More Than a Traditional CDMO

Sterling Pursues a New Standard of Collaboration for the Pharmaceutical Industry

Headquartered in Cramlington, UK, Sterling Pharma Solutions is a contract development and manufacturing organization (CDMO) that provides a range of services to the global biopharmaceutical industry, including active pharmaceutical ingredient (API) development, scale-up and cGMP manufacturing, as well as antibody drug conjugate (ADC) R&D and clinical-scale GMP manufacturing. The company has a strong pharmaceutical and engineering heritage dating back to the founding of its first facility in Cramlington, in 1969. Since then, Sterling has grown significantly, both organically and through a global strategy of acquisitions. Today, it has six facilities across Europe and the US and over 1,350 employees. CHEManager asked Kevin Cook, CEO at Sterling, to analyze current market trends and present his strategy to further develop and grow the company's business.

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Kevin Cook,
CEO, Sterling Pharma Solutions

CHEManager: Which areas of the pharmaceutical value chain can Sterling cover, and how is the company positioned in these segments in terms of portfolio range and core competences?

Kevin Cook: Sterling's main focus is in supporting the development of small molecule APIs, and we work with customers around the world, across the drug development continuum, from preclinical through to commercial supply. Predicting which molecules will be successful is impossible, so our strategy is to follow a molecule for as far as we can through development, adding value by applying expertise at each step, and assisting clients to navigate the technical and regulatory challenges towards commercialization.

Sterling also supports ADC developers, from the design and synthesis of chemical linkers and highly potent warheads, through to final GMP ADC conjugation at our sites in Deeside, UK, and Wisconsin and North Carolina, US.

In October last year, Sterling acquired UK-based contract research organization NewChem Technologies. What was the intention behind this takeover?

K. Cook: Having worked with NewChem over a number of years, we understood its expertise in high-level scientific and technical problem solving. Its close proximity to our manufacturing site in Cramlington provides additional non-GMP development capabilities, which are vital to increase the support and number of early-phase clients in our customer pipeline that need agile and flexible services to overcome initial development challenges.

Do you have other investment plans you can share with us, either in existing facilities and capabilities or in new ones?

K. Cook: Sterling has an ongoing process of organic growth, and we have investment plans in place to increase capacity to meet market needs. Key areas include chemical and analytical development, highly potent API manufac-

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turing, commercial flow chemistry capabilities, as well as additional GMP manufacturing for ADCs.

What do you perceive as the most pressing needs and requirements of your customers?

K. Cook: Increasingly, customers are looking beyond technical expertise and facilities as differentiators between partners as they are taken as a given, and the focus is more on how a partner's culture aligns with its needs. The highest level of customer service is crucial, as well as speed of response, delivery, and the intimacy between partners, as many clients wish to be deeply involved in the process beyond a pure transactional relationship.

Overall, what do you think are the predominant trends in API/drug development?

K. Cook: One of the most important changes that the industry has seen is in volume requirements: the end market for APIs is reduced, as drugs are being developed for more niche applications with lower patient populations. However, this drop in volume demand comes with increased molecular complexity, a greater number of processing steps and the likelihood of complex, and often hazardous, chemical transformations. This means there is a need for greater variation of manufacturing assets to handle the necessary reagents and reaction conditions, as well as a broad range of vessel capacity to efficiently process potential swings in volumetric needs.

In chemical development, Sterling's goal is not only to provide customers with the most efficient process for each stage of a molecule's development but also one that is future-proofed in terms of scale-up and sustainability. This is achieved by carefully selecting reagents and solvents and optimizing their use to be both efficient and have minimal environmental impact.

As small molecule complexity continues to rise, pharmaceutical and biotechnology organizations continue to seek innovative solutions to complex chemistry challenges. How can Sterling help its customers to tackle these challenges?

K. Cook: The decades of experience that Sterling has in manufacturing provides us with a deep level of knowledge and expertise that we can leverage to meet modern day challenges.

We also provide our customers with access to specialized expertise in new methodologies through our Technology and Innovation Program, which sees us work with academic institutions. Sterling has links with numerous international universities and has forged partnerships and sponsored post-graduate research in areas such as flow chemistry and enzyme-catalyzed reactions, to further understand how these can be applied to industrial processes.

Sterling does not define itself as a traditional CDMO, but as a PDMO, or partnership development and manufacturing organization. What does that mean?

K. Cook: As previously alluded to, working with customers now goes beyond a transactional relationship, and for projects to succeed many people across a number of teams within both the manufacturer and the customer come together to share ideas and act as a partnership. Sterling originated, and indeed, trademarked the acronym PDMO for Partnership Development and Manufacturing Organization to recognize this shift in approach, and to build the aspiration of success through close collaboration and the highest quality of customer service.

Driven by the three core characteristics of service, passion, and science, Sterling prioritizes true scientific partnership with all of its customers, is responsive to their needs, committed to their products, and is capable of adding a deep level of scientific value.

What kind of collaborations do you have in place?

K. Cook: Alongside the academic partnerships we have in technologies, Sterling has also joined a number of industrial collaborations such as the Supply Chain Initiative and Science-Based Target Initiative so that as a company, we can work with our peers to drive change and promote innovation for the benefit of all in the industry.

Sterling is part of a consortium of industrial innovators from across the chemical industry supply chain that aims to accelerate the adoption of continuous manufacturing across a range of industries, with a focus on digitalization. In your opinion, what are the key advantages and main areas of application of this technology, also known as flow chemistry?

K. Cook: The consortium to accelerate the use of continuous manufacturing that Sterling joined in 2023 is led by Imperial College London and BASF.

Flow chemistry allows greater control over chemical reactions, and by tuning conditions, the formation of impurities can be reduced, simultaneously increasing both efficiency and yield. Toxic and hazardous materials can be handled safely as the active volumes being reacted or created are much smaller. Additionally, the capital commitment to commercial-scale production is reduced with a flow reactor, as the physical space needed to run a process is significantly less than in batch.

Not every reaction process will be suitable for transfer to flow chemistry, however, if the conditions are optimized and appropriate, these three factors can combine to support an overall lower cost of goods.

The topic of sustainability is increasingly making its way into the pharmaceutical value chain. What role do the various sustainability aspects play for Sterling?

K. Cook: It is my firm belief as CEO that doing the right things leads to getting the right results, and this drives Sterling's commitment to protecting its people and our planet. Our entire team takes sustainability seriously, and we are continually working to reduce our environmental impact, with an initial goal to reduce emissions by 50% by 2025 as the first step towards becoming carbon neutral.

Our Cramlington facility leads the way in finding solutions and creating a roadmap for sustainability. It is almost self-sufficient in electricity, and also has an on-site anaerobic digestion plant that converts complex waste streams into energy to supply back into the national grid, reducing emissions by up to 65%. Trials of a new, ultra-low charge ammonia chilling technology at the site have demonstrated a quantifiable energy cost saving of more than 60%, and we are now looking to roll this out across our global network.

These forward-looking initiatives also demonstrate that sustainability improvements can have economic benefits. In recognition of our ESG policies, actions and results Sterling was awarded a gold medal by EcoVadis, placing it in the top 4% of all companies assessed globally, and in the top 1% of pharmaceutical companies.

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