures) and also for an initial period of practical training (designed to equip the apprentices with the ability to use a clean room properly and to adhere to the requirements of cGMP manufacturing). The reason lies in the so-called 'tyranny of small numbers'; given the relatively small size of the industry, the total number of apprentices demanded by employers in any one geographical area is likely to be too small to make it worthwhile for providers to offer the relevant training in question, given the prevailing funding regime.⁵ Waiting for the industry to grow 'naturally' until it becomes large enough for the number of apprentices to reach the 'critical mass' required to interest providers is problematic: if expanding firms are to have skilled technicians in the not-too-distant future, then given the 2-3 year length of good apprenticeship training programmes, trainees must be taken on now; and firms that find it hard to acquire the skilled technicians they need may exercise the option of locating their manufacturing facilities abroad, where skilled labour of the relevant kind may be more readily available.
- A second challenge that must be faced stems from the rapid pace of technological change in the ATMP sector. This constitutes a barrier to the provision of high-quality apprenticeship training because it implies that training programmes cannot be decided once and for all and then 'set in stone'. On the contrary, it will be necessary to ensure that there are reliable institutional mechanisms for ensuring that training programmes are kept up to date as new approaches to manufacturing, such as those involving automated methods of production, are developed.

4.2. Second research project

This second, follow-up project was carried out between February and April 2017, with a view to exploring in greater detail the demand for technicians in the ATMP sector, impediments to the satisfaction of that demand, and possible solutions to the problems hindering the use of apprenticeship training. Eight organisations active in ATMP development in the UK were interviewed (four of which had also been part of the previous study, four of which had not). In addition, six other employers were interviewed, drawn mostly from biologics, with a view to eliciting information about the extent to which apprenticeship training for ATMPs would

⁴ An 'apprenticeship' can be defined as a contract between an employer and a young person that commits those parties to a structured programme of activities that: combines on-the-job training and productive work with part-time, formal technical education; lasts for 2-3 years; is usually formally certificated; and which aims at level 3-5 skills of the kind required to equip works to fill technician occupations (Lewis 2014a: 1).

⁵ Studies of other parts of UK advanced manufacturing—including the space industry, composites and industrial biotechnology—suggest that this problem is not confined to regenerative medicine (Lewis 2012: 31; Lewis 2013b: 46-47; Lewis 2016: 39-40).

overlap with that required for biologics and small molecule pharmaceuticals. The key conclusions of this second piece of research were as follows:

- The project confirmed that there is indeed interest in apprenticeship training within the ATMP sector. Organisations are interested in the possibility of training apprentices to fill technicians roles in the areas of logistics, engineering and manufacturing. Conservative estimates indicate that around 20 apprentices might be in training from September 2018, taken across the three areas just mentioned, with an additional 30 starting training in 2019 (giving a total of 50 trainees) and 25 more in 2020 (giving a total of 75 apprentices in training by that date). The main interest in Year 1 could well be in logistics/supply chain apprenticeships,⁶ with the proportion of bioscience apprenticeships increasing over time.
- Interest in apprenticeships appears to be driven by the skills shortages created by expansion, the shortcomings of graduates (as described above), and the impact of the apprenticeship levy.
- Some potential barriers to the use of apprenticeships were also identified:
 - Some of the firms were headcount-constrained, making it difficult for them to recruit and employ an apprentice. This may well focus these organisations on training existing staff.
 - There was some concern about the salary costs of employing apprentices.
 - Most of the ATMP organisations interviewed were unfamiliar with apprenticeships, and therefore unsure about their precise requirements. This uncertainty might deter some firms from taking on an apprentice.
 - Relatedly, many of the smaller organisations in particular lacked a large HR department of the kind that could readily take on the challenge of learning about and managing an apprenticeship programme. Such firms may therefore simply decide that it is easier to hire over-qualified graduates to fill technician roles rather than fight their way through a labyrinthine apprenticeship system.⁷
- Interviews indicate that there is significant overlap between the training required for manufacturing technician roles in the ATMP sector and in biologics.⁸ The level 5 Laboratory Scientist apprenticeship standard appears to be a good first approximation to the competences occupants of manufacturing technician roles in the ATMP sector are expected to display, with no more than 10-20% of ATMP-specific training (i.e. 1-2 modules) needed (e.g. a theoretical module on the principles of cGMP manufacturing, and practical training on how to use a clean-room).⁹

⁶ The logistical challenges involved in running a clean room facility and in delivering personalised medicines to patients are considerable, and several employers visited in the second research project studies identified logistics and supply chain as an area in which they would look to take on apprentices.

