

Nigel Smith

Nigel Smith joined our dedicated bioconjugation facility in Deeside, Wales, in March 2024 to head up the analytical services department. As Head of Analytical Services, Nigel leads the team responsible for the analytical activities on bioconjugates.

Can you describe your background?

After studying biochemistry at university, I went straight into industry working for Lonza Biologics, where I spent six years gaining skills in purification and assay development. Working for a CDMO gave me experience working in the analysis of multiple different recombinant protein therapeutics, giving me a good introduction into analytical sciences.

I then joined UCB working on their PEGylated FAB fragment and antibody pipelines, progressing to lead the analytical method development group. This experience deepened my expertise in analytical sciences, and expanded my knowledge of chemistry manufacturing controls (CMC) and the wider drug development process.

Following this, I held several roles in Ireland including, Abbott Diagnostics and PPD, where I supported multiple monoclonal antibody biosimilar programs. I later joined Sanofi's commercial fill finish facility, leading the analytical team, with responsibility for transferring methods across the global network to support process validation, comparability studies and the routine release and stability testing of monoclonal antibody and medical device products.

I then joined Ipsen as MS&T Analytical Manager, where I was responsible for improving the analytical package for legacy commercial products and supporting global regulatory changes via analytical studies.

I then joined Sterling in March 2024 to head up the analytical services team at our dedicated bioconjugation facility in Deeside, Wales.

What does your role as Head of Analytical Services involve?

I lead the team responsible for the analytical activities on the bioconjugates we make at the Deeside facility. The team develops analytical methods which are used to determine the bioconjugate quality attributes (purity, impurity, drug-antibody ratio, activity etc). Following development, we demonstrate that the methods are fit for their intended purpose and validate them in the GMP lab; ensuring that they are ready for use in release and stability testing activities.



Fast Facts

ROLE

Head of Analytical Services

JOINED

March 2024

EDUCATION

BSc in Biochemistry and Biology | Keele University

We also conduct other studies as part of bioconjugate development, including forced degradation or developability studies, formulation development activities, and clinical 'in-use' studies to determine whether there are any interactions between the bioconjugate and the materials used in a clinical setting (pumps, tubing syringes etc.).

A big part of my role is ensuring that the team are supported in terms of what they need to complete their work e.g. training and equipment, to ensure they can deliver the best service possible to our customers. Having worked for a range of organisations, in a variety of roles spanning the drug lifecycle, I've been able to share my experiences, in terms of industry best practice, with the team.

My past technical experience has helped me in my current role as means that I can help to advise customers on development strategies, and on which analytical techniques will be most suitable for their particular bioconjugate.

How do you and your team effectively collaborate with the other teams at Deeside?

We work closely with the technical services/process development and quality control (QC) teams at the Deeside facility. It's important that we collaborate across departments to ensure that all projects are started and run successfully. For example, as soon as a project comes into the site, technical services ensure that we (the analytical services team) have the materials we need to get a headstart on method development activities, ensuring an efficient and streamlined approach.

We also work closely with QC at the site, to ensure that when we pass the project across to them, the analytical methods are QC ready and fit for their intended purpose to be used in GMP release and stability testing.

How do you and your team effectively collaborate with customers?

Working in partnership with customers is the key to achieving successful outcomes both for the customer and the patients at the end of the journey.

We have a program manager and an analytical technical lead on every project at the site, who act as the main sources of contact for the customer when it comes to overseeing the project and keeping it on track.

Flexibility is key to collaboration too. We have to ensure that we are agile, and able to adapt and pivot as a customer's project progresses.

Can you talk about some of your plans for Sterling's ADC analytical offering?

We are currently expanding at the Deeside site. The investment and expansion in our new analytical services lab will provide us with both increased capacity and technical capability to support even more customers and their projects. We are making investments in new equipment such as HPLC with light scattering capability to provide in depth information on aggregation during developability and formulation development studies. Thanks to this investment, we will also be able to grow our team of experts at the site.

Why do you think our customers chose to work with Sterling?

We have a strong technical team, which is something our customers really value when working with us. We have a deep breadth of experience and have worked with a variety of customers on a range of projects, meaning we understand the challenges customers may be facing, and how we can support in overcoming them to achieve their project goals. Our customers recognise our commitment to their project, and the care we put in to treating their molecule as if it was our own.

What is your favourite thing about working at Sterling?

Working as part of a CDMO means we get to work on a large variety of projects. In my role, I enjoy that I get to stay technically involved with the analytical requirements and challenges of customer projects, and to grow and support my team with their own development.