TJ Harper

Director of Operations
Longmont, CO, USA

HIGHLIGHTS

Master's in chemistry from the University of North Carolina

15+ years of analytical, risk analysis, method development, and operations experience

Designed and built several laboratory spaces to meet cGMP requirements

Strong client relationships based on trust, open communication, and delivering outcomes

SUMMARY

TJ has a unique combination of analytical chemistry, operations, and client engagement experience. He has a strong track record for delivering results.

AREAS OF EXPERTISE

- Material characterization, including elemental Impurities by Laser Particle Size Determination (LPS), ICP-MS, X-Ray Powder Diffraction, and Thermal Analysis
- Lab Design and Operations

LINKEDIN

TJ Harper

"We live and die by our clients, so we take their programs and requests seriously. We continue to evolve practices based on client feedback and regulatory guidelines to ensure we deliver the best product in the required timelines."

Where does your energy and excitement come from?

I've spent 18 years working in contract pharma, and what inspires me is the challenge of the work and the impact we can make for clients. A client once said, "I don't think this is analytically possible." My response was, "challenge accepted." We subsequently developed and validated a method that exceeded the client's expectations and have worked together for the last eight years.

The complexities are also motivating. It isn't just the interesting science; it is the ancillary situations that go hand in hand with contract pharma. Unreasonable timeline, "let's see if we can make it happen;" historically revisionist client, "let's see if we can get this report back with no comments." Often, the complexities entirely outside of the science can trip up a program, unforgiving timelines often being one of them.

Lastly, regardless of what any scientist might say, we notice if we see a commercially available product that we started working on in Phase 1.

What do you enjoy most about working in contract pharma?

The diversity. Requests and projects change – even with those clients we've had for several years. The variety of what you're going to be doing day to day makes it interesting. It offsets what can be the very tough and complicated world of contract pharma, where you have 15 different clients at any given time needing your attention. They need that attention because we're working with their babies, for lack of a better term. Especially a lot of the small and the virtual clients, they've got one molecule. If they can't make that go the distance, they don't have any other options. It's our mission to provide the material and information to support these clients and hopefully see a molecule progress. Our clients are counting on us, and we know that.

What does your work in material characterization entail?

I've helped establish quality procedures and guidelines to govern cGMP testing and to analyze excipients, Active Pharmaceutical Ingredients (APIs), and drug products. Traditionally, this involves developing and qualifying impurities and identification methods. However, the other aspect the material characterization laboratory is focused on is characterizing these materials. The characterization side covers a wide variety of solid-state style analyses. One day, we might look for sub 1% crystalline content or an undesired polymorphic form by XRPD; the next, we might evaluate a particularly challenging material to determine an *accurate* particle size distribution using either of my LPS systems.

Personally, the most interesting projects are the thermal evaluations. Understanding what occurs when you see a DSC endotherm by combining TGA, PLM, imaging, and XRPD has led to unique observations. You know you are in good company when you have a crowd of scientists watching a video of an API melting. While elemental impurity testing and illustrating compliance with ICH-Q3D, USP <232> / <233>, and EP 2.4.20 is not the hot topic in the industry it used to be, we still develop and validate multiple methods a month to meet regulatory expectations. After 15 years of supporting these guidances and having two identical ICP-MS instruments, we have this down to an art from an execution and compliance stance.

After working with hundreds of different materials, there isn't much we haven't seen or figured out a solution to. The scars are real, though. I have spent many nights in my career staring at data and wondering why I couldn't get an acceptable recovery. For my colleagues, don't look for ^{44}Ca in a solution of ^{88}Sr. The double-charge pain is real. In all seriousness, the struggles and setbacks that

every contract pharma chemist experiences are what makes us good. We have just seen a lot. The trick is getting us to admit there was ever a time we didn't have all the answers.

This experience makes us tremendous consultants. We can provide regulatory guidance or help with risk assessments. Still, the real value is that when the unexpected happens, the odds are pretty good that we have seen something similar and can resolve the issue quickly.

How do you use time to your advantage?

Time is paramount, especially when you're looking at INDs. Many of these companies are smaller or virtual and are limited in funding. So, your next round of funding that will come down the road will depend on them hitting certain milestones. These milestones are frequently very short, with unforgiving timelines. In a post-COVID world, clinic times are fixed. If you miss your clinical trial window, you could be six to eight months out before you get the next one. That delay could put some clients in a precarious financial situation. The benefit of us is that we can do things faster than our competitors.

What makes the site in Longmont, CO, so unique?

Longmont has full IND services literally under one roof. We can go straight from the preclinical development of salt screening and polymorph monitoring to process chemistry and drug substance manufacturing, then straight into formulation development and manufacturing the drug product. This includes all of the necessary analytical and stability support along the way. Since we are all in one location, several different activities can be executed concurrently instead of a more stepwise approach that comes with having to piecemeal a program together using multiple organizations. The more steps in the process, the longer the timeline. Many companies say they can offer an integrated offering but may use multiple sites. We measure the distances between all these departments in feet, not miles. The furthest department from one to the other is 600 feet.

What's a key benefit of working within a tightly knit community?

Even after doing this for 18 years, I run into walls, and it's just helpful to talk to my managers or analysts and say, "Alright, I need someone to bounce ideas off of. What do you think I'm missing? What could solve this?" And we've solved some complicated problems through ad hoc conversations in the hallway. That's not only within my department but all the departments, especially when looking at some of those issues involved in process chemistry or manufacturing. Someone can comment in the hallway, and the right person happens to hear it and says, "Wait, no, I saw this when I was doing the development. I can tell you what's going on." This is how we can make the data-driven decision to solve problems in two days versus two months.

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

We'll be able to cover you on almost all your bases. Amongst our directors alone, we've got nearly a hundred years of experience. That experience is diverse as

well. Some come from exclusive contract pharma backgrounds, and others from large pharma. That diverse background, coupled with our people, the capabilities of our facility, and the ability to provide pre-formulation, analytical, process chemistry research, drug substance, and product manufacturing, and all the ancillary departments that support those, including material characterization, we can get you where you need to be to hit your next milestone and start that next phase of development for your program.

How does the Cambrex culture impact clients?

We have a vested interest in our client's success—and our team will collectively go that extra mile to try and get them there. Cambrex can help clients through all the phases of development. We take our clients through phases one and two at Longmont to get the early phase work done, and then we can transfer it to High Point to do late-phase manufacturing. At this point, you're lucky. Most molecules don't go that far. But you can stay within Cambrex and go to Charles City for the commercial phase manufacturing. In the US alone, multiple Cambrex sites can carry you all the way through. We aim to build strong relationships from the get-go so that the journey with our clients is positive and collaborative.