

HOW TO CREATE  
SKILLS FOR AN  
EMERGING INDUSTRY:  
THE CASE OF  
TECHNICIAN SKILLS  
AND TRAINING IN  
CELL THERAPY

PAUL LEWIS  
DEPARTMENT OF POLITICAL ECONOMY  
KING'S COLLEGE LONDON  
PAUL.LEWIS@KCL.AC.UK

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GATSBY

## I. INTRODUCTION<sup>1</sup>

Regenerative medicine is a set of methods within medicine that involves the replacement or regeneration of human cells, tissues or organs, in order to restore or establish normal bodily functioning. It encompasses three main approaches, namely: the transplantation of cells, tissues and organs; stimulation of the body's own self-repair mechanisms; and the development of biomaterials for structural repairs. Regenerative medicine is regarded as a potentially important, emerging part of the UK life sciences sector. The UK has a strong research base, which affords the potential not only to develop treatments for a variety of current illnesses but also to generate significant economic benefit. The value of the world regenerative medicine market passed \$1 billion in 2012, and is predicted to grow strongly, so the economic benefits to be had from capturing a sizeable share of the global market are significant (BIS 2011a; MRC 2012; Regenerative Medicine Expert Group 2015).

This report focuses on one of the principal approaches used in regenerative medicine, namely cell therapy. In cell therapy, living cells – as distinct from drug-based therapies – are administered to the patient in order to help deal with illnesses. Examples of cell therapies include the use of stem cell transplants to treat various forms of cancer, such as lymphoma and leukaemia, bone marrow cells being used to build new tracheas, and the use of cells to restore eyesight after corneal damage.

The significance of the choice of cell therapy as the focus on the research reported here is threefold. First, while the rebalancing of the economy desired by policy-makers will of course require the growth of more established industries, such as automotive and aerospace, it will also depend upon the development of innovative technologies and products that can lead to the creation of new markets and new industries. Cell therapy and regenerative medicine is a case in point, along with industrial biotechnology, the space industry, nano-technology, and advanced materials. In considering cell therapy, therefore, the report focuses on the very kind of emerging industry that must develop and flourish if UK manufacturing is to enjoy some sort of revival (Willetts 2013: 35-37).

Second, perhaps because the majority of organisations involved in cell therapy are in the early stages of development, and so have not yet reached the point at which they engage in full-scale manufacturing, policy-makers have tended hitherto to focus on issues relating the supply of high-level skills, such as doctoral training centres and MSc programmes; while there have been allusions to the need to train technicians for industries in the life sciences, such as cell therapy, at least as far back as 2003 (DTI 2003: 95-96), and while similar observations have been repeated more recently (BIS 2011a: 42-43, 2011b: 22-23, HM Government 2012: 7, 34-35), the references to technicians contained in these documents are

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largely nugatory. This report aims to remedy that lacuna by considering the use made of technicians in cell therapy, and their skills and training needs.

Third, emerging industries such as cell therapy pose distinctive challenge for policy-makers and others seeking to ensure that there is an adequate supply of technician skills. The challenge arises from the relative youth of the industry in question, and has two aspects. First, even if there already exist curricula and apprenticeship training frameworks that might be used to train technicians for the industry, the pace of change in methods of production may render them obsolete. There is a need, therefore, to ensure that education and training for people in the industry in question keeps pace with the rate of technological change. Second, although the industries in question are growing rapidly, organisations are typically small in absolute terms, and so want only small numbers of apprentices. This may make it difficult to persuade training providers to offer the training required, because they may well find it more lucrative to offer training for the greater number of apprentices on more established training programmes. Moreover, waiting until the industry grows before starting training apprentices, so that there is more time both to ascertain what the content of the relevant training programmes should be, and also for the demand for apprentices to increase so that it reaches a 'critical mass', may itself cause problems. The reason is that the time taken to train technicians to an adequate standard through apprenticeship programmes implies that if today's emerging industries are to have skilled workers in 3-5 years time, then it is necessary that they be trained now, in the emergent technologies they will be required to use once they have qualified. Waiting to start training will therefore imply that the technicians will not be ready when the industry needs them. A consideration of cell therapy therefore raises interesting issues for those interested in increasing the number of apprentices and technicians in the UK economy.

The goal of the research described in this report is to inform efforts to ensure that employers in cell therapy in the UK are able to acquire the skilled technicians they will need as the move towards full-scale manufacturing, by examining not only how technicians are currently used and acquired but also how they are likely to be used in the future. More specifically, the paper seeks to answer five sets of questions:

- First, are technician roles currently found in organisations involved in cell therapy? If so, how are those roles filled?
- Second, is the incidence of technician roles likely to increase in the future? If so, in what kinds of roles are technicians likely to be used? What kinds and levels of skills and qualification do those technicians need?
- Third, how do employers in cell therapy intend to fill those emergent technician roles?
- Fourth, what problems are likely to arise in the ensuring that cell therapy organisations are able successfully to fill technician roles?
- Fifth, what – if anything – can be done to help employers in cell therapy in their efforts to acquire skilled technicians?

The structure of the report is as follows. Section 2 outlines the research methodology used in this study and describes the set of case study organisations. Section 3 begins the presentation of the study's findings, by examining whether there are any technician roles in cell therapy organisations and, if there are, how those roles are filled. Section 4 continues with the presentation of the results, but shifts attention towards the future, by examining how the use of technician roles seems likely to change as the industry develops from one focusing primarily on research and development to one where many more organisations focus on manufacturing. Section 5 considers some of the institutional issues that will need to be addressed if employers in cell therapy who wish to make use of technicians in the future are to be able to do so successfully. Section 6 summarises the discussion.

## 2. RESEARCH METHODOLOGY AND OVERVIEW OF CASE STUDY ORGANISATIONS

In the absence of a large data set concerning the skills and training of technicians in cell therapy, a case study method was adopted. This has the benefit of making it possible to explore employers decisions how about to obtain and use technicians in considerable contextualised detail.

The process of data collection had two main stages. The first involved a series of 9 interviews with 17 representatives of 9 sector-level organisations, including government departments and various agencies and working parties focusing on skills in the relevant industry, and sector skills councils. These interviews, along with secondary sources such as reports and policy documents concerning the UK cell therapy and regenerative medicine industry, and also attendance at a government-sponsored workshop on skills for cell therapy and regenerative medicine, were used both to acquire information about key issues associated with the industry's use of technicians and also to inform the choice of case study organisations.

The second stage of the project involved the collection of data about technician duties, skills, recruitment, and training from a total of 12 current employers. Information was collected from them via 17 semi-structured interviews with a total of 13 interviewees, whose ranks included: chief operating officers; heads of manufacturing; manufacturing managers; operations managers; heads of research and development; and directors of laboratories. The organisations visited can loosely be divided up according to whether their current focus is primarily on research and development activities (9 cases) or whether they are engage in commercial manufacturing (3 cases). The cases, which were drawn from England, Scotland and Wales, are summarised in Table 1:

TABLE 1: SUMMARY OF CASE STUDY ORGANISATIONS

Type of organisation	Number of cases	Average number of employees	Average share of technician roles in the total workforce <sup>a</sup>
R&D/process development	9	29	8%
Manufacturing	3	37	15%

### Notes

a: Technician roles may be filled by over-qualified graduates.

Unsurprisingly, given the relative youth of the industry, the largest group of organisations concentrates principally upon research and development (that is, on devising new therapies and on new methods of manufacturing therapies). While all of these organisations do manufacture cells, they do not do so on a commercial scale. Consequently, they all reported that the duties associated with the vast majority of

STEM roles in their organisations require people to be qualified to degree level or higher, with only a small number of technician roles (usually, as discussed in more detail below, laboratory technician positions). Only just under 8% of the positions in these organisations would be suitable for technicians (that is, for people with intermediate-level qualifications). Moreover, as we shall also see, such technician roles are typically filled, not by genuine technicians, but by over-qualified graduates.

The second, smaller group of organisations engages in manufacturing on a larger scale, for commercial purposes. These organisations tend both to be a little larger than those in the first category (though still small in absolute terms), and also to contain a significantly higher percentage of technician roles in their workforce (around 15%). Again, however, as we shall see, many of these roles are currently filled by over-qualified graduates.

The picture presented by these data is, however, only a snapshot in time, of a rapidly changing industry. As illustrated by the sample of organisations visited for this study, seven of which are expanding (most very rapidly), the industry is growing at an impressive rate.<sup>2</sup> Moreover, as shown by 3 of the case study organisations in particular, more and more firms are increasing not only the scale but also the scope of their activities, shifting from an exclusive focus on R&D and process development towards full-scale commercial manufacturing. As they do so, they are carrying out more and more routine manufacturing, up to the point at which it is now worthwhile for them to create specialist manufacturing roles. The consequences of this change will be discussed in more detail below. For the moment, it suffices to note that, as the organisations in question move towards commercial manufacturing, the nature of the work they undertake will change, with less emphasis on the development of new products and processes and more on the implementation of established methods of production (cell cultivation) that have been reduced to standard operating procedures (SOPs). This will be accompanied by a corresponding shift in the balance of roles, and associated skills and knowledge, required by the employers in question. In particular, as we shall see, there are likely to be more roles – both in absolute terms and as a share of the total workforce – devoted to routine manufacturing. Correspondingly, there will also be more of an emphasis on employing people who possess the tacit or practical knowledge, and the discipline, to behave in accordance with a set of SOPs and to follow them effectively in the workplace. As we shall see, employers believe that such people are more likely to have been trained via a work-based (apprenticeship) route, and to have intermediate-level qualifications, than via an undergraduate degree. That is to say, they are more likely to be technicians than graduates.

