



Christopher McGee, PhD
Director, Analytical Services at Solvias USA

Meet Our Expert: Christopher McGee

In this brand-new *Meet Our Experts* series, you will get the chance to meet our talented colleagues based in Switzerland, France and the US that are driving Solvias' success. In this interview, Christopher McGee (Director, Analytical Services at Solvias USA) describes the early days at Chemic Lab, revisits some of his team's biggest achievements, reveals the impact of joining the Solvias Group and paints an honest picture of the workplace culture!

Can you tell us about your childhood and what piqued your interest in science?

I grew up in a small town in the state of Rhode Island in the United States. In high school, we had the opportunity to take a chemistry class. It was "old school" with Bunsen burners, flame tests, and color changes, but to me, it felt like some neat type of magic! That experience really started my journey in chemistry.

I went on to study math and chemistry as an undergraduate at Providence College and as part of an internship, had the opportunity to perform environment testing in a commercial laboratory. After graduation, I joined that lab full-time and learned a lot about organic chemistry, including sample preparation and sample extraction. That was my real introduction to analytical chemistry and where I got my first start with chromatography, both gas and liquid phases.

Was the path towards attaining a PhD degree already drawn out for you?

After a year in industry, I felt that I needed to expand my knowledge. That's when I joined the team at Syracuse University in upstate New

York and began my PhD journey in chemistry. It was a great learning experience. I think the number one thing you learn in grad school is how to teach yourself. You learn how to conduct research and how to think independently. At Syracuse, I started in organic synthesis and worked on some different synthetic schemes such as stable isotope labelling. My research focused on carbon-13 labeled materials that would be beneficial for generating nucleotides, to then "string" them together and make a variety of DNA strands. The plan was to make a lot of biophysical measurements via carbon-13 and proton 2D-NMR to determine what the structure would look like. What's interesting when looking at nucleic acids in solution, is that they can almost "breathe" and bend, almost like a ribcage and a set of lungs that expand and contract, but the timescale is so small! So being able to record that motion and studying those interactions [between the nucleotides] was a very interesting use of analytical chemistry!

After grad school, what did you embark on?

After my PhD, I took another job in environmental chemistry by joining Premier Laboratory in the state of Connecticut. We

performed a lot of drinking water and wastewater analysis and all of the associated environmental testing for towns and cities in states throughout New England and New York, including Massachusetts, and Rhode Island, and Connecticut. That experience exposed me to a lot of analytical techniques in a wide variety of areas as well as differing regulatory guidances. After 5 years, starting as a Chemist in mass spectrometry and working my way up to Technical Director, I felt that it was time for a new adventure. So, I decided to make the leap to pharmaceuticals.

What motivated you to join Solvias USA LLC (formerly Chemic Laboratories, Inc.)?

I first joined as a chemist in CMC and QC chemistry. My previous work experience made it a natural transition since a lot of the concepts are the same. What's interesting to realize is that mass spectrometry was starting to become popular at that time, thanks to its ability to yield more specific information. So, we moved away from more traditional detectors, such as the flame ionization detector (FID), electron capture detector (ECD), or the photoionization detector (PID). And things got even more interesting as they got more complicated! *Over the years, I took on additional responsibilities and that got me into extractables and leachables (E&L), which is really what our main focus at Solvias USA is today. We've not only become subject matter experts, but leaders in the field of E&L, particularly in the OINDP (orally inhaled and nasal drug product) space.* Historically, OINDPs were the biggest focus of E&L. A lot of that has to do with the idea that the container closure system or the part of the device that's delivering the drug product is typically intricate. There's a lot of different pieces that go into, for instance a nasal spray pump or pMDI (pressurized metered dose

inhaler) valve. There are gaskets that are made of various elastomeric material (rubbers), and there's a lot of different polymeric pieces (plastics) that make up these devices. And each one of them now is being exposed to the drug product. Therefore, the question is whether those materials can release an impurity or an "adulterant" into your drug product. So, given that the route of administration is usually through the nasal cavity or directly into the oral cavity, intended for the lungs, you're essentially introducing potentially unwanted or even toxic compounds. So, it really is a story of a search for impurities and we're always looking for traces of organic impurities and detecting something at very low levels.

What did the early days at Chemic Lab look like and can you share some milestones you're most proud of?

When I started, we were looking to become experts in the field of chromatography and were expanding into mass spectrometry. In the area of extractables and leachables, there wasn't a lot being done with unknown identification. It was really more of a targeted-type of analysis. If you could work with your manufacturers and suppliers to find out what additive or agent they were using in their material then you knew what to look for and could potentially design a method to track it. Almost like generating a "fingerprint", you had a pattern from chromatography but didn't necessarily know what all the peaks were, where they came from, their concentration or even what their actual identities were. So that's where mass spec expansion became necessary.

