Tackling the unique challenges of capacity planning for autologous cell therapies

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Capacity planning has been a long-standing issue in the pharmaceutical industry. Setting up Good Manufacturing Practices (GMP) compliant facilities is time-consuming and capital-intensive[1], but for products to be able to generate maximal economic returns during the market exclusivity period, timely availability of manufacturing capacity is vital. Capacity crunches faced by the monoclonal antibody (mAb) industry in the 1990s were estimated to have caused around $3-$4 billion losses in total revenue due to insufficient product supply[2,3]. In addition, the uncertainties in clinical trial outcomes, market pressures, and regulations[4] make the multi-objective optimisation of capacity planning and product development decisions critical for the industry.

Previous studies have considered the optimisation of investment strategies for product development[5], manufacturing facility investment decisions and global multi-site supply chain optimisation[6] for drugs and multi-site continuous bioprocess optimisation for biologics[7]. As more advanced therapeutic medicinal products (ATMPs) move from bench to clinic, the unique challenges for autologous cell therapies present a new problem in the capacity planning domain. Firstly, the unique requirement for autologous cell therapies to be produced on-demand with cell material originating from patients have proven to be commercially challenging[8]. Secondly, with geographical and supply chain constraints, companies are considering building multiple facilities in different regions or finding alternative arrangements such as licensing and outsourcing[9]. Thirdly, fast-track regulatory frameworks introduced by various regulatory authorities are improving the speed-to-market[13] and have allowed faster commercialisation of ATMPs for life-threatening diseases[10–12]. The clinical development duration can be reduced from 6-7 years (phase 1, phase 2, phase 3 clinical trial) to 2-3 years (small scale clinical trials with surrogate end-points)[14]. Therefore, the commercialisation timeline for process, CMC development, and capacity planning decisions should also be considered earlier[15].

In this work, we present a detailed analysis of the above challenges, and propose to develop an optimisation model to address the unique challenges of autologous cell therapies. The approach can potentially allow the industry to make better-informed investment decisions and accelerate the commercialisation of these life-saving therapies.

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