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<sup>2</sup> For corroboration of this finding, see Cell and Gene Therapy Catapult (2016: 8-10).

### **3. CURRENT TECHNICIAN ROLES IN CELL THERAPY**

#### **3.1 Current Technician Roles: The Laboratory and Quality Control Technician**

The most common technician role currently found in organisations involved in cell therapy is that of a laboratory and quality control technician. As is typically true of technician work, laboratory technicians facilitate and support the work of other, more highly qualified people (most notably in this case, research scientists) (Barley and Bechky 1994: 88-92, 115-16; Lewis and Gospel 2011: 16-20). More specifically, the kinds of tasks carried out by such technicians are typically threefold: the first centres on obtaining and preparing the materials and equipment used in practical scientific work carried out in their laboratory; the second involves various kinds of sampling and testing; the third involves helping to ensure, and documenting, the organisation's compliance with the regulatory and quality control procedures that govern cell therapy and regenerative medicine in the United Kingdom.

The preparatory activities, all of which will be done in line with work instructions set out by more senior staff, involve the technician performing stock checks and, where required, ordering equipment and consumables in order to ensure that there are sufficient materials, reagents, and so forth, in the laboratory; carrying out routine calibration and maintenance of laboratory equipment; undertaking risk assessments and documenting compliance with health and safety regulations; maintaining the cleanliness of the laboratory to appropriate standards; preparing micro-biological media, buffer solutions, reagents and analytical standards; monitoring the storage tanks where frozen cells are kept; thawing out cells; and carrying out the safe disposal of laboratory waste. It is worth observing that the extremely stringent regulatory regime governing work in cell therapy implies that even apparently mundane-sounding activities such as ensuring that the laboratory has a sufficient stock of the appropriate chemicals and reagents, and that the facilities have been cleaned to an appropriate standard, are in fact rather complex activities, for which significant training is required. It is also important to note that many of these activities must take place in clean rooms, so technicians need to know how to use gowns and gloves correctly and how to move about, and work in, a clean room). Such 'clean room discipline' is also important for some of the activities involved in the second of duties fulfilled by laboratory and quality control technicians.

This second set of duties sees technicians play a role in collecting and preparing samples for testing. The tests in question will involve taking samples from raw materials purchased for the lab, in order to confirm that they have the requisite properties; from the final product, in order to ensure that it is fit to be released to the patient; and also from the production facilities themselves, by using swabs, active air samplers, and contact and settle plates to check for the presence of contaminants in clean room). The sampling must be done aseptically, so that neither the samples nor the production facility becomes contaminated. Technicians may also carry out some of the (relatively simple) tests themselves, in line with standardised procedures. They will not, however, be involved in interpreting and analysing the results of the tasks, which task will be carried out by more senior scientists.

Third, laboratory and quality control technicians will help to ensure that all activity in the organisation takes place in accordance with the requirements of the various regulatory bodies that govern cell therapy and regenerative medicine in the United Kingdom, and also in documenting such compliance

(e.g. cGMP, MHRA, HTA)].<sup>3</sup> For example, technicians are likely to be involved in the ‘verification process’, whereby everything that is done in the course of cultivating cells must be witnessed and signed off by a trained observer, in completing the batch records that are used to record what procedures were carried out on cells, at what time, what reagents were used, and so forth, and also in documenting how the ‘chain of custody’ is maintained when cells that have been produced are transferred to the patient.<sup>4</sup>

### 3.2 Who currently fills laboratory and quality control technician roles?

Rank-and-file laboratory and quality control technicians typically require level 3 skills and knowledge to carry out their duties. However, while the duties associated with such roles can be discharged by people with intermediate-level qualifications, the evidence suggests that in practice the roles in question filled by graduates. Of the 10 organisations that have such positions, 9 reported that some or all of them are filled by people who are qualified to degree level or above. Those cases exemplify what is known as *over-qualification*; the level of formal qualifications possessed by the relevant workers exceeds that required to perform their duties effectively (Wolf 2011: 29). As the head of one manufacturing facility put it, “There are lots of technician roles filled by graduates ... There’s a real mismatch.”

This arguably reflects the impact of the considerable expansion of higher education in the UK over the past two decades. A majority of the organisations visited as part of this study reported that advertisements for technician positions generate many applications from people qualified to degree level or higher. In the words of one interviewee, “There are lots of graduates out there,” which makes it easy and cheap for employers to hire them to fill positions that would in the past have been occupied by people with intermediate-level qualifications. Alison Wolf has explained the broader significance of this state of affairs as follows:

*Higher education subsidies mean that employers are often able to displace a sizeable part of the training they used to do on to higher education institutions. Even if the training is less specific to their needs, and even without the work the apprentice does, they are often at least as well off as under apprenticeship, if not better off ... [so] employers will inevitably recruit as far as possible from graduates (2009: 96; also see Mason 2012: 15-19, 27; Keep and James 2011: 59-60; Wolf 2015a: 73-74).*

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<sup>3</sup> The term ‘cGMP’ refers to current ‘Good Manufacturing Practices’. These are the practices that the regulatory agencies controlling the authorisation and licensing of pharmaceutical products stipulate must be followed by pharmaceutical companies in order to ensure that the products being made are of high quality and do not pose any risk to the public. The Medicines and Healthcare Regulatory Authority (MHRA) is the supervisory authority for UK manufacturers or importers of centrally authorised Advanced Therapeutic Medicinal Products (including (including gene and cell therapy-based regenerative medicine). The Human Tissue Authority (HTA) is the UK’s regulator that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions. See BIS (2011a: 33-35) for details.

<sup>4</sup> The interested reader can compare the descriptions of the duties normally carried out by laboratory and quality control technicians in cell therapy organisations with the more abstract statement of the competences required of a qualified laboratory technician working in the life and industrial sciences by examining the relevant Trailblazer standard, which is reproduced as Appendix I of this report.



The abundant supply of graduates implies, then, that they can be hired at relatively low wages, and without the firms having to incur the costs of apprenticeship training, encouraging employers to rely on graduates rather than vocationally-educated technicians to fill technician roles.<sup>5</sup>

In the course of discussing the use of over-qualified graduates to fill technician roles, several employers also spoke about the status currently accorded to technicians in the UK. According to one interviewee, while it is true that “technicians keep the world running”, they are often not accorded the respect they deserve, the reason being that, “there’s a tendency in the UK not to value you if you don’t have a degree.” Two interviewees who had worked abroad both commented that technicians were held in much higher esteem on the continent. In Germany, an interviewee commented, “technician posts are seen as ones of prestige, that someone takes after a 3 year training programmes ... So technician posts are highly prized and sought after.”<sup>6</sup> A related theme, mentioned by several interviewees, concerned the fact that, “There aren’t good, obvious career paths.” In the words of another interviewee, “It would be very desirable to have appropriate career structures and a path for technicians ... [but] both are absent.” At root, the low status and esteem in which technicians are often held arguably reflects the fact that their work stands at the interface between manual and mental labour. The danger is that, if the more knowledge-related aspects are not acknowledged, then technicians’ work is associated only with physical effort and is therefore accorded low status. Moreover, because their role is to support and facilitate the work of another, more ‘eminent’ occupation, which is also widely seen to exercise authority over them, technicians’ contribution to research tends to remain invisible, with the result that technicians’ standing is not commensurate with the true significance of their work (Shapin 1989; Barley and Bechky 1994, 91, 116). Two interviewees mentioned professional registration as a possible means of bolstering the standing of technicians and of signaling the possibility of a route for career profession, up the ladder of professional designations.

### **3.3 Problems with the use of graduates to fill technician roles**

Employers’ reliance on graduates to fill laboratory technician roles is, however, commonly regarded as a mixed blessing: as just noted, it yields short-term benefits in the form of cheap labour; but it also generates two kinds of problem in the longer term. The first arises from the fact that the graduates in question often become dissatisfied with such roles, not only because of the relatively low wages they are paid but also because the mundane, routine, and repetitive nature of their duties leaves them feeling frustrated about not being able to make full use of the knowledge they acquired during the course of their degree. As the head of one research unit put it, there is a “major problem” with expectations management in the case of graduates, who often become dissatisfied with the “arduous, repetitive nature of the job” which “doesn’t satisfy their expectation of [their own] development [and] of using scientific knowledge.” The upshot is that such graduates often move on quickly in order to find better

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<sup>5</sup> The problem of over-qualification appears to be significant beyond cell therapy with somewhere in the region of one quarter and one third of UK employees falling into that category (Chevalier and Lindley 2009; Green and Zhou 2010; UKCES 2015: 7, 57). Moreover, evidence indicates that the scale of the problem is worse in the UK than in most other European nations (Holmes and Mayhew 2015: 25-28).

