Meet Dr. Michael Rowley

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Partner Success
Story
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Learning from Leaders Successful CFDA Inspection Integrated Services





Meet Dr. Michael Rowley

Dr. Michael Rowley's interest in chemistry began when his high school chemistry teacher, Mr. Hughes, allowed his class to perform any type of experiment. Mike's luminol synthesis was a success, however his friend's attempted TNT synthesis was a failure, as his teacher expected.

Mr. Hughes' showed Mike that chemistry can be fun and bring great benefit, but it was his teacher's enthusiasm and energy that really made the difference. While completing his degrees, Mike surrounded himself with peers who shared this same passion for science—and it's a trait he continues to look for today when building a team.

As Senior Vice President of Pharmaron's Drug Discovery Services in Europe, Mike brings almost 30 years of experience in drug discovery to Pharmaron. While at the Istituto di Ricerche di Biologia Molecolare (IRBM – MSD's site in Rome), his group discovered Isentress[™] for HIV, Grazoprevir (part of the dual

combination Zepatier™ for HCV) and Zejula[™] for ovarian cancer. Mike attributes his team's success to hard work, a positive outlook and a culture of rigorous scientific challenge.

"As a medicinal chemist, I know the chances of bringing a drug successfully to the market is low. But because of the difference a new drug can make for patients, we stay focused on this goal. To be involved with three drug discoveries is a dream come true."

In addition to three drug discoveries at IRBM, he made contributions at AZ in cardiovascular and gastrointestinal research and to Merck Research Laboratories' high level scientific strategy.

This past August, Mike was honored with induction into the American Chemical Society (ACS) Division of Medicinal Chemistry Hall of Fame. What makes this award most special to him is that it is recognition of an individual's overall outstanding contributions to medicinal chemistry.

Now at Pharmaron, Mike is building a world-class small molecule medicinal chemistry group in Hoddesdon, UK. For each new hire, Mike is looking for individuals that bring scientific excellence along with energy and enthusiasm—the same traits he has sought since he was a student.

About Dr. Michael Rowley

Dr. Rowley joined Pharmaron in 2017 as Senior Vice President of Drug Discovery Services in Europe. Prior to Pharmaron, he worked at MSD (UK, Switzerland), IRBM (Italy) and AstraZeneca (Sweden). He received his M.A. and Ph.D. at the University of Cambridge and completed his post-doc at Harvard University. He has published over 130 papers and 40 patent applications, he is a Fellow of the Royal Society of Chemistry, he received the ACS Heroes of Chemistry award in 2013 and he was inducted into the ACS Division of Medicinal Chemistry Hall of Fame in 2017. In his free time, he enjoys watching movies, reading and spending time with his family. In addition, he recently challenged himself to create an iOS iPhone application. But one wasn't enough, so he created two that can both be found in the App Store.

2 Our Goal: Partner Success

From the start of every project, our scientists are committed to partner success. Multi-disciplinary teams work together enabling our team members to have a direct impact on each project. When a partner reaches an important milestone, the good news spreads fast across our offices and facilities in China, UK and the US.

Lycera, a private biopharmaceutical company developing novel small molecule immunomodulatory medicines for the treatment of autoimmune diseases and cancer, has worked with Pharmaron since 2009, including Lycera's novel ATPase program which advanced to a Phase 2 study in ulcerative colitis. Pharmaron also supported Lycera's discovery of novel immuno-oncology candidate LYC-55716. Lycera recently announced the advancement of first-in-class RORgamma Agonist LYC-55716 into phase 2a for the treatment of solid tumors.

Written with permission by Lycera.

4 Successful CFDA Inspection

Pharmaron's Toxicology and Safety Pharmacology (TSP) site, located in Beijing, passed the CFDA GLP inspection and received the GLP certificate in June 2017.

This is the third CFDA GLP inspection of the TSP site, as part of the CFDA GLP re-inspection program. The success of the GLP inspection allows Pharmaron to significantly expand its capacities to accommodate the increasing business volume in the safety assessment area. This includes supporting CFDA IND filings and dual IND filings with CFDA and another international regulatory agency, such as US FDA and OECD member agencies. Our TSP site has passed inspections twice by US FDA, once by EMA and once by Belgium GLP Bureau.

5 Implementing Integrated Services

Integrated drug R&D services at Pharmaron comprise drug discovery, preclinical development and clinical development.

The **integrated drug discovery** service employs medicinal chemistry and computer-aided drug design, DMPK, *in vitro* biology, *in vivo* pharmacology, discovery process chemistry and exploratory toxicology capabilities. In this way, Pharmaron discovers and advances small molecules through different project stages, such as hit identification, lead identification, lead optimization and PCC selection.

Integrated preclinical development services enable IND submission to regulatory authorities, including FDA, CFDA and EMA. Our technology platforms include regulatory DMPK, *in vivo* pharmacology, safety assessment and CMC.

Clinical development services include clinical research from FIH to POC, which encompass SAD/MAD, TQT, PK, safety, tolerability, food effect, clinical pathology, clinical bioanalysis and clinical metabolism studies, etc. As part of clinical development, we also offer CMC services consisting of process chemistry and cGMP API manufacturing as well as formulation development and cGMP drug product manufacturing.

3 Learning from Leaders

Pharmaron held its seventh annual Symposium on Synthetic and Medicinal Chemistry on September 16 at the Beijing Main Campus. Eight world-renowned professors and industry leaders from Europe, China and the US addressed hundreds of Pharmaron scientists and partners.

Presenters discussed the latest advancements in synthetic and medicinal chemistry, as well as innovative approaches for drug discovery which could change the current drug discovery paradigm. Notably, the cutting-edge chemical and biological technologies and their novel combination approaches were presented, which provide a new and potentially powerful arsenal to the industry. The synthetic chemistry discussions included innovative and efficient methodologies and well designed and executed total syntheses of highly complex natural products, along with efficiency and mechanism driven process chemistry examples.

Learning is a critical component of Pharmaron's culture. Pharmaron's symposiums and fora provide our scientists the opportunity to interact directly with academic and industry leaders, learn cutting-edge science and technologies and understand how experts approach challenging problems. This gives our scientists ongoing support to provide high quality, efficient services to our partners.

"The chemistry world is changing and advancing at a rapid pace," said Dr. Boliang Lou, Chairman & CEO, Pharmaron. "Our presenters provide us with not only chemistry updates, but inspire us to think differently and stay innovative."

Symposium Speakers:

Dr. Markus Follmann, Bayer AG, *Germany* Dr. Andras Horvath, Johnson & Johnson, *Belgium* Prof. Jinbo Hu, Shanghai Institute of Organic Chemistry, *China*

Dr. Jianguo Ji, AbbVie, USA **Dr. Garry Pairaudeau**, AstraZeneca, UK **Prof. Sarah Reisman**, California Institute of Technology, USA

Prof. Barry Trost, Stanford University, USA **Dr. Petr Vachal**, MSD, USA

