Meet Our Expert: Andreas Hohenleutner

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, Andreas opens up about his childhood, gives a first-hand account of his responsibilities, shares invaluable tips regarding best practices for manufacturers, and weighs in on what sets Solvias apart from other service providers!

Can you tell us a little bit about yourself?

I'm originally from Germany and grew up in Regensburg, which is about 100 kilometers from Munich. I'm a typical Bavarian, some might say! I had a good and normal upbringing. My parents are both medical doctors and would explain things or present information without oversimplifying excessively. This approach really fostered a scientific curiosity within me, a trait that I continued to carry through my academic journey from school to university.

Why I ended up choosing chemistry is a bit of a funny story! In truth, I was a lazy student during my school days [laughs]. At some point, however, it wasn't enough to get by and I ended up getting a bad mark. My chemistry teacher then wrote a letter to my parents, to express her concern because she knew I could do better. I was so embarrassed! This caused me to pay more attention during classes and I realized chemistry is a fascinating field. This shift in my study habits together with having excellent teachers really deepened my interest in the sciences.

Your interest in the subject drove you to pursue a PhD! Could you share insights into your academic experiences and journey in the field of chemistry?

At school, I chose chemistry for my A-levels and continued to major in the subject at university. During my bachelor and master's, I had the chance to study a semester abroad. I went to Thailand, at Chulalongkorn University in Bangkok, for my bachelor thesis, and to Bangalore India for my master thesis. These experiences were truly the highlights of my studies and piqued my curiosity for other cultures. Honestly, I'm a big fan of Asia!

My PhD thesis focused on the interface between physical organic chemistry and analytical chemistry. More specifically, I was working on organic light emitting diodes, synthesized combinatorial libraries, and screened them using liquid chromatography-mass spectrometry (LC-MS).

What motivated you to transition to industry and how did Solvias come into the picture?

Initially, I wanted to become a researcher. I never thought I would end up in management. It just kind of happened by chance! [laughs] During my graduate studies I had the opportunity to supervise a lot of interns from all over the world.

Teaching is something I very much enjoy. You could say that it was my first exposure to people management! ***Over time, I realized that, as much as I love science, I also really enjoy working with people and seeing them grow.***

Typically, the important decision you have to make after your PhD is whether to stay in academia or crossover to industry. During my PhD, I was working on an industry collaboration and that allowed me to gain a first insight into how the commercial world works. I ended up liking this applied side of research. My first job was at a CRO called Harlan Laboratories in Switzerland. Following an acquisition, the company went through a re-organization phase, and the management had decided to shut down their Swiss location. As a result, I had to look for a new opportunity. ***During my interview at Solvias, what really impressed me as a young scientist was the depth of their portfolio and the access to state-of-the-art instrumentation. Knowing that Solvias can do almost everything you can think of in analytical CMC, motivated me to join the organization. I knew that joining the team would allow me to continue broadening my expertise by working with a great team of experts and a large variety of customers and pharmaceutical products.***

How did your responsibilities evolve over the years?

I started as a Project Leader. Back then, the associated responsibilities were somewhat different than what you'd expect for such a role today. I started at the interface between the customer, the lab, quality and the results. Essentially, I was our customers' point of contact, and my job was to articulate/clarify their needs, provide input for quotations as well as review and communicate results. I would also troubleshoot experiments with the labs and process quality events. In hindsight, I think it was a good starting point because you see firsthand a lot of the value chain, starting from the customer request to data generation and finally, circling back to the customer with the results. I then got the chance to take on different roles of increasing responsibility and eventually became Head of Operations for Characterization and Device Services, which is the position I currently hold.

Can you elaborate on your current role?

I am leading Characterization and Device Services where I am fortunate to work with great experts in Pharmaceutical Materials Science, Drug product and delivery systems characterization, and Impurity profiling across two of our locations (Kaiseraugst, CH and Canton, US). Our work ranges from drug substance (APIs) characterization and development to supporting the development of drug products including complex delivery systems and combination products.

These products can be parenteral (such as prefilled syringes for example), oral or other dosage forms. We also have a dedicated group that characterizes and tests OINDPs (orally inhaled and nasal drug products). The aerodynamic performance characteristics of these delivery systems dictate the efficiency and reproducibility with which an aerosol is administered clinically and are absolutely critical for inhalation devices.

Another important topic across different dosage forms and modalities is Extractables and Leachables (E&L) testing.

Can you expand on the role of E&L in ensuring the safety of pharmaceutical products?