<sup>6</sup> For similar findings in the case of industrial biotechnology, see Lewis (2016).

paid, more challenging work, leading to higher turnover than would be the case if those roles were occupied by genuine technicians. Eight organisations firms mentioned this as a problem in the context of technician roles. “Moving on is more likely with a graduate than with a [genuine] technician,” the manager one manufacturing facility stated. An interviewee from a cell therapy manufacturer elaborated by explaining that, “Graduates don’t understand that they’re coming in at entry level and are too quick to want to move on.” On this view, while bringing short-run benefits, the strategy of using over-qualified graduates is problematic, because it leads to higher labour turnover and a more frequent need to incur the costs of recruiting, inducting, and – as we shall see – training new staff.<sup>7</sup>

The second problem with employing graduates to fill technician roles stems from the fact, mentioned by 6 employers, that many graduates lack practical skills and so cannot put their theoretical knowledge to good use in the workplace. As the manager of one facility explained, “Many graduates are over-confident and don’t have the practical skills ... to back up what they expect themselves to be able to do what roles they expect themselves to be able to fill ... They can’t use them properly in a practical setting.” This deficiency was attributed by 5 employers to the relatively small volume of practical work involved in undergraduate science degrees. “There is,” the head of one manufacturing unit argued, “too little hands-on technical work” in undergraduate degrees, with techniques all too often being demonstrated to students rather than actually being carried out by them. The head of one research and manufacturing facility stated that the emerging regenerative medicine sector is currently “very badly served by the current academic set-up in the UK” due to “the lack of practical ... training” received by undergraduates and consequent “vanishing practical skills” possessed by graduates. On this view, while graduates are often over-qualified for technician roles in the sense that they possess more theoretical knowledge than is required to do the job well, they may nonetheless also be under-skilled, because they lack the requisite practical skills.

The combination of the two problems just described—namely, a lack of practical skills, which implies that graduates require on-the-job training in practical skills, and a high labour turnover amongst the graduates who occupy technician roles—can be especially frustrating for employers. The reason is that, having invested time and effort training graduates in practical tasks in order to make good the deficiency of their undergraduate training and thereby render them fit for a technician role, employers often then lose the graduates in question to another organisation, to which they move in search of better wages and/or a more stretching role, before their first employer has enjoyed a return on its investment. As one interviewee lamented of over-qualified, but under-skilled graduates, “They stay around for two years and then leave ... You’ve just got them good and then they go.” Similar frustrations were mentioned by several other organisations, whose views might be summarised by the point made by one operations manager: “Recruitment of graduates is expensive and it’s frustrating when it doesn’t come off.”

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<sup>7</sup> For similar findings in the case of industrial biotechnology, see Lewis (2016). Such findings are consistent with the work of Green and Zhou (2010) who, using evidence drawn from national skills surveys, find that where over-qualification is associated with a genuine under-utilisation of the skills of graduates, as is the case with the laboratory technicians described in the main text, substantial job dissatisfaction results on the part of the employees. However, some (3) employers in the current study suggested that, while real, such problems are not insurmountable. More specifically, they can, it was argued, be dealt with by a careful selection procedure, designed to identify more practically-inclined and less intellectually-focused graduates who are “only good enough for technician jobs”, coupled with efforts to manage their expectations about the kind of work they are doing, about how much they have to learn, and about how quickly – or, perhaps more accurately, how slowly – they are likely to progress.

The laboratory and quality control technician roles in cell therapy appears, therefore, to illustrate what one recent study of over-qualification describes as a “possibility which tends to get overlooked—that graduates are less capable in some occupations than the non-graduates they are displacing” (Holmes and Mayhew 2015: 12). As a recent UKCES report has put it, “Formal qualifications only serve as an imperfect proxy for skills. Many of the most pressing workplace skill shortages relate to practical skills, and so it’s possible to be formally overqualified while still not being fully competent for a role” (UKCES 2015: 46). The key point is of course that practical skills are often more effectively acquired through workplace learning, rather than in an academic environment.<sup>8</sup>

Interviewees reported that similar problems, arising from the attitudes, expectations and practical skills of graduates, are beginning to arise in the case of another role in cell therapy. The role in question centres on the manufacture of cells and is one that, until recently, did not exist in many organisations and, where it did, was occupied by graduates rather than by people with intermediate-level qualifications. However, for reasons documented below, the vast majority of interviewees argued that more and more organisations in cell therapy will develop specialist manufacturing technician roles. And it is to the nature of, and rationale for, this emerging technician that role that we now turn our attention.

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<sup>8</sup> Similar dissatisfaction on the part of employers in the UK chemical sector, and in industrial biotechnology, is reported in Lewis (2013a: 16-18) and Lewis (2016) respectively. Also see Mason (2012: 25-27). An expression of the government’s concern about the variable quality of practical training provided by biology degrees can be found in BIS (2011b: 20).

## 4. FUTURE TECHNICIAN ROLES IN CELL THERAPY

### 4.1 Emergent technician roles in cell therapy: The Manufacturing Technician

In general, manufacturing technicians operate the systems and equipment involved in routine, day-to-day production. That involves them preparing, starting-up, operating, monitoring, controlling, and closing down the equipment used in manufacturing. In carrying out those duties, they will usually be guided by the standard operating procedures or work instructions set out by more highly qualified scientists and engineers.<sup>9</sup>

Specialist technician roles of this kind are currently rare in cell therapy. The reason is that most organisations involved in cell therapy currently focus on research and development, including process development, rather than full-scale, commercial manufacturing. This has two implications, both of which militate against the widespread use of manufacturing technicians. First, because the organisations in question are not yet involved in commercial production, there is often too little manufacturing taking place to warrant the creation of specialist manufacturing roles. Rather, such work is carried out by the research scientists themselves, as just one part of a broader array of duties they must discharge. In this way, organisations in cell therapy have exemplified one of the oldest principles of economics, first described in Adam Smith's celebrated book *The Wealth of Nations* (1776), namely that the scope for organisations to create specialist roles dedicated to particular parts of the production process is limited by the overall volume of output that must be produced. As the manager of one research laboratory put it, the limited volume of work currently being undertaken implies that research scientists "pretty much have to do a bit of everything," including manufacturing and relatively mundane quality control work, with graduate- and technician-level work being packaged together into one job role. Second, and relatedly, because the organisations are typically involved in researching and developing new therapies, the relevant methods of production are often still in their infancy. As a result, most of the production processes in question have not, until recently, been well enough developed that they can be reduced to, or specified in terms of, a set of standard operating procedures – governing when the media in which the cells are grown should be changed, when glucose and other nutrients should be added to enable the cells to grow, how various reagents should be added, etc. – of the kind that could be used to inform and guide technicians. Both of these factors have militated against the creation of specialist manufacturing technician roles in the past.

However, interviewees averred, this is set to change, for two reasons. First, more and more firms are increasing not only the scale but also the scope of their activities, moving on from an exclusive focus on R&D and process development towards full-scale commercial manufacturing. As they do so, they are carrying out more and more routine manufacturing, up to the point at which it is now worthwhile for them to create specialist manufacturing roles. Second, and relatedly, as they have increased their scale of production these organisations have also developed a set of standard operating procedures that set out, in terms intelligible to someone without a degree in biological science, how to manufacture the cells in

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<sup>9</sup> Descriptions of manufacturing technician roles in the chemical industry, and in industrial biotechnology, can be found in Lewis (2013a, 2016). The Trailblazer standard that sets out the competences displayed by a manufacturing technician working in the life and industrial sciences can be found in Appendix 2 of this report.

question, so that production can be carried out by someone with intermediate level qualifications. The chief operating officer of one organisation that is increasingly engaged in manufacturing has described this process, and its implications for the organisation's workforce, as follows:

*As the manufacturing side grows, and as manufacturing becomes a more routine process, roles will evolve so that we have more distinct roles ... [and] we will have specialist cell culture technicians trained in GMP manufacturing ... The scientists will always be in the room but they won't actually need to do the manufacturing.*

Similar views were expressed by another manufacturing manager, who described her organisation as having "made the manufacturing process more industrial", so that balance of activities had shifted away from process development and towards routine manufacturing carried out in accordance with robust standard operating procedures. In her view, the organisation is "about to get to the point" where a more elaborate division of labour is possible, involving (she expected) teams of three manufacturing technicians working under the supervision of a graduate-level scientist. Finally, another head of manufacturing described his organisation as being about to enter a phase of its development where there is "less creative stuff and a more operational bent to the work." He expects this transition from research and development to manufacturing to lead to a change in the organisation's employment profile, with more specialist manufacturing technicians being employed both in absolute terms and as a share of the total workforce. Similar views were expressed by 7 of the other 8 organisations visited as part of this study other organisations, in addition to the 3 just mentioned.

There was, then, a strong consensus amongst the employers visited for this study that, because more and more organisations are increasing their scale of production, and using methods expressible in terms of standard operating procedures, there is an emergent need to create a cadre of dedicated manufacturing technicians. Interviewees reported that the principal duties associated with the role of a cell therapy manufacturing technician would be to carry out the cultivation of the cells required for various therapies, in line with standard operating procedures and in accordance with the requirements of the relevant regulatory bodies. Accordingly, in addition to learning the relevant techniques for cell cultivation (including being able to perform them aseptically, so as to avoid contamination), interviewees maintained that such technicians would need to be skilled at working in clean rooms, well versed in the requirements of cGMP manufacturing, and equipped with a knowledge of cell biology, microbiology and chemistry sufficient to enable them both to understand the rationale for, and exercise the judgement required successfully to implement, the relevant standard operating procedures. A more detailed statement of the competences associated with the role of cell therapy manufacturing technicians, produced via several rounds of discussion with interviewees, can be found as Appendix 3 of this report.

#### **4.2 How to fill manufacturing technician roles**

The vast majority of interviewees were also conscious of the pitfalls of filling putative manufacturing technician roles with over-qualified, but under-skilled, graduates. The reasons are very similar to those mentioned by the interviewees who recounted the shortcomings of using graduates to fill laboratory and

quality control technician positions, namely inconsistency between the demands of the role and both the attitude/expectations and also the deficient practical skills of graduates.

