Safety Evaluation of Impurities in Drug Substance

Presenter: Michael J. Schlosser, PhD, DABT

When: February 28, 2014 Coffee 8:00, Presentation 8:30, Questions at 9:30
Where: Regis Technologies, 8210 Austin Ave Morton Grove, IL 60053

Abstract: Regulatory agencies have identified that impurities especially, potential genotoxic impurities (PGIs), as a high priority in the drug development approval process. Impurities occur in essentially all small molecule drug substances. Since impurities found in pharmaceutical drug substances potentially posses pharmacological activity, their levels need to be controlled to safely administer pharmaceutical products to humans. Impurities impact not only the safety of drugs, but the development time if not addressed early during the scale-up process. This presentation will provide a general overview of the issues surrounding impurities in drug substance. The topics below will be covered during the presentation:

- ICH Impurity Guidelines - Regulatory
- Qualification Process of Impurities
- Genotoxic Impurities

About the Presenter: Michael is a Pharmaceutical / contract research executive and successful entrepreneur with 20+ years of R&D strategy and business operations experience. He received his PhD from the University of Mississippi, School of Pharmacy in Toxicology/Pharmacology. Prior to starting up MSR Pharma Services, he was the Vice President of WIL Research, a Toxicology CRO provider. Michael was the President and founder of Midwest BioResearch that was acquired by WIL in 2012. Michael also managed the nonclinical safety evaluation department in support of drug discovery, development, and registration of novel therapeutics at Searle/Pharmacia.

Reserve your space at the seminar by emailing or calling Diane Richards 847-583-7675 or drichards@registech.com