E&L studies are a crucial step of drug product development, especially for parenteral, ophthalmic, and orally and inhaled nasal (OINDP) drug products. The goal is to identify and quantify contaminants that may originate from manufacturing, packaging, and drug delivery systems and assess them for toxicological concern. This is critical, because if unwanted compounds leach into your drug product it can adulterate its safety profile.

The first step consists of studying what can be extracted from the packaging/delivery system under laboratory conditions and represents typically an exaggerated or worst-case scenario. This serves to learn about the system and form the basis for design and targets of the leachables assessment. In this second step, you will look at what entities are really present in a packaged drug product because they have leached into the packaged drug product from the packaging/delivery system or manufacturing components under normal conditions of manufacturing, use or storage. ***The whole point is to ensure and demonstrate that there is no negative impact from these leachables on the safety or efficacy of the drug.***

In your interactions with manufacturers, have you pinpointed gaps in awareness, commonly overlooked considerations, or prevalent mistakes in E&L testing?

Most of the people working in our industry and in analytical CMC are aware of the importance and the need for E&L testing. However, in my opinion, many start too late, which can become a real hold up for [regulatory] submission. Such outcome will ultimately delay your time to market and bears significant financial implications for your company…

Although it's a definitive requirement for filing by the authorities, a proper E&L program does take time. Having said that, regulatory requirements and expectations are also constantly changing and evolving. They always get stricter, never the other way around [laughs]. As a result, it can be quite a complex landscape to navigate - especially as current official guidance does often not fully reflect those latest regulatory expectations. If you don't stay on top of the latest requirements and best practices, this can cause significant rework or even major delays on your path to approval.

What would be your best advice to potential customers?

My advice would be to (1) start early and (2) do it right the first time. Make sure you work with the right partner that can help you navigate the scientific and regulatory challenges and has the technical capabilities, expertise, and track record. We unfortunately see a lot of customers that have been burned by working with laboratories that offer "cheap, standard E&L packages" that ultimately fall short of regulatory expectations… ***By starting early, and working with the right experts, you'll de-risk the process and can make sure E&L stays off the critical path throughout your drug development journey. Making sure that you get to the finish line and avoiding common pitfalls along the way is something our experts at Solvias can really support you with.***

What other steps does Solvias take to emphasize the importance of early engagement?

We've recently established a global initiative called Science & Technology Management backed and led by Executive committee members. I think this shows how central

scientific expertise and excellence is to our company. One of the goals is to educate and share our accumulated knowledge internally and externally with the scientific community. We are dedicating some of our experts' time to scientific outreach, and to proactively educate customers on crucial topics for their drug development journey.

What makes Solvias unique as an analytical CMC partner?

Our experts at Solvias truly act as partners. That's really what we want to be for our customers. Many customers seek our advice, expertise, and experience to provide them with guidance on the right approach.

We do our best to connect early on and address their specific pain points by involving Subject matter experts right away – often at the very beginning of conversations about a potential project. Building on this early collaboration we can then help guide the development of appropriate testing and control strategies. ***When crafting study designs for our customers, our focus is on delivering high-quality data and providing compelling evidence, to convince regulators that we've diligently identified potential risks to safety or efficacy of the products and have made sure these are under control.***

What do you enjoy most about working here?

For me, it's the people and the culture. It's a very stimulating working environment with a lot of growth opportunities. It's something I can say not just from personal experience but also, seeing it happen with colleagues and team members. What I also really enjoy at Solvias is the breadth of our service portfolio. As a scientist, it's a very rewarding place to start out and further your career because you gain a lot of experience. Unlike at other companies where you might focus on a few molecules, at Solvias, we work on 30 to 60 different molecules and various modalities! We also see a large variety of delivery platforms and so on. For curious, motivated people and those who like to be challenged, I think it's a great environment. Another element, I'd say, is the impact of our day-to-day activities. That is, being able to perform meaningful work that has the potential to transform patients' lives. On the "flip side" of the coin, because of the fast and highly dynamic environment, some might find it demanding. Nonetheless, being able to accompany our customers throughout their drug development journey is exciting. And it's rewarding when you see that the projects you've been working on make it to market and positively impact patients' lives. Solvias is also rapidly growing, with several acquisitions and internal organic growth, creating exciting opportunities.

Outside work, do you have any hobbies?

I have a three-and-a-half-year-old son and he's my hobby! Whenever I'm not working, I try to spend time with my family. I also have a number of personal interests. I love reading and cooking all kinds of cuisines. Be it Thai, Chinese, Indian, or Italian food. I think it's something that comes equally from our multicultural family and my dad. He's a great cook and my parents have traveled a lot. Still do! After every trip, they'd always bring back new recipes and would try to replicate something they tasted. I also enjoy outdoor activities. I love sailing, skiing and being in the mountains!