Several interviewees noted that the role of a cell manufacturing technician is one that often fails to meet graduates' expectations of what their job will involve. The reason is that once standard operating procedures have been established and commercial manufacturing has commenced, cell cultivation becomes a rather dull, repetitive activity that requires little intellectual input of the kind graduates have been educated to provide and instead places a premium on practical skills of the kind best acquired through work-based learning. As one interviewee explained, "all the intellectual, scientific questions are asked in the course of process development; once the process has been decided upon and manufacturing has started, then the focus is no longer on scientific issues about how to develop the therapy better, but on making the therapy in exactly the same way, in order to keep within the method approved by the regulators and, in the case of clinical trials, to ensure comparability with earlier stages of the trial." The need to adhere with the utmost rigour to standard operating procedures implies that the actual work of manufacturing cell lines is rather repetitive and dull. As one interviewee who oversees a cGMP manufacturing facility said of the staff who undertake manufacturing in his organisation, "They have to park their brain outside the lab and become someone who does everything mechanically." Moreover, in addition to having to adhere rigidly to standard procedures, the people who carry out manufacturing often need to spend long periods of time in quite uncomfortable conditions: the clean rooms where they work are usually noisy, due to the operation of the fans that circulate air in order to help prevent contamination; while the need to wear a set of gowns and masks, which it might take up to 30 minutes to put on properly, makes working hot and uncomfortable. Overall, therefore, in the words of one interviewee who oversees manufacturing in his organisation, "Production is tough ... immensely boring, with a lack of variety ... I need them to do quite a dull, uncomfortable job."

Consistent with this, when discussing the attributes that someone occupying a manufacturing technician role would ideally possess, interviewees tended to emphasise the importance of two things: their practical skills; and their attitude. So far as the former is concerned, interviewees were concerned to emphasise that, notwithstanding the use of standard operating procedures, manufacturing technicians must still possess considerable manual dexterity and practical skill if production is to go well. The reason is that, while the instructions may tell a worker what procedure needs to be performed at each stage of the manufacturing process, they do not specify in complete detail how that procedure is to be carried out. Carrying out the procedures well, interviewees maintained, requires considerable tacit knowledge or know-how, as it is sometimes termed. A rough but telling analogy between cookery and cell cultivation may help to clarify the point. In both cases, the person undertaking the work has a set of instructions specifying what they are supposed to do, either in the form of a recipe (in the case of cooking) or a standard operating procedures (in the case of cell therapy). However, taken on its own, the explicit knowledge provided by the instructions about what need to be done is unlikely to be enough to produce a good outcome, because the person in question must possess the practical or tacit knowledge of how to carry out the instructions properly and to good effect. For example, in order to produce a delicious dish, a cook needs to have more than an explicit knowledge of the instructions contained in the recipe (which might, for example, state that certain ingredients need to be stirred together). The cook must also know how to carry out the instructions found in the recipe properly – for example, how long, and in what way, the ingredients must be stirred together – so that the dish

produced turns out well and tastes delicious.<sup>10</sup> In a similar vein, in order to be good at manufacturing cells, a person who has an explicit knowledge of the standard operating procedures, and so knows what needs to be done, must also have the tacit or practical knowledge of how precisely to carry out the procedures specified in the work instructions. “Reading instructions is one thing,” one manufacturing manager stated, “doing something hands-on is another.” There are many examples in cell therapy of how such tacit knowledge or know-how can make all the difference between a successful outcome, in which the cultivation goes well and produces cells with the desired therapeutic properties, and an unsuccessful one. The Chief Operating Officer of one company put it, “Not everything can be covered by the SOPs ... There is a real element of touch and feel for how to handle cells, especially in the early stages of culturation, that you can’t write down’ [i.e. tacit knowledge] ... so there is quite a lot of judgment involved ... that is not graduate-level knowledge but does imply that they are really skilled.”

Significantly, of course, practical know-how of this kind cannot be learned in the abstract, simply by reading about the relevant techniques or seeing them demonstrated by somebody else. On the contrary, it is best acquired via sustained, personal experience of performing the relevant techniques. As one interviewee explained, “Cell culture and clean room behaviours are ‘hands on’ activities, which people learn by doing ... [so] having people trained in the field makes a big difference to how well they can do the job.” The implication is clear; the main way to teach the skills in question is not through the predominantly classroom-based study upon which university education concentrates, which all too often leaves graduates “having brushed past techniques and only had a brief exposure to them”, but rather via practical, work-based learning of the kind involved in good apprenticeships (which affords trainees considerable practical experience). Of course, as already noted, cell therapy manufacturing technicians do need some underpinning, theoretical knowledge, to help them understand the rationale for, and exercise the judgement required successfully to implement, the relevant standard operating procedures, as noted above. But interviewees were adamant that the requisite fell well short of that required for a full honours degree and that the emphasis ought to be on a work-based approach, that afforded trainees the greatest opportunities to gain the hands-on, practical experience required for them to develop practical skills and judgment (supplemented by block- or day-release at a local college, so that trainees can also obtain the requisite underpinning knowledge).

Interviewees also emphasised how important it is for people occupying manufacturing technician roles to have the “right mindset” (or attitude). This was said to consist in the workers in question being “accurate”, having “a really good eye for detail”, being able to “focus on the task at hand”, and being “careful and really conscientious in following procedures” (including the requirements of cGMP and other regulatory systems). More than one interviewee remarked, not entirely frivolously, that while it isn’t necessary for people engaged in manufacturing to exhibit “OCD behaviour” when it comes to complying with work instructions and regulatory requirements, it helps. These attitudes are not, interviewees argued, confined to graduates: “It’s an ability thing,” one interviewee commented, “not connected to graduate-level knowledge.” Consequently, as another interviewee who is responsible for

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<sup>10</sup> One only has to think of the disasters that have befallen many contestants in the ‘technical challenge’ element of the BBC television series *The Great British Bakeoff*, where they have to follow a series of instructions in order to bake a cake, to see how badly things can go wrong when the explicit knowledge provided by the recipe is not complemented by the tacit or practical knowledge of how to follow those instructions to good effect.

manufacturing in her organisation put it, “Too many years of education are useless to me.” Indeed, several interviewees argued that too much education might even encourage people to develop attitudes inappropriate for cell therapy manufacturing. The reason is that people educated to degree level or above often want to “do science” by using their scientific knowledge to try to improve the production process. As a result, they may sometimes be tempted to deviate from the standard procedures in a well-intentioned, but ultimately counter-productive, attempt to increase the efficiency of the production process. Such “freelancing” is of course anathema to the strictures of cGMP manufacturing, where rigorous adherence to the specified methods of production is of paramount importance. And, as noted above, the frustration experienced by graduates who cannot deploy their scientific knowledge to full effect in technician roles, in this case because they are occupying a manufacturing position rather than a process development scientist role, can lead to dissatisfaction and high turnover. As one HR manager put it, “People interested in research often struggle with manufacturing as they’re not allowed to tinker.” As one interviewee with experience of using graduates in production roles put it, “Graduates don’t want to train for 3-4 years and then be in a clean room 6 hours a day.” The upshot of all this is that, in the case of manufacturing technician roles, as the Head of Manufacturing at one growing firm concluded, “The best people are not high-powered”, so using graduates in such roles is a distinctly “mixed blessing”. This consideration reinforces the conclusion, also suggested by the superior practical skills possessed by people who have been trained via the work-based route, that routine manufacturing roles really are technician roles, not positions best filled by graduates.

Overall, then, it seems clear that in considering the kind of person who is best suited to filling the role of cell therapy manufacturing technician, employers set less store by degree-level scientific knowledge and place more of a premium on people having the practical skills and the attitude required to ensure that the specified methods of production are put into practice consistently and effectively. An interviewee summarised the situation as follows: “There is a long-term need for a skilled, technical people who don’t see themselves as scientists but as production people [i.e., technicians]. There is a drive to simplify the process [of producing cells] and to decrease cost, which will increase the need for technical people ... as the sector moves from a [purely] research to a production basis.” And, as we have seen, people of that kind are best trained via a work-based, rather than a purely academic route, because it is the hands-on, practical training afforded by an apprenticeship that offers the best way for trainees to acquire the skills needed for cell cultivation. And it is to apprenticeship training for cell therapy that we now turn our attention.

### **4.3 Apprenticeship training for manufacturing technician roles**

An apprenticeship is a contract between an employer and (traditionally) a young person that combines a structured programme of on-the-job training and productive work with part-time, formal technical education (Steedman *et al.* 1998: 11; Ryan 2012; Lewis 2014a). Apprenticeship training, which is usually formally certificated, equips people with intermediate (level 3-5) skills of the kind required to fill roles that fall under the heading of ‘Skilled Trades’ or ‘Associate Professional and Technical Occupations’ in the UK’s Standard Occupational Classification system. It follows from this definition that any training for roles whose occupants need only be semi-skilled (i.e. require no more than level 2 skills) will not count as an apprenticeship, as it does not aim at the level 3-5 skills that are the hallmark of apprenticeship



training (cf. Steedman 2010: 3; Richard 2013 4-5, 33-35). Equally, training programmes that do not offer a substantial (20%) proportion of time spent on formal, off-the-job technical education and training, so that trainees can acquire the technical knowledge that underpins that practical skills, do not count as an apprenticeship.

