LIFECYCLE BRIEF

Sterling

Launch

Providing efficient, quality-focused commercial manufacture

Pharmaceutical patents protect intellectual property for **20 years.**[1]

Commercial approval is among the most exciting milestones for a pharmaceutical or biotechnology organisation, as a product can finally make its way into widespread availability for patients. Commercial-scale manufacturing, however, brings about an entirely new set of process considerations and challenges to be navigated.

Once a product is approved for commercial sale, organisations are under intense pressure to meet demand while containing costs and ensuring ongoing quality and efficiency. In addition, the potential for risk and the waste generated intensify as a project scales. Overcoming these challenges requires a partner with manufacturing expertise, support for a range of process requirements and a deep-rooted understanding of the pharmaceutical lifecycle.

Below are some key areas that can present challenges for pharmaceutical and biotechnology organisations as they launch their products commercially.

Demand expectations

Meeting deadlines during clinical trials can be challenging, but nothing compares to the flexibility and scalability that are needed when a product is manufactured at a commercial scale. Meeting heightened demand while ensuring ongoing product quality and process efficiency is critical to ensuring continued commercial success. **Look for an outsourced partner that has successfully met commercial demand many times before, and can help you adapt to changing scale.**

Process improvements

Process optimisation is not limited to early phase development. As a product makes its way into the market it is important to continually seek new ways to enhance efficiency and improve economies of scale. This is very important as a product reaches the end of its patent. **Make sure your outsourced partner is committed to continually refining processes during manufacture, and supplying the necessary supporting data for any process changes to maintain continued regulatory compliance.**

Risk mitigation

While hazard evaluation is critical at the onset of any programme, the potential for risk increases as processes are carried out at a larger scale. Maintaining safety throughout manufacturing requires a deep knowledge of potential hazards and how to overcome them, as well as specialised equipment and highly trained teams. **Make sure to identify a partner that is known for hazardous expertise, state-of-the-art facilities and knowledgeable personnel.**

Process waste

With large-scale manufacturing comes substantial process waste. To minimise a project's environmental footprint, it is imperative that this waste is properly handled. **The outsourced partner you choose should be focused on minimising and recycling waste wherever possible, and appropriately treating any waste that is produced so as to mitigate its environmental impact.**

At Sterling, we have the specialised teams, state-of-the-art facilities and equipment, and extensive expertise to support our customers' molecules through every stage of their journey to market, from early phase development through to full commercial manufacturing.

Here's how we support our customers once their products are approved for commercial sale:

World-class manufacturing capabilities

We have more than 50 years of experience supporting customers throughout the full project lifecycle, including extensive API manufacturing capabilities. Our work in bringing customers' products from grams to tonnes is supported by comprehensive experience spanning the entire molecule lifecycle and cGMP manufacturing expertise. We also deliver the asset flexibility needed to support a range of manufacturing considerations.

Continual process optimisation

Our team consistently reassesses and adjusts processes to improve efficiency and contain costs, all while maintaining throughput and continuing to deliver a high-quality product. Our process engineers and analytical team members collaborate to identify areas for sustained improvement and deliver new manufacturing advantages to our customers, and we provide the resulting data required to ensure continued compliance.

Hazardous chemistry expertise

Our experience in hazardous chemistry enables us to safely support a wide range of hazardous processes and materials. We perform comprehensive hazard assessments on an ongoing basis to affirm safety and mitigate risk. By re-evaluating the potential for risk through scale-up and amid any process changes, we protect both our customers and our valued employees.

Sustainable waste management

We prioritise environmental sustainability and work with customers to minimise waste throughout their projects, especially during commercial manufacturing. We have treated aqueous waste at our on-site biological treatment plant, located at our Northumberland, UK site, for more than 25 years to reduce the environmental impact of our customers' projects. We continue to seek new ways to recover and reuse waste wherever possible, and are actively pursuing carbon neutrality.

Comprehensive capabilities for commercial success

At Sterling, our experience, facilities, and equipment enable us to support a diverse range of API manufacturing requirements at the commercial scale. As a PDMO®, or partnership development and manufacturing organisation, we value close scientific collaboration with our customers to enhance their projects' success from the lab to the market.

Service

We pride ourselves on being easy to do business with, removing layers of complexity, maximising flexibility and adaptability to your requirements, and doing what we say we will do, again and again.

Passion

We promise to treat your molecule as our own, drive progress by continually exploring new and emerging capabilities, and do the right thing for people and planet.

Science

We combine our expertise in complex and hazardous chemistry, our world-class facilities and our full-lifecycle capabilities to place scientific excellence at the core of every solution we deliver.

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1. Berger, J. et. al. How Drug Life-Cycle Management Patent Strategies May Impact Formulatory Management. AJMC [Online] 2017, 16. https://www.ajmc.com/view/a636-article (accessed June 9, 2021).