

Meet
Dr. Mandy Xu

DMPK Studies for
R&D Efficiency

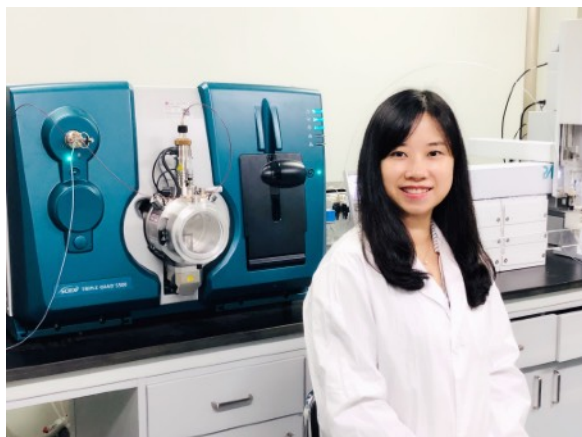
Chemistry
Innovation

Roche Green Chemistry
Partner Award

Integrated DMPK
Service Platform



Meet Dr. Mandy Xu



This past March, Dr. Mandy Xu, Vice President of DMPK, celebrated her ten-year anniversary with Pharmaron. It's a milestone that not only recognizes one of Pharmaron's many home-grown leaders, but it also marks ten years since Pharmaron launched its DMPK services platform. These two anniversaries are not a coincidence—Mandy was hired to launch *in vitro* ADMET services at Pharmaron.

Now, ten years later both Mandy and her team continue to thrive. Since her first day at Pharmaron, Mandy has stayed focused. The tasks have changed over the years, but the end goal has remained the same, which is to provide efficient and high quality *in vitro* ADMET services to our partners. In her first year, she built a state-of-the-art lab, hired scientists and validated over 50 assays.

These days she leads a large research team working in *in vitro* ADMET that provide services for solution properties, drug absorption/transport, drug metabolism, drug-drug interactions and safety screening. Her scientists deliver high quality *in vitro* ADMET data to collaborators in biotech, pharmaceutical companies and academic institutions worldwide. Projects range from early drug discovery supporting PCC nomination to programs for IND/NDA submission. Mandy also leads a global team responsible for regulated bioanalysis in supporting both GLP toxicology studies and clinical sample analysis studies for small molecules.

Mandy believes her team's success stems from striving to be chosen as our client's partner and not solely as a service provider. Accuracy, precision and reproducibility are key elements for assessing *in vitro* ADMET assay quality. To achieve this high quality of assays, this group has built state-of-the-art automation capabilities and high throughput screening platforms. In addition, a carefully designed program management system was established to streamline the entire process of assays, from compound reception through assaying and data generation and interpretation, to report submission. As a result, Pharmaron is able to reduce the cycle time and provide more cost-effective solutions, providing efficient and effective services to clients.

A contributing factor to the great services provided is the culture of learning to stay updated on current science and technology. Pharmaron recently held its 2nd DMPK Symposium at its Beijing headquarters, which brought together global leaders from both industry and academia. The DMPK scientists gained important insights from each presentation and had in-depth discussions with speakers on a broad spectrum of DMPK subjects during networking times.

Mandy is proud of her team and their hard work and she feels like they are family. As the division grows, Mandy recognizes the importance of keeping the group bond strong. To celebrate their success and growth, fun events are planned each year. Just recently the fourth singing competition was held, called "ADME Voice." Mandy is eager to plan the next fun event, that will recognize the ten-year anniversary of *in vitro* ADMET services.

About Dr. Mandy Xu

Dr. Mandy Xu is Vice President of DMPK. She leads an *in vitro* DMPK research team and a global team for regulated bioanalysis in supporting both GLP toxicology studies and clinical sample analysis studies for small molecules. Dr. Xu obtained her B.Sc. and Ph.D. in Pharmaceutical Sciences from Peking University, where her studies focused on pharmacokinetics, drug distribution and excretion, *in vitro* drug metabolism, and metabolite identification by using LC/MSⁿ technology. She has published over 20 research articles in peer-reviewed international journals. In her spare time, she enjoys spending time with her family and playing basketball, badminton and table tennis. She also looks forward to planning her group outings.