⁷ Also see Lewis (2016a: 23-24, 2016b: 46-47).

⁸ Also see Lewis (2016a: 20).

⁹ See

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/411712/LIFE_INDUSTRIAL_SCIENCES_-_Laboratory_Scientist.pdf. A more detailed statement of competences and outline training syllabus are set out in Lewis (2016a: 31-35).

5. POLICY RECOMMENDATIONS

The research described above indicates, therefore, that there is indeed a growing interest in apprenticeship training on the part of employers in the ATMP sector. However, as we have also seen, there are several barriers to the take-up of apprentices. On the supply-side, the industry faces two difficulties. The first is that posed by the 'tyranny of small numbers'; the total number of apprentices is likely to be small in absolute terms, and in the absence of efforts to pool demand the number of apprentices in any one geographical area may be insufficient to persuade training providers that it is worthwhile offering the relevant training. The second supply-side problem concerns how to keep training programmes up-to-date in the face of rapid technological change (stemming in particular from ongoing efforts to automate production processes). Moving on to the demand-side of things, employers may be deterred from taking on apprentices by their unfamiliarity with apprenticeships, by the absence within their organisations of a significant HR team that can master the often-labyrinthine process of taking on and training an apprentice, and by head-count constraints. These challenges could be overcome by facilitating a partnership between the relevant employers to enable them to amalgamate demand and coordinate activity with other relevant parties such as the catapult centres.

Aggregating the demand for training, so that the number of trainees exceeds the threshold required to make it worthwhile to offer the relevant courses can be achieved in numerous ways.

- First, ATMP training should be coordinated by one organisation (the 'ATMP Training Hub'). The hub should be located in an area where there is a significant concentration of ATMP employers, preferably at the Cell and Gene Therapy Catapult (CGTC).
- Second, in order to extend its reach further and thereby increase the number of trainees who use it, the hub should offer training via distance learning, supplemented by periodic residential courses which apprentices could attend on block release. This would also serve to bring the community of ATMP apprentices together as one cohort, as they are likely to be with different training providers across the country for the core training. Given that there are important ATMP firms in both Scotland and Wales, it is also important that the scope of activities extends beyond England to include those countries as well, which will of course further bolster demand for the training it offers.
- Third, as far as possible the training courses should be designed so that they are suitable not only for apprentices from ATMP firms but also for two other groups of people: (i) apprentices from biologics firms (whose requirements, as noted above, are very similar to those of the ATMP sector); and (ii) graduate recruits and 'converts' from other industries who, while they may have already received significant education and training, may still need additional instruction in the particular requirements of working in the ATMP and biologics sectors (e.g. cGMP, clean room working). This will further increase demand for the training programmes in question, increasing their financial viability.

The initial financial outlay, and risks, associated with the provision of the practical component of the training, in particular in clean-room working, could significantly be reduced by utilising existing facilities (rather than building new ones). The use of existing

facilities should reduce the size of the investment required to establish the training programmes because some of the relevant equipment and personnel will already be in place; and it will reduce the risk because the facilities can be used to generate income from sources other than training, such as research/process development work (Lewis 2016a: 19-20; Lewis 2016b: 44-45).

Solving the second supply-side problem, namely that of keeping the training programmes offered up-to-date in the face of rapid technological change, requires that the ATMP Training Hub works closely with the relevant Catapult Centre, in this case the CGTC, and the leading academic centres. Catapult Centres were established in order to encourage the commercialisation of new technologies and products by providing various forms of support that are designed to reduce the risks associated with that process. As a result, they are familiar from an early stage with developments in manufacturing processes, leaving them well placed to assess what new knowledge and practical skills the technicians carrying out those processes would need.¹⁰ The ATMP Training Hub should therefore work closely with the CGTC—indeed, in our view, the hub should be located within the CGTC. This will ensure that there exists appropriate apprenticeship training that as new technologies are developed and implemented on a commercial scale there exists a supply of workers able and ready to operate them.

