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MICHAEL BUONARATI

IMMUNOCHEMISTRY SERVICES |intertek.com/pharmaceutical

PROFILE

OVERVIEW

Mike Buonarati specializes in regulated bioanalysis, pharmacokinetics and drug metabolism. For more than 30 years, he has worked in the fields of drug discovery and drug development for the pharmaceutical and contract research organization industries.

PUBLICATIONS

15 published articles, conference reports, and presentations at industry events

EXPERIENCE

Senior Director of Immunochemistry Services • Intertek Pharmaceutical Services • 2010 – Present
Critical review and final approval of SOPs, procedures, invoices and reports for GLP compliance and scientific integrity. Oversees and manages laboratory staff and operations. Maintains high standards of customer relations and service. Manages lab testing and administrative activities.

Laboratory Director / Director of Bioanalytical Services • Intertek Pharmaceutical Services • 2001 – 2010
Managed the operations and overall oversight of the scientific laboratory. Developed strategies for technical and business advancement. Conducted pharmacokinetic analysis. Assisted with budgeting and hiring of personnel. Approved documents and reports.

Principal Scientist • Alta Analytical Laboratory • 1998 – 2001
Managed design and conduct of bioanalytical method development and validation studies. Designed and conducted specialty drug metabolism studies and pharmacokinetic analysis. Wrote and reviewed bioanalytical procedures and reports.

Principal Scientist • Hoffmann-LaRoche • 1996 – 1997
Responsible for design and conduct of nonclinical pharmacokinetic and toxicokinetic studies supporting drug discovery and development. Developed and validated bioanalytical methods, conducted sample analysis measuring drug and metabolite concentrations in biological fluids for GLP / non-GLP studies.

Postdoctoral Fellow, Biomedical Sciences • Lawrence Livermore National Laboratory • 1989 – 1992
Characterized in vitro and in vivo metabolism of the food-derived mutagen PhIP using subcellular, cellular and whole animal assay systems. Developed HPLC methodology for analysis of PhIP and metabolites.

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Research Assistant • University of California, Davis • 1986 – 1989
Developed analytical methodology to quantify isomeric mercapturic acid pathway metabolites and circulating reactive metabolites of naphthalene. Examined biotransformation synthetic naphthalene-glutathione adducts in mice. Conducted isolated hepatocyte studies to evaluate cytotoxicity and metabolism of epoxide intermediates of naphthalene.

EDUCATION / PROFESSIONAL ACCREDITATIONS

Ph.D. in Pharmacology and Toxicology • 1989 • University of California, Davis

B.S. in Biological Sciences • 1981 • University of California, Davis

INDUSTRY ASSOCIATION INVOLVEMENT / CONTINUING EDUCATION

AAPS Annual Meeting and Exposition

AAPS/FDA Workshop on Bioanalytical Methods Validation

AAPS/FDA Workshop on Current Topics in GLP Bioanalysis: Assay Reproducibility for Incurred Samples – Implications of Crystal City Recommendations

ASMS Conference on Mass Spectrometry

PESCIEX API 365 Operator Training

BSAT Applied Pharmaceutical Analysis Conference

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