Currently only one of the organisations visited for the study trains apprentices (at level 3, for a laboratory technician role rather than for a manufacturing role). However, 5 of the other organisations visited for this study – as well as several of the employers who participated in an advanced therapies skills workshop organised by the Department of Business, Innovation and Skills – have indicated a desire to start training apprentices. The reasons are straightforward, and have largely been rehearsed above, so will only be summarised here. More and more employers in cell therapy are moving towards turn towards full-scale manufacturing, and so will be increasing the number of specialist manufacturing roles. Employers believe that such roles are best filled by specialist technicians – that is, by workers qualified only to intermediate level – rather than by graduates, both because of the superior practical skills and attitude that technicians are expected to possess. However, because cell therapy is a relatively young industry, there has not yet been time to develop a sufficient pool of workers skilled at manufacturing. In the words of one interviewee, “There’s no industry yet, so there’s a void” with regard to technician training. Similar concerns were expressed by another interviewee from an organisation that is rapidly expanding its involvement in cell therapy, who commented that, “the ‘people pipeline’ will be a big challenge as there’s no pool of skilled workers” on which to draw. It follows that organisations that are seeking to engage in commercial manufacturing need to train technicians themselves. Hence, the burgeoning interest in apprenticeships. As one manufacturing laboratory manager put it, “We would like someone with that kind of training.” Or, in the words of another interviewee who manages a growing manufacturing facility, “It would be good to have a pipeline of apprentices.” An indication of the practical skills, and associated underpinning knowledge, towards which such an apprenticeship should aim is provided in Appendix 3, which represents the results of several rounds of consultation with employers about the skills and knowledge required of a cell therapy manufacturing technician.

While as noted above one of the major sources of the appeal of apprenticeships for employers lies in the efficacy of work-based learning for equipping workers with the appropriate practical skills, interviewees also noted that the training programme should contain a substantial element of off-the-job training, so that apprentices would also obtain the theoretical knowledge that underpinned their practical skills. The goal of such off-the-job training, which would be provided either on day release or block release, would be to equip trainees with a sufficient knowledge of cell biology, microbiology, and chemistry, along with a grasp of the principles of—and rationale for—the regulatory regime under which cell therapy manufacturing takes place, for people who have completed the programme to be able to do two things. First, to make informed judgments about how, within the margin of discretion afforded them by the standard operating procedures that govern their behaviour, they should act in response to various situations that might confront them in the course of carrying out their duties. Second, to understand why compliance with the standard operating procedures and regulatory requirements are important and why it is important for them to act consistent with those procedures (thereby encouraging technicians to adhere to the relevant rules). A tentative conclusion indicated by

interviewees is that the requisite off-the-job training would involve apprentice cell therapy manufacturing technicians taking level 4-5 qualifications in subjects such as Applied Biology.<sup>11</sup>

Examples of qualifications that illustrate very broadly what might be required include the Foundation Degree in Applied Bioscience Technology, introduced as part of the Higher Apprenticeship in Life Sciences and offered by the University of Kent (BIS 2011b: 22), and the HNCs and HNDs in Applied Biology taught at Forth Valley College (on which see Medway School of Pharmacy 2016 and Forth Valley College 2016). Readers should note that interviewees were not systematically shown either of these documents. Some interviewees who were already aware of the programmes in question argued that a greater emphasis on cell cultivation—involving more time spent on a greater number of techniques, using a wider variety of cells—would ideally be required in order for these programmes to be appropriate for cell therapy technicians. Accordingly, the programmes in question should be treated as no more than useful starting points for a discussion about what appropriate off-the-job technical education for cell therapy manufacturing technicians should look like.

## **5. INSTITUTIONAL REQUIREMENTS FOR APPRENTICESHIP TRAINING IN EMERGING INDUSTRIES**

In light of the evidence, presented above, that there is likely to be an increasing demand for genuine technicians in the future, in particular to occupy manufacturing roles, it is worth exploring some of the potential problems, and potential institutional solutions, that may be encountered.

### **5.1 Keeping the contents of apprenticeship training programmes up-to-date**

This discussion of the contents of apprenticeship training programmes provided in the previous sections leads on to an important issue, namely the importance of establishing an institutional mechanism for ensuring that any such programme be kept up to date and attuned to the needs of industry. The reason for emphasising this point is that a notable feature of emergent industries such as cell therapy is that methods of production are in many cases still being developed. In particular, as several interviewees mentioned, efforts are afoot to try to automate the manufacture of cell therapies, typically using bioreactors rather than manual methods of production. If and when this kind of technique is widely adopted, it will have important implications for what technicians are required to do. It is important, therefore, that those responsible devising statements of competence for technicians, and associated training programmes, be kept abreast of technological developments, so that their implications for skills and training can be worked out.

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<sup>11</sup> Significantly, this estimate of the level of skills and knowledge required for a cell therapy manufacturing technician is consistent with that required for manufacturing technicians in parts of the industrial biotechnology sector where production closely resembles that used in cell therapy, and where some firms have begun training people to fill manufacturing technician roles via apprentices at level 4/5 (Lewis 2016).

The obvious locus of responsibility for such this task lies in the so-called Catapult Centres (hereafter, CCs), in particular the Cell Therapy Catapult (or CTC). In order to see why, it is necessary to elaborate briefly on the nature of CCs, in order to understand why playing this kind of role in skills and training is consistent with their overall remit and rationale. CCs are institutions whose goal is to connecting the UK's research community, as found in universities and other research institutes, with business, in order to facilitate the development of new products and services on a commercial scale (Hauser 2010). Briefly, the rationale for the creation of the CCs stems from the fact that many innovative businesses, especially small and medium-sized enterprises, lack the resources, expertise, equipment, and contacts required to develop research ideas into new, commercially viable technologies, products, and services. CCs are independent, not-for-profit centres that aim to facilitate the commercial development of ideas generated by the UK's research base by providing access to state-of-the-art technology and technical expertise, either by making their facilities available for firms to carry out research themselves or by undertaking such work on firms behalf on a contract research basis, so that solutions to such problems can be found. More specifically, CCs offer: research and development facilities containing up-to-date, specialist equipment; technical expertise; expertise in accreditation and in meeting technical and regulatory requirements; advice on taking ideas and products to market, on developing supply chains, and on increasing the scale of businesses; and assistance with accessing finance. Individual companies, especially small and medium-sized enterprises, are often unable to afford the substantial, indivisible, long-term investment required to develop such facilities and expertise themselves. There is, therefore, a case for the public sector to take a sector-wide, long-term view and make the requisite investment. By creating an institution, based in one physical location, that is open to all businesses and research centres with an interest in a particular technology and/or sector, the CCs can 'create a critical mass of activity' that can justify the investment required to create the resources in question in a way that is not open to individual firms operating in isolation. In this way, CCs can assist in such activities as the production of technology and application demonstrators and the scaling-up of manufacturing processes from laboratory to the factory level. And by doing so, they are able to reduce the risks associated with innovation – that is, with commercialising new goods and services – and thereby increase the speed and effectiveness with which ideas generated by the research base in universities and other research centres can be brought to market in the form of profitable goods and services, thereby helping to increase the presence of UK industry in strategically important global markets and ultimately creating jobs, economic growth, and prosperity in the UK (Technology Strategy Board 2011a: 2-5, 9, 11, 2012: 6; HM Government 2012: 14, 19; also see Hauser 2010: 7 and Technology Strategy Board 2011b: 3-4).

The significance of all this for skills and training is twofold. First, the role of CCs in the development and scale-up of new technology gives them early access to technological developments, leaving them well placed to distil off the implications of those developments for technician skills and knowledge, and use them to inform the development of appropriate training programmes. As an interviewee noted, the CTC is "in touch with multiple centres" where new methods of production are being developed, so it "would be a good source of updates" on what skills manufacturing technicians would need. If the CPI and similar organisations did this then they would be moving more closely into line with similar organisations elsewhere in the world, such as Germany's Fraunhoffers and Singapore's 'Singtechs', that

play an important role not just in stimulating innovation but also in developing the skills required to operate innovative technologies.<sup>12</sup>

A second role for CCs in technician skills and training, which also arguably reflects their underlying purpose of promoting the development of new industries by reducing the risks associated with setting up enterprises using innovative technologies at commercial scale, concerns their role in helping to overcome some of the risks associated with the provision of high-quality apprenticeship training for emerging industries. This second role will be discussed in the following sub-section of the report.

## **5.2 Overcoming the problem of the ‘tyranny of small numbers’**

Evidence from other industries, such as (aero)space, composites, and industrial biotechnology, suggests that if and when employers in cell therapy turn towards apprenticeship training, they may find it difficult to find a training provider willing to offer the requisite training (which might involve either an initial period of training in practical skills, such as cell culture and clean room working, provided before apprentices return to their employers for additional training, or a series of more theoretical modules designed to equip apprentices with the requisite underpinning knowledge, or both) (Lewis 2012a: 31-32, 2012b: 31, 2013b: 46-48, 2016: 39-40, 42-47). The reason lies in what one might call the ‘tyranny of small numbers’, namely the fact that, given the relatively small size of the industry, the total number of apprentices demanded by employers in cell therapy in any one geographical area may well be too small to make it worthwhile for the relevant colleges to offer the training in question, given the prevailing apprenticeship funding regime. The upshot is an outcome where there are both frustrated employers, who cannot access the training they want, and also frustrated training providers, at least some of whom are in principle are willing to offer courses but find it imprudent to do so in practice.

It is worth distinguishing two aspects of this problem, because doing so will point towards some of the issues that need to be taken into account in thinking about how to overcome it.

- The first, and most obvious, source of the problem is the lack of current demand for training courses. Of course, this mainly reflects relatively small size of the industry, which implies that the number of trainees is likely to be correspondingly small in absolute terms.
- The second aspect of the problem concerns uncertainty over future demand. If a provider is going to find it worthwhile to invest in the staff and equipment required to provide high-quality training, then it must be confident that demand will be sustained over enough cohorts or years of trainees for it to earn a decent return on its investment.