Past experience suggests that the people in industry and in government who are charged with the task of developing emerging industries and helping firms to commercialise all too often neglect the development of technicians, focusing on people qualified to graduate level or above. One potential impediment to the successful implementation of this suggestion is that, unlike their counterparts in other countries, the Catapult Centres do not have (a measure of) skills development as one of their key performance indicators. Therefore, their record when it comes to skills development, especially at the technician level, is mixed. Some, such as the Advanced Manufacturing Research Centre and the Manufacturing Technology Centre, have become involved in apprenticeship training to very good effect. However, others have paid little attention to technician skills and training, concentrating instead on training people qualified to graduate level or above. Given the importance of having a well-trained technician workforce to carry out manufacturing, the current, rather haphazard approach seems to be mistaken. The Catapult Centres should be given clearer remit in this area of technician skills and training, and encouraged to work with training providers to ensure the provision of high-quality apprenticeship training. This could be done through the explicit inclusion of (indicators of) skills development as one of the key benchmarks against which their performance is assessed (Lewis 2014b, 2016a: 21, 2016b: 44-45). Demonstration of skills development could also be a criteria introduced to the application criteria for those applying for Innovate UK R&D grants.

The hub also has a role to play in overcoming the demand-side impediments to the take-up of apprenticeships. As noted above, some employers may be headcount-constrained, making it hard for them to take on new members of staff, including apprentices, onto their payroll. Some organisations, especially may lack the experience and expertise required to access the apprenticeship system effectively and at reasonable cost in terms of time and other resources. This is especially likely to be a problem for small and medium-sized enterprises, who may not have a dedicated human resource department that can take charge of managing the recruitment and training of apprentices.

¹⁰ For more on this point, see Lewis (2016c: 17-19).

There exist various possible ways of alleviating some of the burden on small employers, thereby encouraging them to take on apprentices. Two will be briefly outlined here. One involves what is called ‘over-training’. This involves a large employer, who currently offer high-quality apprenticeships, playing a role in the training of more apprentices than they themselves require to meet their own anticipated needs, with the extra apprentices being employed from the outset of their apprenticeship by other firms (often small and medium-sized apprentices). The larger firm will typically manage the training and assessment of the apprentices, using its own apprentice managers, instructors and assessors to do so. It may also provide some of the on-the-job training itself, especially if it has its own training facilities. The smaller firms that have their apprentices managed in this way can gain access to a more experienced, and effective, way of managing and training their apprentices than they themselves could provide on their own. Moreover, the large employers that offer such over-training do not do so as a charitable act, but rather because they expect to benefit from doing so, for one of two reasons: either because the government funding and fees they gain from over-training help them to cover some of the fixed costs of running their own apprenticeship schemes; or because, by training apprentices for firms in their supply chain, they stand to gain from having better quality, and /or more reliable, input supplies. Several large employers in UK advanced manufacturing already engage in over-training and there exist some firms in the ATMP and biologics industries that are well situated to join their ranks (Lewis 2014c).

A second possibility would be for smaller firms to take their apprentices via the Apprenticeship Training Agency (ATA) run by Cogent Skills. ATAs are organisations that employ and manage the training of apprentices but which, rather than providing work for the apprentices themselves, hire them out to separate ‘host employers’ for the duration of their training. The hosts pay the ATA a fee for its services, the size of which depends both on the apprentice’s wage and also any management fee charged by the ATA. The ATA helps to recruit the young people, matches them with employers, and organises their training. It is hoped that ATAs will encourage small and medium-sized organisations to take on more apprentices, for two main reasons. First, they remove most of the burden of managing the apprenticeship from the host employers. Second, because the apprentices are employed by the ATA, and not by the ‘host employer’ itself, organisations that might be reluctant or unable to take apprentices if they had to commit themselves to employing them—because of headcount constraints, for example—are more likely to be able to become involved. By relieving employers of much of the burden of managing the apprentices, and by affording them the option of not directly employing the apprentice, therefore, the involvement of the ATA might encourage more employers to offer to host apprentices.¹¹

Which of these is the best approach to encouraging and assisting small and medium-sized organisations to take on apprentices, or where there is some other superior solution, is something that the ATMP Training Hub will need to explore, in conjunction with employers in the AMTP sector.

