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Bioanalysis

Meet the Editorial Board – an interview with Min Meng and transitions from small regional labs to global CRO

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Min Meng received her PhD in biomedicinal chemistry from the School of Pharmacy, University of Maryland, in 1996. From 1996 to 1998, Meng was a postdoctoral fellow at the American Health Foundation, focusing on the carcinogenic toxicity of tobacco smoke using various chromatographic technologies such as LC-UV, GC-MS/MS and LC–MS/MS. From 1998 to 2017, Meng worked for Tandem Labs/LabCorp/Covance, a bioanalytical contract research organization (CRO), holding various positions from scientist to lab director and technical director. In 2017, Meng moved back to her hometown and set up a bioanalytical CRO, Denali Medpharma, Chongqing, China. In October 2023, Denali was acquired by Resolian Bioanalytics, a global bioanalytical CRO. Currently, Dr Meng is the chief scientific officer and president of the Asia Pacific region for Resolian Bioanalytics.

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Jack: Could you please provide an introduction to yourself for the readers?

Thanks for arranging this interview with me. It is a great honor. I started my industry career in a startup bioanalytical contract research organization (CRO) in Salt Lake City, Utah, USA, more than 25 years ago. At that time, it was named Northwest Bioanalytical and later it was renamed Tandem Labs. Tandem was acquired by LabCorp in 2008. A few years later, LabCorp acquired Covance, and Tandem Labs moved under the Covance umbrella. While all of these company names may sound very confusing, to keep the record straight, I have worked for the same company for 20 years. The primary difference is that my responsibilities and titles grew while the company grew. I must be an outlier, for I read that the average [tenure] is 7 years for Americans before changing jobs during their professional career. In 2017, due to family reasons, I decided to move back to China to set up my own bioanalytical lab, Denali Medpharma. I have been the CEO and cofounder for the company during past 6 years. This month, Denali was acquired by Resolian (formerly known as Alliance Pharma, PA, USA). After the acquisition, Denali will become its China lab along with the other Resolian labs in Australia, US and UK and will provide biaoanalysis services to pharma and biotech companies globally. As for myself, I will continue working for the company with my new title and responsibilities.

Jack: Could you share some of the experiences & achievements in your career?

There are three distinct periods or phases for my career so far. One is 20 years at Tandem Labs/Covance. The second is 6 years with Denali. I am looking forward to the third phase with Resolian. During the first period, I was initially a scientist and grew into a laboratory and personnel manager. For the second one, I became a start-up entrepreneur, the third one is an executive for a global company. Each period brought new experiences and challenges for me.

My years with Tandem really shaped me in many ways. It is quite profound, and is my longest tenure. When I joined Tandem Labs it had only twelve employees. This was my first industry position. As a new research scientist, I had to do everything myself, including changing rough pump oil and CEM [channel electron multiplier] for the mass spectrometers. I also learned a lot about GLP [good laboratory practice] and regulated bioanalysis. I like to work on method development and found myself very good at it. It has become my lifetime passion or hobby even up to now. Over the years, I always joke that I am a 'blue collar lab director' or 'blue collar CEO', for even as lab director for Tandem/Covance or CEO of Denali, I always came back to the lab in the evenings or weekends

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working on challenging methods or troubleshooting an assay. I enjoy spending weekends in the lab surrounded by any available instrument and slowly figuring out the method. The most recent method I developed in our lab was a LC–MS/MS method simultaneously quantifying the inhalation drugs fluticasone, indacaterol and glycopyrrolate at 1 pg/ml for each analyte. It feels really good when I can successfully develop an extremely challenging assay. I also believe that a great bioanalytical method development scientist needs to be both a scientist and artist. First to tackle the scientific issue of the assay, then to make it as simple and smooth as possible so an entry-level scientist can execute the method flawlessly.

Retrospectively, there are several memorable events and topics worth sharing here. One is to identify phospholipids as a key matrix effect component. The time goes back to 2002 when I was just a senior scientist and Pat Bennett was lab director in our lab. During that time, we often found that our method was not robust from run to run, and it would fail randomly for one analyte but not others. We knew something in the matrix was affecting our data but did not know what caused it. Thus, we decided to figure it out. After Q1 full scan and fragmentation search using PPE (protein precipitation extraction), we found that all of them generated 184 *m/z*. Initially we did not know what this meant other than it was a class of molecules versus a single molecule. We searched online and determined these were phospholipids. We performed a lot of additional experiments, including ways to deal with this. The solutions ranged from changing how we ran our LC programs, forward or backflushing columns or removal prior to extraction. We published our finding in the 2003 AAPS [American Association of Pharmaceutical Scientists] as a poster and made an SPE [solid-phase extraction] plate called 'Blue Sky' specifically to remove phospholipids and later licensed it to Waters. Although we were the first group that identified phospholipids as the major matrix effect contributor, we did not get too much academic recognition, for it was only an industry conference poster. I wish we had published it in a peer-reviewed journal like yours. Well, still, I feel good having participated in this endeavor and how much it has helped the thousands of bioanalytical scientists when they developed their own method later.