Uncertainty over both the immediate demand for training courses, and also concerning whether the demand for training is likely to be sustained for long enough to make it worthwhile to invest in the relevant tutors and facilities, can make providers reluctant to offer training.

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<sup>12</sup> For more on the role played by CCs in technician skills and training, see Lewis (2014b).

What can be done to overcome these problems? In keeping with the points just made, ways need to be found both to aggregate the demand for training, so that the number of trainees exceeds the threshold required to make it worthwhile for providers to offer the relevant courses, and also to reduce the risk faced by potential training providers. A number of points are worthy of consideration. The first is that, given the overall limitations of the demand for training, there is likely to be a need for only a small number of such providers (perhaps only one or two in the entire United Kingdom). Ideally, these centres of excellence or – to use the latest government terminology, ‘Institutes of Technology’ – would be located in areas where there is a significant concentration of expanding cell therapy employers (cf. UKCES 2014: 19 and Department for Business, Innovation and Skills and Department for Education 2015: 18; HM Treasury 2015: 25-26).<sup>13</sup> Consider, second, three potential ways of potential way of aggregating demand, and thereby also of reducing risk faced by providers. The first is to share or combine as much as possible technician training for cell therapy with training for other process and science-based industries. Some interviewees observed that there is a good deal of overlap between the skills and knowledge needed by manufacturing technicians in cell therapy and in parts of industrial biotechnology, most notably biologics. For example, the manufacturing technicians employed in both industries require training in cell cultivation, in clean room working, and in cGMP manufacturing, as well as a grasp of the principles of cell biology and microbiology. To the extent that there is common ground between the requirements of the two groups of technicians, then there is the potential to use the same training courses for apprentices in both industries.<sup>14</sup> Second, and finally, those training providers who are offering technical education in the underpinning knowledge required by apprentices should strongly consider doing so via distance learning, supplemented by periodic residential courses or stints of block release. By extending their reach beyond the geographical area in which they are located, this should enable them to increase the size of the cohorts they attract. Third, as far as possible training courses should be developed so as to make them suitable not only for apprentices and also for 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 cell therapy (e.g. cGMP, clean room working), further increasing demand.

One way of reducing the risk faced by potential training providers is to utilise existing facilities, which are used also used for purposes other than training (perhaps most notably, those facilities run by process development organisations such as catapult centres). The use of existing facilities to provide training will help to reduce both the size, and the riskiness, of the investment required to set up a training programme: it will reduce the size, 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. (While a specialist training

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<sup>13</sup> An analysis of the current geographical distribution of GMP cell therapy manufacturing capacity in the UK can be found in Cell and Gene Therapy Catapult (2016: 13-27).

<sup>14</sup> Such a strategy would be in keeping with the Trailblazer approach to apprenticeships, as established in the aftermath of the Richard Review of Apprenticeships (Richard 2012; HM Government 2013) and as administered by Cogent and the Science-industry partnership (SIP) in the case of the process industries by the Science-Industry Partnership (SIP 2014, 2015, 2016). The Trailblazer approach highlights the importance of apprentices receiving training that is broad enough to enable them to work in an occupation, such as that of a manufacturing technician, in a variety of different firms and sectors (rather than the training being closely tailored to the needs of specific firms in specific sectors). That of course implies that there should be a considerable part of the training that is generic or cross-sectoral, which is exactly the possibility being suggested here.

facility would be redundant if no trainees came to it, a mixed-use facility of the kind under discussion here, providers could be used for other purposes, thereby diversifying the sources from which the assets in question generate income.) For instance, one organisation visited for this study reported that its laboratories and clean rooms are not always being fully used for research and that at times it used them for CPD training for graduates who needed to learn techniques for cGMP manufacturing and for working in clean rooms. The same facilities could in principle be used to train apprentices in those techniques.

There already, or soon will, exist a number of facilities that might well prove to be suitable for such a dual-purpose role. Perhaps the most prominent is the Cell and Gene Therapy Catapult Manufacturing Centre currently under construction at the Stevenage bio-process innovation campus. Its primary purpose is to provide large-scale manufacturing facilities that will facilitate the Phase 3 clinical trials of cell and gene therapies, as well as their commercial supply (Cell Therapy Catapult 2014; Thompson 2014; Cell and Gene Therapy Catapult 2016: 10, 26-27). Depending both on its capacity and also on the priorities that come to govern its utilisation, its facilities could be also used to provide training in the practical skills required by cell therapy manufacturing technicians. As noted above, such multi-purpose use of facilities would help to reduce the riskiness of the investment required to provide high-quality training for an emergent manufacturing workforce and would therefore be quite consistent with the broad rationale for catapult centres as a means of reducing the risks associated with the commercialisation of new technologies. As such, it would be a natural extension of their role (cf. BIS 2011a: 39; HM Government 2012: 19; MRC 2012: 16; Regenerative Medicine Expert Group 2015: 7-8, 19-22). At present, however, the indicators by reference to which the performance of Catapult Centres is judged centre on how much income they generate from external grants and contracts, and exclude measures of their contribution to skills development. Consequently, the incentive for them to become involved in training, especially at the technician level, is weaker than they might otherwise be. Strengthening the incentives for Catapult Centres to become involved in developing skills at all levels would be a welcome way of encouraging them to take more seriously their potentially very significant role in developing the technician workforce required for emerging industries (Lewis 2014b).

Other locations across the UK have facilities that could be similarly used in order to provide practical training, in line with that proposed at Stevenage. Two possibilities will be mentioned here. The first is the Scottish Centre for Regenerative Medicine, an MRC research centre with state-of-the-art GMP manufacturing facilities located in Edinburgh and situated in close proximity to a significant cluster of highly-regarded organisations involved in cell therapy, including ground-breaking manufacturers. Second, in light of the possibility of substantial common ground between the training required for manufacturing technicians in cell therapy and biologics, another possibility would be for training to be provided at the National Horizons Centre, which is located in Darlington and run by another CC, namely the Centre for Process Industries (CPI and Teeside University 2015). There are undoubtedly other facilities of a similar nature that might also be used (e.g., the EPSRC Centre for Regenerative Medicine, located at Loughborough University).

There are, then, a number of existing facilities that might be appropriate for providing some of the training required by cell therapy manufacturing technicians. The precise arrangements that are appropriate for the UK cannot be determined on the basis of the evidence gathered for this study. It

might well be that using one or two of these existing facilities in order to provide an initial period of on-the-job practical training—focusing on cell culture, GMP manufacturing and clean room discipline—in conjunction with a distance learning programme of the kind offered by the University of Kent in order to provide apprentices with a grasp of the relevant underpinning knowledge, could be an effective approach: it would acknowledge the importance of avoiding the unnecessary duplication of expensive facilities; but it would also recognise the costs and other shortcomings of having apprentices having to travel potentially very long distances to a single national residential centre.<sup>15</sup> A concrete example of the kind of model envisaged here is provided by Ireland’s *National Institute for Bio-processing Research and Training*. NIBERT, as it is commonly known, is a multi-functional facility, containing state of the art equipment, where both research and education, including technician training, takes place. Facilities include a realistic, simulated GMP manufacturing plant, so that manufacturing technicians/operators can receive training.<sup>16</sup>

What can be said with some confidence is that the current situation faced by emerging industries such as cell therapy poses a challenge to the increasingly devolved skills system that characterises both England and the UK more generally. The fact that the absolute number of apprentices is likely to be small, coupled with the high fixed costs of offering high-quality training, makes it likely that such a facility will be viable only if it is a national one, attracting apprentices from several LEPs, rather than a local solution targeted solely on employer located within the area of one LEP. The danger to which this gives rise is that no one LEP may wish to fund the centre in question. Put slightly differently, if such centres are to be funded, it may well be that an agreement between several LEPs will be needed. Cross-LEP cooperation, and perhaps even cross-border cooperation between England and Scotland, may well be necessary if plans for a high-quality training programme are to come to fruition (cf. SIP 2015: 26). Alternatively, it may well be that a *national* policy is needed for a small number of emerging industries, whose employers lack critical mass in any one region.<sup>17</sup>

### 5.3 The Apprenticeship Levy

Another important set of issues is raised by a recent shift in government policy, which promises to change the funding regime under which apprenticeship training is provided. In its 2015 Autumn statement, the government announced that from 2017 it will implement a so-called apprenticeship levy (Department for Business, Innovation and Skills and Department for Education 2015; HM Government 2015a; also see Wolf 2015b). This will involve the imposition of a payroll tax of 0.5% on employers with a payroll in excess of £3 million. The revenue thereby raised will be used to create a National Apprenticeship Fund, the resources in which will be used to subsidise those employers who train

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<sup>15</sup> One advantage of providing an initial block of practical training at a central facility — “a kind of PEO2 for the life sciences”, as one interviewee described it — aside from the access to good facilities/equipment and specialist trainers it would afford, is that it would address the concern expressed by some employers interviewed for this project that, especially given their relatively small size, they would find it difficult to release their own staff from the main jobs in order to provide the instruction in practical skills required by apprentices. A period of block release in a training facility, after which apprentices would return to their employer for more specialised/advanced training, would help to deal with this problem.

<sup>16</sup> See <http://www.nibrt.ie/>.