7. CONCLUSION

Emerging industries in advanced manufacturing, such as the ATMP sector, will need to employ more and more technicians as the scale and scope of their activities increases. Their efforts to do so will be greatly assisted by the creation of an ATMP Training Hub that will

¹¹ For Cogent’s ATA, see <http://www.cogentskills.com/new-talent/employers/apprenticeships/apprenticeship-training-agency/>.

take responsibility for establishing and championing apprentice training programmes in the ATMP sector. The ATMP Training Hub should:

- work with employers in ATMPs and closely related sectors, such as biologics, to devise a statement of the competences required for various roles in the industry, drawing on—and modifying only where strictly necessary—existing apprenticeship training standards;
- work closely, and on a sustained basis, with the CGTC to ensure that the training remains up-to-date as technology changes;
- work with colleges or universities to develop courses that will impart the relevant off-the-job technical education, probably by distance learning coupled with summer schools (so the apprentices can be drawn from the widest possible geographical range, including from outside England);
- identify and liaise with the managers of existing clean room facilities in order to arrange hands-on training programmes that will equip apprentices, and ideally also other trainees such as graduate recruits and recent ‘converts’ to the industry, with the practical skills required to working in the ATMP sector (e.g., the use of clean rooms and the principles of cGMP manufacturing);
- explore ways of encouraging small and medium-sized enterprises to take on apprentices (e.g. via the use of ‘over-training’ and ‘ATAs’).

The government has committed £197 million from the £1 billion Industrial Strategy Challenge Fund for the development of new technologies for the development of new technologies for manufacturing medicines (House of Commons Science and Technology Select Committee 2017: 14). But the successful implementation of new technologies requires skilled technicians, who will conduct the manufacturing in question. Accordingly, government should provide time-limited funding to support the creation of the training hub for the ATMP and biologics sectors, to be housed with the CGTC.¹² This hub should take responsibility for devising statements of the competences required for various roles in the sectors, and related training programmes, and be a focal point for coordinating efforts to ensure that the ATMP sector has the skills it needs. The government should also reward the CGTC for taking seriously the training of technicians, as well as postgraduate students, because — as argued above — the catapult has a key role to play in the continued provision of the training of the workforce required for the successful implementation of new manufacturing technologies. In this way, we believe, an institutional framework can be established that can ensure an adequate supply of skilled workers for emerging parts of the medicines manufacturing industry, and the shortages of technicians that have hampered the development of other emerging industries avoided.

¹² The National Biologics Manufacturing Centre (part of the High Value Manufacturing Catapult) focusses on biologics and is envisaged as a partner in this initiative.

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APPENDIX 1: Organisations Interviewed in second study

1. Allergan Biologics (Large Biologics Group)
2. Autolus (Small ATMP Company)
3. Cell and Gene Therapy Catapult (Medium ATMP Group & Government sponsored Organisation)
4. Cobra Biologics (Medium ATMP Company)
5. Eisai (Pharma & and leading MMIP)
6. FUJIFILM Diosynth Biotechnologies (Large Biologics Company)
7. GSK (Large ATMP Group)
8. Lonza (Large Biologics Company)
9. NHS Blood & Transplant (Large Government Employer involved in ATMP)
10. NightstaRx (Small ATMP Company)
11. Oxford BioMedica (Large ATMP Company)
12. Pfizer (Pharma and involved in National Apprentice Development)
13. Porton Biopharma (Large Biologics Company)
14. ReNeuron (Medium ATMP Company)

(The organisations interviewed in the first study must remain anonymous.)