The second one is about the creation and implementation of a systematic approach for method development [the program is nicknamed as 'Amoeba Program', published in *Bioanalysis*, 2013 Jan;5(1):91–115. doi: 10.4155/bio.12.295]. When we developed this program, I was managing a team of PhD method development scientists in our lab. They are smart and talented and from various academic and industry backgrounds. We found that these scientists developed methods based totally on their own previous experience and personal preference. The inventory for LC columns, mobile phases, solvents and reagents became out of control. We realized that this can be very costly and error prone for a GLP bioanalytical lab. Therefore, we decided to streamline our method development process. We decided to meet during lunchtime, brainstorm ideas and identify our favorite solvents, column and LC–MS conditions. Finally, each of us voluntarily wrote protocols and created specialized forms to track the method development. The finalized Amoeba Program utilizes significantly fewer variables in the lab and dramatically shortened the time for method development. Someone may argue how can you standardize the method if each compound is structurally different. We also had these doubts until we saw the success of the Amoeba Program with our own eyes. Not only did it streamline the method development progress, allowing quick method development and simplified lab inventory, it also became a great training tool for new scientists.

One additional item which I have a long track record for and is consistent throughout my whole career is that I like to write papers and posters. While leading the Tandem/Covance MD team, we published many posters for ASMS [American Society for Mass Spectrometry], AAPS and WRIB [Workshops on Recent Issues in Bioanalysis] meetings each year. I also wrote research papers with our pharma clients. At Denali, during the past 6 years, we published five research papers with both Chinese and international clients. This is not driven for my personal fame or gain. I typically must write these during my personal time. It is because of my passion for research, the scientific mind and curiosity and the belief of having a greater impact by sharing our knowledge and findings in the scientific community. Additionally, as a mentor to many young scientists who worked with me, it is also my way to help them so they can be rewarded and recognized for their hard work and is of great benefit for their future career. Everywhere I go, from Tandem/Covance to Denali, I brought this tradition with me. I expect that I will do the same at Resolian.

Jack: How about being an entrepreneur. Your lesson & experience?

This is a big change. Looking back, I did not know where I gathered the courage. In China, there is a saying: 'The ignorant are fearless'. That was exactly me at the time. Two facts. First, I had very little knowledge about finance, such as EBITDA [earnings before interest, taxes, depreciation and amortization], cash flow and balance sheets, etc. Second, I had left China 25 years earlier, and my entire professional training was rooted in the US and Western

style of business. During my time in the US, this was also the period in which China had grown and changed exponentially. Other than I can speak Chinese, I truly did not know the new culture, the business environment and the regulatory requirement and had no connection with local pharma clients. Fortunately, I had great support from former colleagues and friends. Some moved back to China with me. Some introduced customers to us. Once we settled down and the lab was built, I started to go out to find customers but also found that there are hundreds of bioanalytical labs in China and nobody knew who we were. I know there is a point of no return, and we had to fight through to win the battle. In the beginning, I was on the road a lot, literately knocking on the doors of many companies where I didn't know anyone. In addition to these cold visits, I also joined conferences as much as possible and wrote self-recommendation letters to the meeting organizers so I can speak at the podium. We started with small and difficult projects. Eventually, the business started to take off. Currently, we are known in China for challenging assay or modalities such as liposomal or lipid-based formulations, inhalation drugs, oligonucleotides, peptides and biologics, and mRNA vaccines.

There are many challenges to run a bioanalytical CRO business in China. Here I would like to share the two most important lessons I have learnt so far and maybe interest to our audience. The first one is the regulatory requirement in China. I was involved in US FDA inspections previously and was confident in how to conduct GLP studies in the US. I was surprised that this past experience was actually not enough. The standard is definitely higher and more stringent, which results in more documentation or redundant resources as well. For example, when sample accessioning sample in a LIMS system, it is not acceptable to add a checkmark to indicate that the sample accessioning process was performed on dry ice. Instead, we needed to set up a camera aimed at the dry ice box and record the entire procedure. We also needed to have two people for accession samples, one to scan the barcode and the second to verify and monitor the scanning process. Also, blank matrix is not allowed to be purchased from a vendor. We must obtain it from a clinical center. Basically, the process is treated as a clinical trial minus dosing a drug. We need to have contracts, clinical protocols and IRB [institutional review board] approvals. For the usage of blank matrix, we need to track the volume used so the auditor can confirm that the volume used matches the volume collected. Initially I was reluctant and felt it was unreasonable. Now I am used to it and feel it does make our operation better in general. During the last 6 years, especially the last 4 years, we had 21 NMPA [National Medical Products Administration] inspections, and most of them are for bioequivalence studies.