<sup>17</sup> For a general account of the relevant model of public service delivery, see Ostrom and Ostrom ([1971] 2000: 35, [1977] 1999) and V. Ostrom 2008: 16-17, 63-65, 79).

apprentices. The goal of the levy is to shift the incentives facing training providers away from the lower-level apprenticeships, in areas such as customer services and business administration, towards intermediate-level qualifications in STEM subjects such as those suitable for employers in cell therapy. In this way, it is hoped, it will become easier for employers to obtain access to the apprenticeship training they want. As Wolf (2015b: 16; also see pp 21-22, 25 n. 28) notes, “The [levy’s] purpose is to shift incentives, substantially, at the margin [towards high-quality apprenticeships].” Significantly, if the implementation of this scheme does indeed lead to an shift in incentives, and thereby to an increase in the number of genuine (level 3+) apprentices being trained in STEM disciplines, then it should also help to alleviate the problem of the ‘tyranny of small numbers’, simply because there will now be more apprentices needing training, both now and in the future, thereby making it more worthwhile for providers such as FE colleges to incur the fixed costs of making the relevant investment in tutors, workshops, etc.

The levy is part of a set of policy reforms intended to increase the influence that employers have over the content of vocational training provision (Department for Business, Innovation and Skills and Department for Education 2015; HM Government 2015a; also see Richard 2012, Wolf 2015b). Such ‘employer leadership’ is thought to be important to ensuring that the UK’s vocational education and training system serves employer needs. However, employer leadership is costly and some employers may lack the experience and expertise required to access the skills 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.

In this context, it is worth considering briefly two possible way of alleviating some of the burden on smaller employers, thereby encouraging them to take apprentices. One possibility involves what is called ‘over-training’. This involves larger employers 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 SMEs). The larger firm will typically manage the training and assessment of the apprentices, using its own apprentice managers and 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 SMEs 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 helps 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 it might be worthwhile for some of the larger



organisations that have divisions focusing on cell therapy considering playing such a role (Lewis 2013c, 2014c; cf. HM Government 2015a: 24).<sup>18</sup>

A second possibility involves what are called Group Training Associations. These organisations, some of which have been established for many years, are not-for-profit bodies whose goal is to facilitate cooperation between employers concerning various aspects of training, including: standard-setting; the development of curricula; the recruitment and selection of trainees; and the actual delivery of training (including the provision of facilities and instructors, the management of training, and the assessment of certification of knowledge and skills) (Gospel and Foreman 2006, Cooney and Gospel 2008). In this way, GTAs promise to alleviate the administrative burden falling on employers who participate in apprenticeship training. There are proposals for the SIP to form a GTA whose member organisations will be drawn from the science-based industries, potentially including those in cell therapy (SIP 2016; also see HM Government 2015a: 26). This might enable the SIP to coordinate activities between firms so as to ‘aggregate’ employer demand in emerging industries, in order to persuade LEPs to offer the requisite training.

Of course, none of the solutions described above to the various difficulties associated with apprenticeship training can be a universal cure (cf. UKCES 2015: 12). On the contrary, the ideas sketched above are better thought of as elements in a portfolio of options, and the best approach to adopt will depend on the precise context in which it is to be applied.

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<sup>18</sup> The larger employers in question, whose apprenticeship schemes are often over-subscribed, could also act as ‘clearing houses’, passing on the details of good applicants whom they cannot take on themselves to the smaller firms with whom they are dealing, who often struggle to recruit high calibre apprentices (Lewis 2014c: 505).

## 6. CONCLUSION

Employers in the field of cell therapy are beginning to turn towards full-scale manufacturing. The evidence suggests that, as they do so, they will create an increasing number of specialist manufacturing roles. Employers believe that such roles are best filled by specialist technicians (that is, by skilled workers who are qualified to below degree level). The use of over-qualified, but under-skilled, graduates to fill manufacturing roles in cell therapy/regenerative medicine firms is problematic, both because graduates lack practical skills and also because they become dissatisfied with the work and pay associated with technician roles. Given that there does not exist a pool of trained technicians from which employers in the industry can draw, they are likely to have to begin to train apprentices.

Evidence from other industries, such as (aero)space, composites, and industrial biotechnology, suggests that as and when employers in cell therapy turn towards apprenticeship training, they may find it difficult to find a training provider willing to offer the requisite training. The reason lies in the so-called 'tyranny of small numbers', namely the fact that, given the relatively small size of the industry, the total number of apprentices demanded by employers in any one geographical area may well be too small to make it worthwhile for the relevant colleges to offer the training required by apprentices (whether that be an initial period of block release for training in practical skills, or the technical education in cell biology, chemistry and microbiology required to give apprentices the requisite underpinning knowledge). Experience from other industries suggests that if this difficulty is to be overcome, it will be necessary to aggregate the demand for apprenticeship training across cell therapy employers so that the number of trainees exceeds the minimum required to make it worthwhile for a provider to offer training, and also to reduce the risk faced by potential training providers.

More specifically, the industry / policy-makers should consider:

- developing only a small number of centres of excellence that offer the training in question, located in areas where there is a significant concentration of manufacturers in cell therapy/regenerative medicine;
- ensuring that those centres offer training via distance learning, supplemented by periodic residential courses or stints of block release, in order to extend their reach beyond the geographical area in which they are located;
- mandating that, where possible, at least some of the relevant training courses should be developed so as to 'double-up' as CPD modules for more established workers, further increasing demand;
- reducing the risk faced by potential training providers by utilising *existing* facilities, which are also used for purposes other than training (e.g. for process development). Obvious candidates in the case of cell therapy would be the manufacturing facility currently being built in Stevenage and the Scottish Centre for Regenerative Medicine.

## APPENDIX I

### Apprenticeship Standard – Laboratory Technician\*

\*Taken from: [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/448943/LIFE\\_AND\\_INDUSTRIAL\\_SCIENCES\\_Laboratory\\_Technician.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448943/LIFE_AND_INDUSTRIAL_SCIENCES_Laboratory_Technician.pdf) (made available via the terms of the Open Government Licence: [www.nationalarchives.gov.uk/doc/open-government-licence/version/3](http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3)).

**Occupation** – Laboratory Technician

**Level** – 3

**Duration** – Minimum of 18 months, typically 24 months duration.

#### Occupational profile

Laboratory technicians work in a wide range of organisations, including but not exclusively, chemical, primary and secondary pharmaceutical, biotechnology, formulated products, nuclear companies; and analytical science services. A laboratory technician may carry out both routine and one-off laboratory testing and perform a variety of technical support functions across the organisation. In any context working safety and ethically is paramount and many companies operate under highly regulated conditions because of the need to control the quality and safety of products, for example medicines. Laboratory technicians are expected to work both individually and as part of a laboratory team. They are able to work with minimum supervision, taking responsibility for the quality and accuracy of the work that is undertaken. They are proactive in finding solutions to problems and identifying areas for improving the business.

#### Occupational Skills & Knowledge

A laboratory technician can:

1. Work safely in a laboratory, maintaining excellent housekeeping whilst following appropriate safety, environment and risk management systems.
2. Understand and follow quality procedures to meet the requirements of quality standards relevant to the workplace.
3. Understand the internal and external regulatory environment pertinent to the sector and the employer and comply with regulations proficiently.
4. Prepare for laboratory tasks using the appropriate scientific techniques, procedures and methods.

5. Perform laboratory tasks following specified methodologies, such as Standard Operating Procedures.
6. Demonstrate technical competence in the use of specified instrumentation and laboratory equipment, including calibration where required.
7. Produce reliable, accurate data and keep accurate records of laboratory work undertaken and results.
8. Analyse, interpret and evaluate data and identify results requiring further investigation seeking advice of senior colleagues as appropriate.
9. Understand and apply statistical techniques for data presentation.
10. Communicate scientific information appropriately, including the use of Laboratory Information Management systems, either digital or paper based.
11. Recognise problems and apply appropriate scientific methods to identify causes and achieve solutions.
12. Participate in continuous performance improvement.
13. Develop and apply theoretical knowledge of relevant science and technology required for the sector & job role.
14. Understand the business environment in which the company operates including personal role within the organisation, ethical practice and codes of conduct.

### **Behaviours**

15. A laboratory technician also demonstrates the required attitudes, behaviours and interpersonal skills associated with the professional workplace including:
- communicate effectively using a full range of skills: speaking; listening; writing; body language; presentation
  - work and interact effectively within a team
  - work independently and take responsibility for initiating and completing tasks
  - understand impact of work on others, especially where related to diversity and equality
  - time management and ability to complete work to schedule
  - ability to handle change and respond to change management processes.

### **Qualifications**

Apprentices without a level 2 English and mathematics will need to achieve this level prior to completion of their apprenticeship.

Apprentices must complete a level 3 or 4 qualification in a science or technology discipline relevant to their occupation, which is recognised for professional registration by RSciTech, prior to completing the end-point assessment. Example qualifications are detailed in the assessment plan for this standard.

**Link to professional registration**

The apprenticeship is recognised by the relevant professional bodies at Registered Science Technician (RSciTech) level, for which there is a requirement that the technician will participate in subsequent continuing professional development on completion of the apprenticeship.

**Review date** - June 2018

## APPENDIX 2

### **Apprenticeship Standard – Science Manufacturing Technician\***

**Occupation** – Science Manufacturing Technician

**Level** – 3

**Duration** – Minimum of 18 months, typically 30 months duration.

\*Taken from: [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/384224/LIFE\\_SCIENCES\\_AND\\_INDUSTRIAL\\_SCIENCES\\_-\\_Science\\_Industry\\_Maintenance\\_Technician\\_-\\_Final\\_081214.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384224/LIFE_SCIENCES_AND_INDUSTRIAL_SCIENCES_-_Science_Industry_Maintenance_Technician_-_Final_081214.pdf) (made available via the terms of the Open Government Licence: [www.nationalarchives.gov.uk/doc/open-government-licence/version/3](http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3)).

