Daniel Kirschner

Executive Director, Analytical and Biopharmaceutical Services

Durham, NC, USA

HIGHLIGHTS

Ph.D. from the University of Alaska Fairbanks in Bioanalytical Chemistry

Scientific leader with nearly 15 years of pharmaceutical experience (biotech and CDMO)

Experience in all stages of clinical development from pre-IND through to registration

Author of multiple manuscripts in analytical and organic chemistry and holds several patents

Responsible for all aspects of CMC analytical support

SUMMARY

Daniel combines his passion for chemistry with strong leadership and problem-solving skills to progress the development of new drug therapies.

AREAS OF EXPERTISE

- Analytical and organic chemistries leading to method development, validation, transfer, quality control, impurity ID, and trace quantitation supporting CMC programs for drug substances and products
- Experience authoring CMC sections for IND, IMPD, and NDA and routinely participating in audits
- Training programs and SOPs for developing talent in highly regulated environments
- Stability studies, instrument calibration, CRO/CDMO management, and process improvement
- Lean Six Sigma Green Belt

LINKEDIN

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"I love chemistry: Being in the lab and having an opportunity to see and study new molecules every day. I think of chemistry like a puzzle with new pieces getting shuffled into the pile. We're constantly trying to find new ways to solve the puzzle utilizing the core principles of chemistry. That's why I embrace every chance to look at a new chemical process and try to figure out the analytical controls around that process."

What type of solutions and services does your team work on?

We provide full CMC services spanning biologics and small molecules throughout the life cycle of the drug, from early preclinical through commercial. We do method development, method validation, release and stability. We do impurity identification, nitrosamine testing, extractables and leachables. We also provide a massive array of services across the Cambrex sites.

What are some common challenges you tend to see?

We see challenges on a day-to-day basis around our clients' CMC control strategies, and we help them navigate that landscape. We have the expertise to save them time and frustration – and avoid delay. We work in early and late phase, so we see a lot of diverse workflows where a lot of the challenges are defining critical quality attributes. Once you get into the late phase, it's about refining those quality attributes, figuring out if your methods need additional improvements prior to going into commercialization and validation.

Why is analytical excellence so important from the start?

We see it as an important component in early development because you still haven't figured out your critical quality attributes. You still don't know where your baseline is for your drug. As you start developing those critical quality attributes, you need robust methods, even in the early phase, to be able to handle the changes in the methods so you're not constantly redeveloping your analytical methods.

For clients who are still working towards their IND application, it boils down to us having a thorough understanding of their current and future state controls. Usually, clients at this stage of development don't clearly understand their critical quality attributes because they haven't made the drug before. Navigating that with our process chemistry, manufacturing, and analytical teams can be challenging. But we have a solid background in understanding the guidelines, ICH Q3A, B, C, and D. We can clearly help them set their specification strategy and develop a control strategy to get them into the early phases and be able to get into first in human.

From a capability perspective, are there unique ways Cambrex flexes those muscles?

We have the full gamut of analytical testing for biologics and small molecules. We have method development, validation, release and stability. We can provide these services, whether its quantitative NMR, HPLC, or mass spec.

Not only do our labs show well, but they flow really well. We can be efficient in our laboratories, with a diverse amount of equipment that allows us to pivot quickly to different projects. We have the agility our clients need and often don't have internally.

It comes down to excelling in three primary areas: Capability, capacity, and workflow. We really focus our analytical laboratories to be differentiated, and it's a big contributor to our success.

Have you seen significant changes in analytical testing over the past few years?

The introduction of the ICH Q3D requirements, which came out several years ago, changed how we look at elemental impurities using ICP-MS. Recently alkyl boronate, a new class of mutagenic impurities, came up. They're used in Suzuki cross-coupling reactions, which is one of the most fundamental reactions for carbon bond formation, so it impacts a lot of pharma. We've been developing techniques for that. Additionally, the introduction and refinement of new guidelines for nitrosamines has continued to change the control strategy landscape for mutagen analysis. We are seeing a strong growth in this area, both in risk assessment strategies as well as in sensitive MS/MS development and testing.

What is the most time-consuming element of the work you do?

I like to use an analogy. As analytical scientists we like to talk about molecules as having handles, and the handle is something you can hold onto when you look at the molecule, its your tool. It may be a carboxylic acid or an amine or it may be an aromatic group that gives you a a chromaphore. Each handle has a purpose to an analytical scientist.

If a new client is coming to Cambrex and doesn't really know what to expect, what will you tell them?

Having been a client myself, it's critical to build trust from the start. We want our amazing scientists and experts to show in the work that we do. If you ask most of our clients what sets Cambrex apart, they'll probably talk about our scientists, tools and facilities – and there's another factor you can't quite put your finger on. But you know it when you see it.

Do others around you, including clients, feed off your love for chemistry?

Given the work we do, I want them to feel how excited I am about chemistry. I hear it all the time; people sense my passion for the work we do, and it's genuine. I couldn't imagine being in any other field, and I try to spread that energy with my colleagues and clients. Having this attitude is important in leadership roles as I try to set an example for others, maybe earlier in their career, so they can see the potential to truly love what you do.

What's the key to being a truly client-centric CDMO?

Cambrex has a really strong scientific reputation and an even greater reputation for being a trusted, collaborative partner. Across the Cambrex sites, we have project teams aligned to our clients – from beginning to end. We try to minimize team members coming and going. That level of consistency and a track record of success is something our clients depend on and appreciate.

We get to work on the project from start to finish – maybe we only have a small or broader aspect, but we get to develop strong relationships with our clients. That's one reason we have so many repeat clients.

From a leadership perspective, how do you maintain agility in the way you work, always ready to adapt and shift directions?

It starts by eliminating silos. We focus on trying to cross-train our team members to be able to handle an impurity ID, as well as a method validation, or a release or stability testing, so that we can flex to whatever the client needs. We also have an incredibly deep bench of experts in very specific areas, so we're able to tap into that institutional knowledge to find solutions more quickly. I think that's a really differentiating aspect of how Cambrex operates.