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Bridging the Gap: why do we need to think beyond traditional R&D labs?

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This article will focus on the manufacturing of Advanced Therapy Medicinal Products (ATMPs). ATMPs are medicines for human use that are based on genes, tissues or cells. They offer groundbreaking new opportunities for treatment of disease and injury[1].

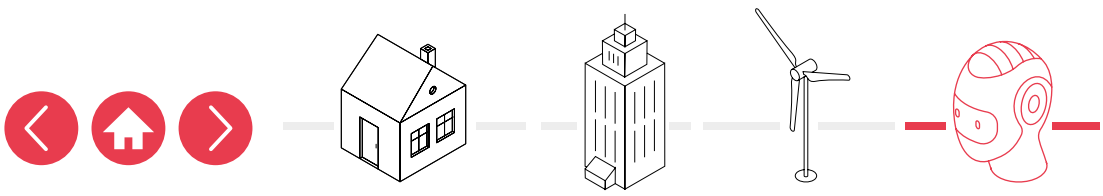
The creation of any ready-to-use product from Research & Development (R&D) needs to consider the 'five Ps' of Good Manufacturing Process (GMP): 1. A clear Product, 2. skilled People, 3. clear Processes, 4. correct Procedures, and 5. clean, safe and appropriate Premises.

To put the Premises part of GMP into context, creating the right premises is a prerequisite for any successful commercialisation of R&D, via GMP, to be realised, be it for bioscience or any other manufacturing. The Premises need to be efficient, safe and purpose built as the manufacturing Process for life science companies is complex, with strict Procedures, requirements (MHRA, EMA and FDA certification required) and environmental conditions required to ensure that the Product is safe for human use.

At the center of this are People; without People there is no Product. The skills required for manufacturing are different to those needed for R&D, therefore, it is integral that your Premise is located among relevant skilled workforce. Seventy per cent of the UK's manufacturing workforce live within a 2-hour drive of Stevenage[2]. This workforce, combined with the government, launched the Cell and Gene Therapy Catapult (CGT Catapult) in 2012. This has led to Stevenage becoming the third largest Cell & Gene Therapy cluster globally, and the largest outside the US[3]. Cell & Gene Therapy (CGT) is classified as an Advanced Therapy Medicinal Products (ATMP) and involves an extremely high regulatory hurdle given the application to human genes, tissues and cells.

So why is manufacturing (GMP) so critical to the commercialisation process? The journey from product discovery to pre-clinical and clinical stage is often long and complex. Critically, even at the product discovery stage, there needs to be an understanding of how the product can be manufactured, in order to ensure viability.

This initial stage of product discovery is largely conducted in an R&D lab until a conceptualisation point is realised, following which initial manufacturing of the product can take place. It is at this stage that a company would require GMP space. Therefore, manufacturing is critical to the commercialisation of a Product.



Case Study

The importance of the manufacturing process can best be demonstrated through the case study of Autolus - a CAR-T cell therapy company, was looking to transition from a firm focused on early-stage research to a robust clinical development company.

To achieve this, Autolus needed to establish the capability to manufacture its autologous cell therapy candidates in an environment that met the stringent GMP requirements. Autolus initially worked with CGT Catapult to develop its commercially scalable manufacturing process for autologous CAR-T products before scaling their operators eventually into The Nucleus; a ca 80,000 sq ft facility developed by UBS Asset Management (UBS AM) jointly with Development Manager, Reef Group.

The Nucleus was the UK's first CAR-T cell therapy site and was delivered in less than 2 years. The facility was built to accommodate growth and has allowed Autolus as a company to expand alongside its batch capacity. This is most notably evident in their recent strategic partnership with BioNTech, a next-generation immunotherapy company, enabling their pipeline to advance and the expansion of their programs . BioNTech will be able to access Autolus's manufacturing capacities within UBS AM's facility.

The UK is already home to multiple high-value manufacturing hubs, underpinned by the strength of the ATMP sector, with 1 in 3 European ATMP companies operating in the UK . The sector has seen strong growth in recent years, with the number of ATMP clinical trials in the UK increasing by 20% in 2020 .

Additionally, data from the UK BioIndustry Association details that the number of jobs in CGT doubled between 2019 and 2023. This momentum is set to continue with CGT deemed the 'next wave of medicate innovation '. A clear priority is the need to increase GMP manufacturing capacity in the UK. Given the expertise and existing clustering of ATMP companies in the UK, there is significant opportunity for real estate to help support this fast-growing sector .

CGI of The Assembly, The Nucleus and future Cryoport development

1. European Medicines Agency: Advanced Therapy Medicinal Products Overview
2. Great gov, Cell and gene therapy in Hertfordshire
3. ABPI, Advanced Therapy Medicinal Products (ATMPs)