A CDMO With Flexibility & Efficiency

SGS Quay Pharma's Facility Brings Formulation and Manufacturing Expertise to North America

The lifeblood of any pharmaceutical company is new product development.

From discovery through commercialization, pharmaceutical companies must navigate through many obstacles to bring a new product to market.

The need for comprehensive, technically advanced, and integrated services from contract service providers is needed now more than ever.

SGS, a provider of a diverse range of contract service solutions to help pharmaceutical companies bring new products to market as efficiently and safely as possible, recently added a contract development and manufacturing facility in Hudson, NH to its portfolio of services.

The new 55,000 square foot cGMP facility brings to the SGS network full formulation and development capabilities to support Phase 1 – 3 clinical manufacturing focusing on early-phase development. Specifically, the new US facility consists of analytical and formulation labs as well as GMP manufacturing space designed to support and provide much-needed assistance to help organizations successfully bring products for oral and topical delivery to market.

SGS' Global Network and Services

SGS is the world's leading testing, inspection and certification company providing critical support services across nearly all industries

For the pharmaceutical and biopharmaceutical industry, SGS offers comprehensive integrated solutions from exploratory development, analytical testing, regulatory support, safety studies and clinical research, to commercial QC and post-market testing. The addition of the SGS Quay Pharma facility to the SGS network has bolstered the company's offerings and provides an important service and manufacturing location in the United States.

A Collaborative Relationship

In December, 2021, SGS acquired Quay Pharmaceuticals Limited (Quay Pharma), a UK-based provider of innovative, formulation research and development bringing the first Contract Development and Manufacturing Organization (CDMO) to SGS's network.

This collaboration seamlessly integrates SGS's extensive analytical expertise with Quay's world-class formulation and manufacturing expertise.

Niveen Mulholland, SGS Vice President for Drug Development in North America explains, "The acquisition of Quay Pharma represents a key milestone in the evolution of the SGS Drug Development business. Adding formulation and development capabilities alongside our analytical laboratory capabilities provides for a complete end-to-end solution for our customers who are building the bio/pharmaceutical product pipeline." Maireadh Pedersen, Quay Pharma's Commercial Operations Director adds, "In turn, as a part of the SGS network Quay is now able to offer a much broader analytical capability to the formulations that we do, which means that formulations can be done faster, will be more robust and are better positioned for what our customers need for their patients." After all, you don't have a formulation without your analytics. In turn, as a part of the SGS network Quay is now able to offer a much broader analytical capability to the formulations that we do, which means that formulations can be

done faster, will be more robust and are better positioned for what our customers need for their patients."

"That was really the reason for the acquisition, it was to tie everything together and provide a synergistic effect," says Pedersen. "Quay has been in the small molecule space since 2002. It gave SGS that pathway immediately with regard to small molecules. We have been looking at formulation of large molecules over the last several years but we weren't strong in analytics, so being part of SGS now brings us that strength in biopharma analytical capability because we can really tie-in to the SGS lab network in the life sciences space."

Pedersen also mentions that Quay Pharma was the first CDMO licensed to bring live bacteria into a multi-product facility for manufacturing and facilitated the move into the microbial-based medicines space.

"SGS clients can gain faster access into that area because we have been working in that space since 2014."

Facility Details

Acquired in late 2021, the SGS Quay facility in Hudson, NH is designed to support analytical and formulation projects, as well as GMP manufacturing. The work the site is capable of supporting starts at the preclinical stage performing formulations for toxicology studies, enabling faster First in Human development and clinical manufacture.

The site is equipped to support Phase1 to 3 clinical manufacturing for a variety of dosage forms, including traditional solid dose capabilities, as well as scale up to support oral liquids/suspensions. This is particularly suitable for specialized products for orphan and rare diseases and pediatric medical supply.

The facility is also equipped to support the clinical process through packing, labelling, randomization, and blinding and is able to distribute globally with relevant Qualified Person (QP) services. The US and UK sites are also capable of handling transfer of products between sites for local clinical supply.

Market Drivers for CDMO Services

The decision to add the new SGS Quay Pharma site in Hudson, NH was based on the need to add a customer-focused and technologically flexible facility to provide customized product formulation and manufacturing services.

Founded in 2002, Quay Pharma was built on its formulation expertise. The key part to its success has been that it is not dependent on utilizing specific formulation technologies or pre- determined platforms. Pedersen explains, "We don't have standard platforms. When determining a formulation strategy, we look at the drug itself, we look at what the physico-chemical properties are, the target patient population and the indication. Then we offer customized formulation around that."

Pedersen adds that SGS's services are very consultative and their procedure is to work one-to-one with their customers. SGS tailors its services to customer requirements and what the customer's goal is – whether it's getting to First-in-Human as quickly as possible, or giving their drug the best chance during formulation.

"We go through a risk mitigation strategy." Pedersen says. "We'll give clients all the possibilities of how to get the drug substance into a suitable formulation and then into clinic. Then we'll provide options in terms of what the benefits or risk are regarding each approach and how we can mitigate risk by applying our expertise."

Not being tied to a particular process technology or platform allows SGS to apply virtually any system to move the product forward.

"We look very closely at the properties of the drug substance and then find a way to overcome any formulation issues," says Pedersen. "We don't offer a platform; what we develop we give back to the customers so that there's no tie-in. A lot of other CDMOs would be keen to tie the customer into a certain platform to take them through to commercialization, we don't, we're focused on getting them into clinic in the best way that suits them and then allowing them to through clinical trials as efficiently as possible."

Pedersen adds that since they don't offer a "platform technology" the site is very flexible in terms of suggesting manufacturing technologies to move products through formulation and development.

"We look very much at what is going to be the best route to take the client's product forward," says Pedersen. "We can do simple processes to get to First In Human supply quickly and also more complicated, enabling processes like hot melt extrusion, extrusion spheronization and spray drying, but currently one of the most used technologies involves developing lipophilic systems which is a way to enhance solubility and bio-availability and Quay Pharma was one of the initial pioneers in this technology and offers full support through manufacturing as well.

Flexibility and Efficiency

As pharmaceutical products and the route to commercialization becomes more complex, innovator companies need options and they need the companies that they work with to be flexible and fast.

The addition of the new SGS Quay Pharma CDMO facility in Hudson, NH has been based on this premise. The combination of formulation and manufacturing capabilities with analytical capabilities allows clients to choose the level of support they need – whether they need full support through every stage of the drug development cycle, or they just need targeted support in specific areas where in-house capabilities or capacity is restricted.

The company's agility to provide multiple formulation options and the expertise to effectively troubleshoot development challenges is a strength the company has demonstrated for 20 years.

The customized, consultative approach that SGS offers paves a clear path for drug developers to get their products to the clinic safely and quickly.