I was fortunate enough to help the team reach the conclusion that we needed more sophisticated instrumentation. Therefore, we were able to bring in our first time-of-flight mass spec and that really was our

introduction into high resolution, accurate mass. Having access to these newer tools gave us a better opportunity to determine a molecular formula more precisely for our customers' unknown compounds. Then once you have your choices of molecular formulas, you can then work on your structural elucidation, and hopefully solve the "puzzle." That's what we do when we're working with impurities, we're trying to figure out what the impurity is.

With initially a small team of about 50 people in Canton, just outside of Boston, MA, we're definitely proud to have been able to introduce that technology and help our customers even further.

What was the impact on Chemic Lab after joining the Solvias Group?

We've been under the Solvias family now for a little over two years. The acquisition allowed us to collaborate with even more scientists and experts and gave us access to even more techniques and instrumentation. In fact, Solvias encouraged us to expand our capabilities in high resolution accurate mass spectrometry. *With their help and guidance, we've been able to expand our department from our original time-of-flight instrumentation to include two new orbitrap-based mass spec instruments. So now, we have the capability of making high resolution accurate mass measurements utilizing both liquid chromatography and gas chromatography for volatile, semi-volatile, and non-volatile type compounds.* From a market perspective, the potential for growth in our work area is enormous. *We are very excited to be part of the Solvias group and are truly honored to be their first US site.*

Can you elaborate on your role and responsibilities at Solvias USA?

As the Director of Analytical Services, I am responsible for the analytical laboratory and chemistry staff. All of the chemistry staff performing the scientific testing and analysis act as one team. *We not only operate in the area of E&L but we do also offer CMC and QC services. We provide support to manufacturing from early R&D through the various phases of clinical supplies.* We are essentially trying to become a full-service laboratory so if there's something that we can't perform in-house, we are blessed to be able to reach out to our colleagues across the ocean for support. *Solvias AG can support us with additional techniques and expertise regardless of the project. So, it really makes the Solvias family a one stop-shop for all of your analytical needs.*

What differentiates Solvias from its competitors?

I would say it's the personal touch. *We pride ourselves in being not just a service provider, but a partner. Giving our sponsors access - during regular conference calls for instance- to our scientific experts is a great value I find. It's this "free" consultation that sets us apart from a typical sales approach, because we're really involved and do care about our sponsors' success. Their success is our success!*

Are there any exciting news and/or developments you'd like to share?

If we take the example of the cell and gene therapy (C>) field, an up-and-coming promise of biopharma, one aspect of that is to find out how E&L comes into the process. In fact, when you start talking with the scientists

operating at the bench scale, there's not always a lot of thought given to the equipment that they're using (e.g., single-use systems and/or disposable materials). And again, just like the container closure system, you're talking about polymeric materials coming into contact - in this case – with C> materials. So, the question of E&L has to be considered particularly in the disposable space. *My colleague and I are going to speak on a [webinar](#) in December to discuss the application of E&L to single use technology, and why that is important for those in the CGT space.*

How would you describe the work environment?

It really is a team environment. Everyone here is not afraid to share what they've learned in the past, the challenges, admit their mistakes and grow from them. As a CDMO/CRO company, we have the opportunity to work on dozens and dozens of drug products or drug substances in any typical year. That's what makes our job so interesting and fulfilling.

Another thing is, constantly learning and really learning how to learn. Because you never know everything, it's important to always try and learn something new every day. And I think we've set out to accomplish that whether it's technology, science, or molecule behavior-wise. In our case, hunting for unknowns, gives us the opportunity to learn every day. We also pride ourselves in developing young talent. My staff is fairly young and a lot of them joined us right out of college. Be it after their bachelor's, master's or PhD degrees. They come to Solvias USA and they have the opportunity to learn about the pharmaceutical drug development, about chromatography, about the use of different analytical chemistry techniques, etc. We have and continue to help train young chemists. And

if they decide to start a new chapter elsewhere, they usually end up getting hired by large pharmaceutical companies, after having their initial foundation built here at Solvias. But really, what is most important to us, is that we participate in helping ensure the safety of pharmaceuticals every day. You never really know if the project you're struggling with today might help your loved ones in the future.

Outside of work, do you have any hobbies that you enjoy pursuing?

Sure! My fiancé and I are active in fostering rescued dogs. So, we're big on the idea of training new puppies. Playing with puppies is a great stress reliever! In addition to that, I'm an avid American football fan! So those activities consume a lot of my free time. I never considered playing or coaching football professionally, but I am a life-long season ticket member of the New England Patriots, our local American football team. Go Pats!