Kevin Cook – CEO, Sterling Pharma Solutions, UK

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30.08.2018

Tags: UK, Sterling Pharma Solutions, CMO, CDMO

Sterling Pharma Solutions is a rapidly growing GMP contract API manufacturer based out of Dudley, Cramlington in the Northeast of England. The company was set up in its current structure only two years ago after an MBO led by current CEO Kevin Cook, but its roots date back almost 50 years. Kevin Cook explains the company's evolution, their API capabilities and their impressive rate of growth – doubling revenues in the past three years and hiring over 100 new staff.

The global CDMO market is expected to reach USD 80 billion by 2020. What do you identify as the primary drivers of growth?

There are many factors which serve to explain this strong growth trajectory. Firstly, large pharmaceutical companies continue to focus on drug discovery, drug development, and marketing. Moreover, manufacturing elements within Big Pharma companies have become less prominent, and the outsourcing trend continues. Over the years, a certain capacity has been taken out of the western world, and roughly ten years ago there was a shift to the East to solve financial problems and resolve API manufacturing issues. We now observe a reverse trend of manufacturing returning to the West manifested as a result of documented quality issues.

Despite a number of commentators articulating that pharmaceutical API manufacturing across the West was on the way out, I am delighted to observe that there is now a long, sustainable future for API manufacturing. Certain projects will never return to the West, nonetheless, where there is a degree of complexity and hazard, Sterling Pharma Solutions in particular is well placed to add value. Regarding pharmaceutical innovation, roughly 70 percent of innovation comes from

companies outside the big pharma group, primarily emanating from North America. Indeed, North America is a crucial target customer base for us, typically funded by private equity, as they can drive forward programs. We now see strong growth in the CDMO space, particularly within emerging pharma.

In summary, a combination of big pharma strategy, funds supported by tech and emerging pharmaceuticals, and also molecules becoming more complex and being required at smaller volumes with higher value have all ramped up demand for global CDMOs.

What do your clients most value about the made in Britain brand?

Assurance of supply and reliability. From a compliance point of view, at Sterling we operate a simple approach: safety, quality, and quantity. If we cannot perform the operation safely, we will not accept the project, but there is an excellent framework within Sterling to help find a way to do things safely. We take our time and are meticulous, engaging high levels of discipline regarding process understanding to ensure we offer a high-quality output while controlling process safety. In addition to our internal procedures, the external regulators in the UK such as the HSE, EA and MHRA that support product development and manufacture provides our clients with a high degree of confidence that operations are being well maintained and managed.

What challenges or opportunities does Brexit offer?

Brexit is a huge topic which we struggle to influence; therefore, we must focus on the parameters that we can control. The concerns we observe are the changes to the regulatory framework and when they will occur, although this is more of a concern for secondary manufacturers—those who work in drug product manufacturing rather than APIs. The UK has spent years harmonizing FDA and EMA practices, and as such, there will be less of an impact. However, tariffs and import duties could affect the competitiveness of the UK. Currently, Brexit has made the UK more competitive when we consider the dollar-pound relationship—let’s hope that continues.

What was the rationale behind creating this CDMO, and what is the overall vision of Sterling?

We will celebrate our 50th birthday next May, and over that time the pharmaceutical industry has evolved. We have been party to acquisitions, mergers, divestments—not only with British companies. We have been part of a listed organization, part of Sanofi, and we were even in partnership for a time with an Indian generics manufacturing company, Shasun, which then merged with Strides to form Strides Shasun. Being part of an Indian organization that was predominantly generic while we were focused on the innovator API space made it very difficult for

us to position ourselves in the market and compete in promoting our brand in the innovator space. In effect, the merger of Shasun with Strides magnified this issue, forming a generic product to market organization. As a result, our ability to serve the innovator space was compromised.