### **Occupational profile**

Science manufacturing technicians work in a wide range of companies, including, but not exclusively, chemical, primary and secondary pharmaceutical, biotechnology, formulated products and nuclear manufacturing. A science manufacturing technician will operate the systems and equipment, involved in the production of products. They may work in varied conditions including wearing specialist safety equipment, shift work and on sites running 365 day operations. Many companies operate under highly regulated conditions and a premium is placed on appropriate attitudes and behaviours to ensure employees comply with organisational safety and regulatory requirements.

Science manufacturing technicians are expected to work both individually and as part of a manufacturing team. They are able to work with minimum supervision, taking responsibility for the quality and accuracy of the work they undertake. They are proactive in finding solutions to problems and identifying areas for improving their work environment.

### **Occupational Skills & Knowledge**

Science manufacturing technicians are able to:

1. Both independently and within a team start-up a manufacturing batch or continuous process in line with appropriate Standard Operating Procedures, understanding the principles of operation.
2. Both independently and within a team operate a manufacturing batch or continuous process in line with appropriate Standard Operating Procedures, understanding the principles of operation.
3. Both independently and within a team shut down/complete a run of the manufacturing batch or continuous process in line with appropriate Standard Operating Procedures, understanding the principles of operation.
4. Work safely in a science manufacturing environment, understanding personal responsibility for Health, Safety and the Environment and principles of risk management
5. Understand and follow quality procedures to meet the requirements of quality standards relevant to the workplace.
6. Understand the internal and external regulatory environment pertinent to the sector and the employer and comply with regulations proficiently.
7. Control and monitor a process or plant and equipment, effectively, efficiently and securely, and resolve problems or correct abnormal conditions.
8. Complete documentation relevant to the manufacturing process including relevant calculations.

9. Understand the business environment in which the company operates including personal role within the organisation, ethical practice and codes of conduct.

10. Participate in continuous performance improvement.

11. Develop and apply theoretical knowledge of relevant science and technology and its application to the required sector & job role.

### **Behaviours**

12. Science manufacturing technicians are able to demonstrate the required attitudes, behaviours and interpersonal skills associated with the professional workplace including:

- communicate effectively using a full range of skills: speaking; listening; writing; body language; presentation
- work and interact effectively within a team
- work independently and take responsibility for initiating and completing tasks
- understand impact of work on others, especially where related to diversity and equality
- time management and ability to complete work to schedule
- ability to handle change and respond to change management processes.

### **Qualifications**

Apprentices without level 2 English and mathematics will need to achieve this level prior to completion of their apprenticeship.

Apprentices must complete a level 3 or 4 qualification in a science or technology discipline relevant to their occupation, which is recognised for professional registration by RSciTech or Eng Tech, prior to completing the apprenticeship's end-point assessment. Example qualifications are detailed on the assessment plan for this standard.

### **Link to professional registration**

The standard is recognised by the relevant professional bodies at Registered Science Technician (RSciTech) level, for which there is a requirement that the technician will participate in subsequent continuing professional development on completion of the apprenticeship.

This standard meets the professional standards of the Engineering Council for registration as an Engineering Technician (EngTech). Registration is subject to candidates successfully completing the appropriate learning, developing the appropriate competence, and undergoing professional review.

**Review date** – June 2018

## **APPENDIX 3: CELL THERAPY MANUFACTURING TECHNICIAN: STATEMENT OF COMPETENCES / BROAD OUTLINE TRAINING SYLLABUS<sup>19</sup>**

### **Practical training**

#### **Practical training in using clean rooms**

e.g.

- How to put on and use gowns and gloves and how to check that this has been done correctly (e.g. by using 'finger dabs')
- 'Clean room discipline', i.e., how to move about, and work in, a clean room (e.g., how to take things into, and out of, a clean room, so as to avoid contamination, how to clean up after yourself by disinfecting every surface you touch, etc.)

#### **I.2. Clean room 'housekeeping' (i.e. helping to maintain the clean room)**

e.g.

- How to clean a clean-room
- Microbial control (environmental monitoring and sampling to test cleanliness of the room, for quality control purposes), e.g.:
- How to take swabs from parts of clean room for testing surfaces for contamination by bacteria
- setting out and collecting settle plates and contact plates (to test for presence of contaminants)
- using active air samplers to test for the presence of viable and non-viable particles (to test for air contamination)
- How to check water systems, air circulation systems, communications systems for remote monitoring, alarms, and back-up systems to ensure they are all working properly)

#### **I.3 Practical training for supporting production/manufacturing**

e.g.

- Checking that all disposables and reagents are ready for use in the clean room (e.g. gas cylinders, supply of 'injectible' water)
- Ordering consumables, stocking-keeping and inventory (in accordance with stringent QC requirements)
- Preparing media, buffers and other reagents (weighing things accurately, pipetting, serial dilution, using PH meters)

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<sup>19</sup> Compiled by Paul Lewis as part of this study.



- Maintaining calibration of some equipment and instruments (e.g. balances, pipettes, temperature probes in fridges)
- Good distribution practice (how to prepare products for shipment by packing the product up in ice-boxes for controlled temp shipping to maintain its condition, to label it appropriately, etc)

#### **I.4. Practical training in Quality Control and in GMP certification**

e.g.

- The ‘verification’ process (whereby everything that is done as part of the production process must be witnessed and signed off by a trained observer)
- Filling in the ‘batch records’ used to record what procedures are carried out on cells at what point in time, what reagents were used, etc. (in order to ‘verify’ what other people in the manufacturing process have done)

#### **I.5. Practical training in production/manufacturing**

e.g.,

- Cell cultivation (introduction to practical techniques for cultivating mammalian cells in a sterile fashion, all in line with standard operating procedures SOPs and under supervision)
  - How to freeze and thaw cells
  - How to change media
  - Feeding cells
  - ‘Passaging’ (i.e., taking the cells and splitting them into more flasks and culture dishes)
  - How to do ‘cells counts’ (to see how many cells are alive) and viability tests (to see if population of cells is growing as it should), using both manual and automatic techniques
  - Aseptic manufacture and sampling
  - Using bio-reactors (for manufacture)
  - (Possibly) how to select and purify a population of cells (may or may not be appropriate for this training programme, depending on the specific nature of the process and cells in question)

## **2. Off-The-Job Training/Underpinning Theoretical Knowledge**

### **2.1 Basic cell biology**

e.g.

- What is a cell?
- The cell cycle (how do cells grow, how and why do they differentiate to form particular kinds of cell, how do they behave if they (not) fed properly, and why do they behave that way?)
- Different types of cells (e.g. pluripotent stem cells, T-cells, neuronal cells, cells that grow in suspension versus adherent cells)
- What controls cells, what influences how they behave?
- Calculating growth curves (for checking viability of populations of cells)
- Some awareness of the kinds of tests used to assess the nature/properties of cells (thought the actual tests will probably be done by a QC technician, on which see below)

### **2.2 Basic microbiology**

e.g.

- What are bacteria? What is a micro-organism? What are viruses?
- What is 'contamination'? What is 'cross-contamination'?
- Why do bacteria and (cross-)contamination matter?
- Where do bacteria come from? What are the sources of contamination?
- What are the risks of (cross-)contamination and how can they be minimised? How can you deal with and control bacteria (e.g. via aseptic manufacture and sampling)?

### **2.3. Basic chemistry (e.g. to help make buffers to the correct specification)**

e.g.

- understanding solutions
- calculating molarities
- PH (measuring and balancing)

## 2.4. Human tissue issues

e.g.

- Basic knowledge of nature and properties of human tissues
- Grasp of the kind of diseases (e.g. auto-immune, cancer) that Cell Therapy can be used to treat
- Tissue-typing
- Some background on gene therapy might be useful (as there is significant commonality in the requisite training → occupationally-oriented training, not sector-specific)
- HTA (Human Tissue Authority) regulations (e.g. for donor consent)

## 2.5 Principles of, and rationale for, Good Manufacturing Practice (GMP)

e.g.

- Documentation (e.g. keeping batch records, how to record data in ways that ensure availability in 20 years time)
- Verification and validation
- 'Cross-outs' (for late data entry)
- How to train and retrain people in GMP so that their competence is maintained (and they understand what 'maintaining competence' entails and why it's important)

## 2.6 Other underpinning knowledge

- How the clean room functions as a system (e.g. what is the significance of air flow and positive air pressure in clean rooms, so staff understand how air flow affects the integrity of the clean room)
- Some knowledge of Good Clinical Practice (GCP) (so technicians can appreciate the context into which the product they make will be used).
- An understanding of the role of QA and the QP (so the technicians know how their work articulates with the broader context in which production occurs, concerning quality assurance in particular.)
- Chain of custody – for when product goes to patient (esp. for patient-specific products)
- Knowledge of requirements of MHRA licensing and HTA (Human Tissue Authority) regulations

- An understanding of process of drug development at a broad level (e.g. distinction between phase 1 and phase 2 trials).

(There exists the possibility of another role, for a specialist Quality Control [QC] technician, who would specialise in testing inputs and outputs as well as the environment in the clean rooms (using, e.g., PCR techniques for testing cells, fluorescent microscopy, flow cytometry, ELISPOT tests, testing for 'markers' of various cell types; bio-burden testing, mycoplasma testing, endotoxin testing; doing environmental monitoring of clean rooms, using contact and settle (agar) plates, etc. There might be quite a lot of overlap in the training of the two kinds of techs initially, but would diverge later in specialist techniques learned.) EU GMP regulations specific that manufacturing and training must be done by separate people (to avoid conflicts of interest)

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