SCIENTIST SNAPSHOT

Chris Seekamp

At Sterling, our highly experienced team members and their passion for what they do are central to who we are. This month, we spoke with Chris Seekamp, Director of CMC (Chemistry, Manufacturing and Controls), to learn more about how Sterling supports its customers in shaping their CMC strategies for successful regulatory submissions.

Can you briefly describe your background and current role at Sterling?

After receiving my PhD, I worked in process development chemistry for a smaller biotech. This gave me a strong understanding of the full project lifecycle, as I was able to experience projects first-hand as they moved from early development to the full commercial scale.

I started my work in the CDMO space heading up the research and development department at Sterling, and moved into my current position as head of CMC last year. In this role, I work closely with our customers to guide them in their CMC strategies, helping them to balance costs with successful regulatory submissions. In addition, I actively collaborate with our development team to shape an appropriate strategy for the API that will meet regulatory requirements and ensure ongoing adherence to the strategies our customers define.

One of the things I most enjoy about my current position is that I have the opportunity to engage with a variety of people in different roles across our customers' organisations, including professionals with technical, regulatory, or financial backgrounds. Each of these specialties brings a unique point of view that shapes the organisation's perspective on its CMC strategy.

What CMC services does Sterling offer its customers?

We offer CMC support as an additional service to our customers to ensure continuity throughout their projects; we can be as involved as customers want or need us to be in this area. Some of our larger customers have their own CMC departments, and I am primarily there to offer guidance and answer questions. For other customers, particularly smaller biotechs, we are more heavily involved in the CMC function.

Fast Facts

ROLE

Director of CMC

YEARS AT STERLING

7

EDUCATION

PhD in Organic Chemistry, The Ohio State University

SPECIALISATIONS

CMC, R&D, process development

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In general, my goal is to help customers achieve regulatory success throughout the lifecycle of their product while containing costs and adhering to their desired timelines. This involves providing CMC advice based on our customers' needs, highlighting potential risks and advantages of their desired approach, explaining regulatory expectations, and reviewing CMC packages to offer commentary. We want to ensure that our customers receive approval while also remaining within budget. Achieving this requires a pragmatic perspective that balances long-term regulatory implications with their budget and phase.

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It also requires us to define an appropriate regulatory starting material as well as to clearly identify at what stage it makes sense to adhere to cGMP in their processes. While it may seem wise to minimise cGMP steps in the process to contain costs, this is not always optimal from a regulatory standpoint. On the other hand, starting too early is also a concern, as it can result in unnecessary added costs and project delays. We help our customers find that optimal balance between cost, quality, efficiency and compliance. This answer can vary a lot from customer to customer and project to project, so our guidance is very tailored.

What are some major focuses within the regulatory landscape today?

There is a lot of focus within the industry on the ICH M7 guidance, which centres on mutagenic impurities. As these impurities are carcinogenic, the guidance provides recommendations to control and prevent them from entering final products at a concentration that is hazardous to human health. There have been recalls in recent years because of such impurities, so our customers often seek guidance on how to appropriately address them in their projects. We are very experienced in working with these guidelines, and we help our customers identify when in their processes to start assessing these impurities in order to mitigate risk. Our analytical team also has the equipment and specialised expertise needed to navigate these guidelines and carry out robust impurity assessments.

Another thing we are trying to encourage more is direct outreach to regulatory agencies. Customers are often surprised to learn that the major regulatory bodies are quite responsive to questions and concerns. While they don't provide concrete answers prior to official submission, they can be helpful in assessing whether a project is on the right track. This empowers our customers to proactively overcome any potential issues or challenges early in the process.

How do you address global variations in regulatory guidance?

We have a lot of expertise and familiarity with customers and regulatory bodies around the world. When it comes to regulatory submissions, our customers' main focuses tend to be the FDA and EMA. Since Sterling is based in the US and UK, as are many of our customers, we are especially experienced with these agencies.

We consider where our customer intends to file first, and we provide recommendations on how to handle subsequent submissions to best position them for success.

Fulfilling FDA and EMA requirements is typically satisfactory for most other major regulatory agencies around the world. However, there are different subtleties between regulatory bodies that can at times be challenging to navigate. For example, Japan's requirements may be quite different from the EU's in some cases. We consider where our customer intends to file first, and we provide recommendations on how to handle subsequent submissions to best position them for success. It is important to set this expectation early in the project to ensure that all processes moving forward adhere to guidelines in the markets where the customer intends to seek approval.

How do you expect Sterling's CMC services to grow over the next several years?

CMC and regulatory success are top priorities for our customers, and we are looking to grow our CMC team to provide even more support. With more members on the team, we'll be more readily accessible to address any CMC challenges or concerns our customers have in real-time. We continue to expand our scope, and we ultimately hope to serve as a full CMC department for customers who may not have one internally.

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