2 DMPK Studies for R&D Efficiency

Pharmaron's DMPK service helps our partners improve their drug R&D efficiency with our integrated discovery, preclinical and clinical DMPK platforms.

Pharmaron works together with our partners to develop new assays, conduct investigations to support innovative ideas and establish a better model for drug screening and study. In addition, we support IND submission reports, provide clinical research to support phase I and II clinical trials, as well as offer clinical sample bioanalysis.

AstraZeneca recently published two papers on drug metabolism and disposition focused on prediction of *in vivo* clearance and plasma concentration for a range of flavin-containing monooxygenase substrates. Pharmaron performed a series of *in vitro* hepatic stability and protein binding assays, that helped to support this work.

[Drug Metab Dispos, 46 (9) 1259-1267, September 2018]
[Drug Metab Dispos, 45 (10) 1060-1067, October 2017]

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4 Pharmaron Receives Green Chemistry Partner Award

Pharmaron is the proud recipient of Roche's Green Chemistry External Partner Award, received earlier this year. This award recognizes an energy-saving technology developed by Pharmaron. This new technology enables the recovery and reuse of approximately 30% of the carbon-14 (¹⁴C) used in custom radiosynthesis, that has significantly reduced the quantity of radioactive waste produced.

Pharmaron performs multi-step custom synthesis of ¹⁴C-labelled compounds, that are used as radiotracers in pharmaceutical development.

5 Integrated DMPK Service Platform

Pharmaron's global DMPK platform is part of our integrated services, which cover the full range of drug discovery and development. Pharmaron helps our partners reduce the drug discovery cycle and identify potential DMPK issues early.

Pharmaron's global DMPK platform provides integrated DMPK services to support the preclinical candidate (PCC) nomination, IND submission and NDA submission. The Discovery DMPK teams offer comprehensive *in vitro* ADME and *in vivo* PK services for fast compound screening (5-day turnaround) at the drug discovery stage. Pharmaron's radiolabelled metabolism teams provide animal and human metabolism services with cutting-edge technologies. In addition, Pharmaron has experienced teams conducting the full package of DMPK studies, that support IND and NDA submission and prepare reports suitable for submission to regulatory agencies.

3 Focusing on Chemistry Innovation

Pharmaron held its eighth annual Symposium on Synthetic and Medicinal Chemistry at the Beijing headquarters on September 15. Each year this symposium brings distinguished leaders from industry and academia to Pharmaron and offers the unique opportunity for our partners and colleagues to learn from and interact with chemistry experts.

The presenters discussed latest advancements in synthetic and medicinal chemistry, that included newly developed synthetic methodologies, total synthesis of highly complex natural products, design and synthesis of biologically active molecules. In addition, the philosophy of innovation and team work were discussed.

Innovation is the key to achieving sustainability in Pharmaron's business. By renewing and building knowledge and skills, we can serve our partners' needs better. This symposium represents one of many learning opportunities our team takes advantage of each year.

Symposium Speakers:

- **Dr. Michael Brands**, Bayer AG, *Germany*
- **Dr. Chengyi Chen**, Johnson & Johnson, *Switzerland*
- **Dr. Martin Eastgate**, Bristol-Myers Squibb, *USA*
- **Dr. Frank Narjes**, AstraZeneca, *Sweden*
- **Prof. Larry Overman**, University of California, Irvine *USA*
- **Prof. Masakatsu Shibasaki**, Microbial Chemistry Research Foundation, *Japan*
- **Dr. Jingjun Yin**, MSD, *USA*
- **Dr. Wendy Young**, Genentech, *USA*
- **Prof. Biao Yu**, Shanghai Institute of Organic Chemistry, *China*

