SCIENTIST SNAPSHOT

Victoria Waddington

As part of Sterling's focus on customer success, we deliver regulatory support throughout the entire product lifecycle. We spoke with Victoria Waddington, Regulatory Affairs Manager at Sterling's Dudley site, to learn more about the regulatory landscape and Sterling's offering.

Can you describe your background and current role at Sterling?

I first received my Bachelor's Degree in Medicinal and Pharmaceutical Chemistry from Loughborough University and then went on to earn my PhD in Organic Chemistry there. I was always interested in the pharmaceutical space, and the regulatory side appealed to me because of its significant impact on the quality practices of the entire industry. For this reason, I started my career in regulatory affairs straight out of university.

I have over 25 years of experience working in regulatory affairs specifically for APIs. For 20 years, I worked for Macfarlan Smith in Edinburgh, first as a Regulatory Affairs Officer, and then as Head of Regulatory Affairs. I dealt with both new and old generics for worldwide markets, and had a great deal of customer interaction in my role, which is one of my favourite aspects of regulatory affairs. Close customer communication is particularly important in the regulatory space because of the monumental importance of regulatory success and the highly unique requirements based on product stage, category and region of the world.

In March 2022, as Sterling continued its expansion, I was offered the Regulatory Affairs Manager position. Now, I am focused on continually expanding our regulatory offering. While Sterling has always provided strong regulatory support and guidance to our customers, we are now focused on providing an even more robust range of regulatory services, which can be delivered as an integrated or standalone offering, depending on each customer's needs.

How has the regulatory landscape evolved over the course of your career?

Since the pharmaceutical industry is highly regulated and new discoveries occur at a rapid pace, the regulatory landscape has evolved significantly since I began my career. Regulations can vary greatly across regions, and new regulations continue to surface and change on an ongoing basis. For example, the European Commission has recently published proposals for the revision of the EU's pharmaceutical legislation. This is the first time in decades that the legal framework has been up for review, so it's a critical year for the pharmaceutical industry. Another example is the work of ICH, who are continually developing new guidance such as Q13 on continuous manufacturing, and revising existence guidance such as Q2 on analytical validation and Q1 on stability. While these are quite substantial changes, we see smaller, more incremental changes to guidelines in various parts of the world rather frequently. Whether there is a small update to guidance or a brand new regulation being introduced, Sterling is adept at updating guidance to our customers with outstanding timeliness and precision.

Fast Facts

ROLE
Regulatory Affairs Manager

JOINED STERLING
March 2022

EDUCATION
PhD in Organic Chemistry, Loughborough University

SPECIALISATIONS
Regulatory affairs, API manufacturing, organic chemistry

LINKEDIN
Victoria Waddington

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This has always been one of the things I've loved most about regulatory affairs. Since the landscape is always changing, I am constantly learning and adapting in my role. It's really interesting to watch these changes keep pace with the industry's rapid and sustained progress.

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Can you tell us more about your involvement in the Active Pharmaceutical Ingredient Committee (APIC)?

APIC is a trade association within the European Chemical Industry Council (Cefic). I've been involved in this committee for over 20 years, previously serving as Chair of the Regulatory Affairs Working Group, and now as Vice Chair. The committee represents the best interests of the API and API intermediate producers in Europe, focused specifically on quality and regulatory matters. Membership in the committee is company-based, and so it has a strong representation of different industry sectors involved in API manufacture. I enjoy being involved in this committee because it helps me remain up-to-date with changes in the industry and play a larger role in upholding best practices. I have the opportunity to connect with colleagues involved in similar roles, as well as to communicate directly with regulators.

What are some of your goals for Sterling's regulatory offering?

As part of our integrated, full-lifecycle service offering, Sterling has always delivered regulatory support to our customers over the course of their projects. We have served as a key point of contact for our customers to direct their regulatory questions and requests throughout the product lifecycle. Now, we've grown our department to take on standalone regulatory projects in addition to our work with existing customers.

While regulatory requirements become more stringent and critical at the commercial stage, we make sure to provide guidance early on and over the course of a project to proactively account for considerations that may impact approval down the line. Because we deliver a full-lifecycle perspective, we help our customers make decisions early on that provide tangible cost, efficiency and compliance benefits in the long run.

As part of our regulatory offering, we help our customers with compiling dossiers, clinical trial applications, marketing authorisations and more. We also provide assistance with the submission of regulatory documents in any of our customers' intended markets. Looking ahead, we will continue to expand our department and team as we take on additional standalone regulatory projects.

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What is the role of collaboration in maximising regulatory success?

Cross-departmental collaboration is really important from a regulatory standpoint, because regulatory success requires the cooperation of every role at every level of the company. I am regularly in touch with chemists, project managers, analysts and other team members to make sure I know exactly what regulatory support is needed at each stage in a given project. As these team members are working on the frontlines with the processes and the data, their perspective is integral to compiling complete and accurate regulatory documentation. I have also been working closely with Sterling's global regulatory teams to align best practices, continue to expand our services across the entire organisation and keep up with changing demands. This is a critical part of working together as One Sterling.

Customer collaboration is equally important to regulatory affairs, and I participate in weekly technical meetings with all of our regulatory affairs customers. Some of our customers do not have an internal regulatory department and may be less familiar with how guidelines vary in different parts of the world. It is my responsibility to provide them support and guidance, respond to questions as they arise, replace uncertainty with confidence and ensure that they are meeting all of the necessary requirements. A high level of collaboration with customers, internal teams and APIC has been integral to maximising customer success, as it allows me to gain a deep understanding of customer requirements, project progress and changes in the landscape that may impact our approach.

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