

Meet Dr. Jufeng Wang
SVP, Safety Assessment

Achieving IND
Filing Success

Site Opens in
Hoddesdon, UK

Xceleron
Acquisition

Focus On:
SEND



Meet Dr. Jufeng Wang

Dr. Jufeng Wang has his mother to thank for two things—for becoming a scientist and a good cook. But we'll get to cooking later.

Jufeng, Pharmaron's Senior Vice President of Safety Assessment, can't remember a time when science wasn't a part of his life. His parents, both doctors, were a strong influence. From reading their medical textbooks as a kid, to observing his mother interact with patients at the hospital, he saw first-hand the importance of medical science to everyday life. He chose medical school for his college education. Pharmacological experiments caught his interest and he completed Master's and Ph.D. degrees in pharmacology.

During a post-doc in Boston at Beth Israel Deaconess Medical Center, Harvard Medical School as an NIH-supported research associate, Jufeng had an eye-opening experience working on cardiac toxicity resulting from drug abuse. His research work demonstrated a mechanism for sympathetic nerve toxicity due to cocaine abuse. His results suggested a clinical treatment strategy for drug abuse. Jufeng received the Young Investigator Award from the American College of Cardiology in 2001 as a result of his research. From this experience, he recognized the importance of drug safety issues and this interest has continued to be a driving force in his career.

Prior to Pharmaron, Jufeng played an important role in the technical review of preclinical safety drug evaluations and GLP guidelines at the China Food & Drug Administration. His team evaluated over a hundred new chemical entities, biologics, and traditional Chinese medicines. In addition, he led a team that developed new methods for evaluating potential drug toxicity, especially related to cardiovascular risk.

Since joining Pharmaron in 2016, he has been applying his international experience from both China and the US in the GLP regulatory environment to strengthen Pharmaron's leading position in safety assessment services.

About Dr. Jufeng Wang

Dr. Jufeng Wang joined Pharmaron in 2016 as Senior Vice President, Safety Assessment. Prior to Pharmaron he held a position of Director of National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control, CFDA, in China for five years. Dr. Wang received his Ph.D. at the Academy of Military Medical Sciences, China, followed by post-doctoral training at Harvard Medical School. He worked at several US pharmaceutical companies and is an author/co-author of 81 publications and book chapters. He is a deputy vice president of the China Safety Pharmacology Society.

In his spare time, he enjoys cooking. Starting from childhood, he always stayed in kitchen and watched his grandmother and mother cook, and read cooking books bought by using gift money from his parents at Chinese Lunar New Year. His specialty dishes are a combination of Jiangxi (spicy) and Guangdong (sweet) styles.

2 Achieving IND Filing Success

IND filing is an exciting milestone for any life science firm to achieve. Reaching this goal, however, can be challenging as it requires perfectly timed and executed preclinical development activities. GLP toxicology studies are one of the critical components for an IND package and require precise scheduling and frequent communication amongst different technical teams for each toxicology study.

Pharmaron has helped our partners with dozens of IND filings – and one thing we learned is that each one is unique. Rgenix's recent IND filing in 2016 was no exception. The company conducted three GLP toxicology studies in parallel: two in rodent species and one in non-rodent, as well as toxicokinetic analysis, slide processing, expedited histopathology evaluation and report generation. In a 6-month period, our team initiated, conducted and submitted audited reports for all three GLP studies ensuring Rgenix had the needed information. Their IND was successfully filed on time and the drug is now in clinical trials. *Written with permission by Rgenix.*

4 Pharmaron Acquires Xceleron

Pharmaron is pleased to announce a new addition to the Pharmaron family. On January 10, Pharmaron acquired Maryland-based Xceleron, a globally leading Accelerator Mass Spectrometry (AMS) specialist for life sciences. Xceleron's track record is impressive – its proprietary approach with high sensitivity has made it possible to support regulatory filings for dozens of marketed drugs.

The addition of Xceleron develops and differentiates our capabilities in translational science and clinical development services, which is part of our strategy to provide fully integrated, end-to-end R&D services to our partners and collaborators.

5 Focus On SEND: Standard for Exchange of Nonclinical Data

The US FDA has requested that by end of 2017, Investigational New Drug (IND) submissions will be conducted in a SEND-compliant format as part of its efforts to improve not only the efficiency and quality of the review process, but also the rigor of scientific assessment. Data submission to support New Drug Application (NDA) and Biologic License Application (BLA) filings with FDA has already been mandatory.

Recently Pharmaron has been implementing hardware and software necessary to meet the SEND guidelines. We are in the process to have fully validated the SEND system by the middle of 2017, thereby meeting the timeline set by FDA for regulatory filings. Pharmaron is committed to ensuring full compliance of regulatory requirements and the high quality of studies conducted at our facilities.

3 Site Opening in Hoddesdon, UK

On February 10, Pharmaron held its opening ceremony of the newly acquired Merck Sharp and Dohme (MSD) Hoddesdon facility for process research and development. This important acquisition is part of Pharmaron's vision of global leadership in the small molecule-based drug R&D service industry and its mission to support the success of its partners in discovery, development and commercialization of innovative drugs. "It is a great honor for us that MSD's skilled scientists and facilities at Hoddesdon have joined Pharmaron. This strategic action will allow Pharmaron to continue tapping into the talent pool in the UK and establish a foothold in Europe, with a world-class platform already in place," said Dr. Boliang Lou, Chairman and CEO of Pharmaron.

To recognize the occasion, clients, staff and distinguished industry and academic leaders attended the opening ceremony and Pharmaron's Symposium on Synthetic and Medicinal Chemistry at the Hoddesdon site. This full-day symposium, including presentations from world-class industry and academic speakers, reflects Pharmaron's long-term commitment to excellence in science.

Symposium Speakers:

Prof. John Blacker, University of Leeds
Prof. James Bull, Imperial College London
Prof. Darren Dixon, University of Oxford
Dr. Richard Tillyer, SVP, Preclinical Development, Merck Sharp & Dohme
Dr. David M. Wilson, Senior Director & Head, Oncology Medicinal Chemistry, AstraZeneca
Prof. Shu-Li You, Shanghai Institute of Organic Chemistry, CAS



Pictured (Left) Dr. Richard Tillyer, Merck Sharpe and Dohme (Right) Dr. Boliang Lou, Pharmaron Chairman & CEO