The second lesson is about business. Once we became profitable and known in China, many people from the financial sector approached us and showed their interest in us. Some were clinical CRO or GLP centers that want to add an analytical lab to their company. Others were just pure financial investors. Some even wanted me to develop new drugs. Regardless, their goals were to quickly grow the business, to become a public company and earn money from the stock market. Even if they painted a great picture, I felt that their motivation was for money or financial gain. They did not persuade me; rather, I am even more focused and know exactly what I want. I have spent my whole professional life in bioanalysis service. This is the only thing I am passionate about and am good at it. All I want to do is to use my skills to help pharma clients in their endeavor for new drug development. Money is important but never the first priority in my career. That is why I held one job for 20 years. I always believe that if we chase money, we may get nothing. But if we are patient and have passion, keep learning and do what we are good at, money will find its way to us. My career is true testimony in this regard.

Jack: What are some ideas you have for the journal?

The *Journal of Bioanalysis* is like a home journal for me. I have been on the editorial board for many years. I have also published many articles in it, ranging from commentaries, editorials, research papers, etc. I regularly read the search article from the journal and try to repeat some methodology in our lab as well. I specifically like the WRIB or EBF [European Bioanalysis Forum] white papers in the journal. In our company, we even organize our team members to study these together. It always generates a lot of interesting ideas. Sometimes, these have resulted in revisions of our SOP [standard operating procedures] or new procedures. Interestingly, I have used them many times to address questions from NMPA auditors during inspections. At those moments, I am very thankful for your journal and the authors of these white papers. You have literally spared us from an unnecessary regulatory finding.

Jack: What are your perspectives on the importance of the journal to the community

The *Journal of Bioanalysis* is very important to our community. I believe that sharing knowledge and reaching consensus in our industry is important. The *Journal of Bioanalysis* provides the platform for the scientist or researcher to publish the latest scientific findings; for regulatory professionals to voice their opinions so our practice

is sound and less risky, thus ensuring a better drug product; and for community and association leaders such as WRIB, EBF, CBF [Chinese Bioanalysis Forum], GBC [Global Bioanalysis Consortium], etc., to publish their survey and promote best practice globally.

Jack: What is your opinion on the future of the bioanalytical industry?

Throughout the [process of] new drug development, bioanalysis is important yet plays a supporting role. Bioanalytical data are crucial for the determination of a new drug candidate that can be moved to the next milestone or not. During my career, the bar for regulated bioanalysis has grown higher and higher. For example, I personally went through an ever-evolving process for the introduction of the ISR [incurred sample reanalysis] to a mandatory practice. I still remember how we were reluctant to adapt to the ISR requirement back in 2008. Now I must admit that this is the one of the best practice and regulatory requirement in bioanalysis. I am also glad that we finally only need to follow one unified guideline, the ICH M10, regardless of which country we reside in or have filed for approval.

Bioanalysis is also highly technology dependent. As a bioanalytical scientist, we are limited by the availability of the instrument within our company. For example, I have developed tiotropium LC–MS/MS assay four times. Every time we have a more sensitive MS, we revamp the method and validate it again, with the LLOQ [lower limit of quantitation] from 1 pg/ml, 0.5 ng/ml, 0.2 pg/ml to 0.1 pg/ml, respectively.

Previously, because formulations were rather simple, we only needed to develop a method for the quantitation of the active drug. A little bit more complicated case is a combo assay including prodrug or metabolite. Nowadays, many new modalities have emerged, and bioanalytical methods became more and more complicated. For example, for liposomal formulations, not only do we need to measure total drug, but we also need to measure free and encapsulated drug. We recently got involved in the bioanalysis of LNP [lipid nanoparticle]-mRNA. This project needed the collaboration of both small and large molecule teams in which the small molecule teams focus on the bioanalysis of cationic lipid and PEGlated lipid using LC–MS/MS and the large molecule team analyze mRNA using qPCR. For oligonucleotide drugs, we set up multiple platforms ranging from LC-UV, LC–MS/MS, LC-HRMS, LC-FD, LBA and qPCR depending on the stage of the drug development. It seems there is no single technology that can dominate or fulfill all our needs. This presents great challenge as well as the opportunity for a bioanalytical scientist.

Jack: Could you please describe your experience at CBF & any interesting points you would like to share with the journal audience?

I am the scientific advisory member of the CBF. Since moving back to China, I participated in every annual CBF meeting except 2020–21 during the COVID-19 outbreak. In 2023, we had our annual meeting in Suzhou, 9 to 11 June 2023. Nearly a thousand participants joined the meeting. In my opinion, this meeting is the one of the best bioanalytical meetings in China. It is also my favorite meeting too. Traditionally, academic researchers or scholars have more influential status in Chinese society. This is the same in the view of the Chinese regulatory agent. CBF is trying to break the barrier and bias and let pharmaceutical scientists voices out. Also, because a lot of the scientific advisory members are from the US or other countries, we can invite US pharma or CRO speakers to give talks onsite or online. One of the best features of this meeting is that there are workshops and youth scientific forums. The former is specifically for newcomers. The latter allows young scientists to have a podium opportunity.

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The authors have no competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, stock ownership or options and expert testimony.

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