Arun Kumar, the founder of Strides, and a pharmaceutical veteran, very quickly realized the issue and saw the potential of the CDMO business. He saw what is now known as Sterling Pharma Solution surviving better outside of Strides Shasun. Following a management buyout , we founded Sterling, a UK Ltd private company.

We have seen excellent market traction with the Sterling brand, we reformulated our strategy and focused on projects where we can add value, tackle complexity and hazards. We also extended our offering into controlled substances. Our ability to handle complexity and our well-documented compliance record allowed us to move into the controlled drug space, an exciting area for us where we now have a number of projects.

We are now an active pharmaceutical ingredients supplier to some of the largest animal health organizations and human health organizations in the world.

How would you describe your expertise and capabilities?

Our expertise and focus is small molecule APIs. We have the full spectrum of CDMO capabilities meaning we have true development capabilities through to large scale manufacturing. Many companies underestimate the need for significant ‘D’ capabilities in CDMO—something that Sterling can provide. Nurturing expertise in this area allows us to take a loosely defined process and create something scalable and commercially viable.

What is Sterling’s vision?

Our vision is to grow the operation we have on-site to GBP 125 million (USD 165 million) and we have a detailed roadmap that will lead us there. We are investing GBP 11.6 million (USD 15.2 million) in one project, and we have expanded our pilot plant from five to eight trains to support demand in a multistep synthesis. We offer small-scale options that complement our large-scale equipment. We are also adding a milling and micronization facility, which is often required for the final API, and rather than outsource, we will create an in-house capability in this area. Finally, we are building a solid state laboratory onsite and four small-scale manufacturing cells, to be concluded by quarter one next year.

Our second investment – which will first bring us to GBP 125 million revenues by 2023- involves upgrading some of our larger scale equipment to improve flexibility and capability. This will create

four new reactor trains. Equally, we are actively looking for opportunities in API manufacturing sites in Europe and are looking to inorganic growth. We are looking for a lab and kilo capacity in North America, and we may consider an early formulation development facility in the future.

68 percent of your business is today generated in the US, and you have plans to expand in Asia, notably Japan. How would you describe your internationalization strategy moving forward?

The US is the world's biggest pharmaceutical market and the most prominent space for pharmaceutical innovation. It will remain one of our key focuses, and we will continue to grow our presence and our customer base in the US. Over the past two years, we have approached the challenging Japanese market, where we have gained traction. We are in conversation with three Japanese customers who offer high potential projects.

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What is the comparative advantage of operating in the Northeast of England?

Being based in the Northeast of England offers several advantages, notably operating a conservative cost base. The cost of living is relatively cheap compared to the South,

allowing for Sterling to offer an attractive average salary. Moreover, there is an excellent work ethos in the Northeast based on its industrial heritage—and it is also a nice place to live!

Our operating staff take extensive training programs, and we develop people to work in the way that we want them to work. Some of our employees study abroad for higher education or their Ph.D.'s and come back to the north-east afterwards. We also have excellent retention rates as once people settle here they begin to realize just how excellent the quality of life is. Our culture is important, and we like clients to understand that we are enthusiastic, caring and we can be trusted with customers' projects.

How will you be the future partner of choice in the competitive CDMO market?

The issue revolves around bringing value to business relationships; we are nor will we ever be the cheapest or the dearest, and therefore we focus on how we can bring value, reliability and a strong track record of compliance to each relationship. We operate a proactive, collaborative relationship with our customers—actively inviting customers to come on site and take part in the process.

Furthermore, we have a number of examples of our technology in action and how we can bring technology into our differentiation strategy. Having the right assets and the right level of compliance is crucial, but of course, the competition claim they have the same qualities. For Sterling, we differentiate by being an organization that is easy to do business with, and we differentiate through our people and the way that we do things—the Sterling way. Indeed, we make decisions today on how we change things tomorrow.

Do you have a final message for our international readers?

The UK and within that, the Northeast is a fantastic place to do business. Our ambition is to create a business based in the Northeast that can compete in a global space.

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