



Agenda

- 10:30 am - 11:00am: Registration & Coffee
- 11:00 am - 11:10am: Welcome and Introduction
-Luca C. Matassa, Senior Director, Intertek ALTA LCMS
- 11:10 am - 11:35am: **Bioanalytical ISR Perspective and Case Studies**
-Mike Buonarati, Ph.D., Laboratory Director, Intertek ALTA LCMS
- 11:35 am – 12:00pm: **Challenges and Solutions to High Speed Quality Bioanalysis from Tissues**
-Stan Murakami, B.A., Principal Investigator, Intertek ALTA LCMS
- 12:00 pm – 12:45pm: Lunch
- 12:45 pm – 1:15pm: **Quantitative Analysis of Biomarkers using LC-MS/MS**
-Young Shin, Ph.D., Scientist, Genentech
- 1:15 pm – 1:40pm: **Comparison of Dried Blood Spot Sampling Methodology to Whole Blood Matrix for Paclitaxel Bioanalysis**
-Dale Schoener, M.S., Scientific Director, Intertek ALTA LCMS
- 1:40 pm – 2:00pm: **Regulated Bioanalysis: Towards Globalization of Science and Compliance**
-Luca C. Matassa, Senior Director, Intertek ALTA LCMS
- 2:00pm: Adjourn



Intertek Pharmaceutical Services: San Francisco Bay Area Bioanalytical Symposium



Wednesday, June 9, 2010
10:30 AM to 2:00 PM
The Westin
San Francisco Airport

Biography

Michael H. Buonarati, Ph.D.

Mike has over 17 years of experience in the pharmaceutical and CRO industry, and over 25 years of experience in bioanalytical chemistry. Mike joined Alta Analytical Laboratory in 1998, and as the Laboratory Director, he oversees all bioanalytical method validation and sample analysis activities.

In 1989, Mike received his Ph.D. in Pharmacology and Toxicology from the University of California, Davis, followed by completion of his post-doctoral fellowship at the Lawrence Livermore National Laboratory. His graduate and post-doctoral work was focused in the areas of biochemical toxicology, genotoxicity and drug metabolism. In 1992, he joined the Department of Drug Metabolism and Pharmacokinetics at Hoffmann-La Roche where his duties included bioanalytical method development, method validation and sample analysis. In addition, Mike was involved in assessing the metabolism of new drug candidates, and as Group Leader of Pharmacokinetics, he was involved in the conduct and analysis of pharmacokinetic and toxicokinetic studies in drug discovery and development.

Luca Matassa, Ph.D

Dr. Matassa joins Intertek with over 20 years of scientific research and management experience in advanced bioanalysis in the contract research organization (CRO) sector. Most recently, Dr. Matassa served as General Manager of Tandem Labs bioanalytical operations in West Trenton, New Jersey. From 2004 to 2008, he served as Laboratory Director at Tandem's Salt Lake City, Utah facility. As Associate Director of Operations he was previously responsible for establishing and managing operations for a high-throughput bioanalytical laboratory for Covance in Indianapolis, Indiana from 2000 to 2004. Prior to this role, Dr. Matassa served in successive positions at Maxxam Analytics Inc. (formerly NOVOMANN Inc, Mann Testing Laboratories) including Manager of the Bioanalytical Department from 1989 to 2000. Over his career, Dr. Matassa has published over 45 scientific papers and posters primarily focused on bioanalytical laboratory processes and the use of LC/MS/MS for quantitative bioanalysis. Dr. Matassa played an instrumental role in establishing the first Sciex API LC/MS/MS based contract bioanalytical laboratory in Canada.

Dr. Matassa earned his Doctorate in organic chemistry from the University of Windsor, Ontario, Canada in 1989.

Stan Murakami, B.A.

Stan joined Alta Analytical Laboratory in 1995 and currently oversees a team of scientists as a principal investigator. He has over 30 years of experience in bioanalytical chemistry within the pharmaceutical and CRO industry, specializing in bioanalytical mass spectrometry. Stan has extensive experience in method development, validation and drug discovery bioanalysis applications. Prior to joining Alta Analytical Laboratory, Stan was employed at Syntex Research as a mass spectrometry specialist. He was responsible for the development of bioanalytical methods and for the analysis of biological samples for toxicology and clinical studies. In addition, Stan was responsible for metabolite identification for new drug candidates and participated on drug discovery project teams. Stan received in bachelor's degree from the University of California, Berkeley in Biochemistry.

Dale Schoener, M.S

Prior to working in the pharmaceutical industry, Dale was the laboratory director of an in-vitro medical device manufacturing company for the clinical chemistry industry. In this position he was involved with bioanalysis, manufacturing quality control, and new product development. He subsequently became involved in mass spectrometry in graduate school and then joined the pre-clinical DMPK group at DuPont Pharmaceutical where he was a principal investigator for pre-clinical PK and TK studies and performed the validation in support of these assays. After DuPont Pharmaceutical he became a research scientist and principal investigator for a pharmaceutical CRO and was involved with bioanalytical method development and validation. He continues this work at Alta Analytical Laboratory where he is currently Scientific Director. Dale holds two Masters degrees, in clinical chemistry and chemistry.

www.intertek.com/pharmaceutical/bioanalysis/lcms-california/



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Young Shin, Ph.D

Young Shin is a scientist of Drug Metabolism and Pharmacokinetics at Genentech, CA. He received Ph.D. in Pharmacy from the Seoul National University, South Korea in 1997.

He joined the University of Illinois at Chicago (UIC) as a postdoctoral researcher, and contributed himself to two major anti-cancer programs for discovering novel anti-tumor agents or cancer chemopreventive agents from natural products using bioassay-linked high throughput LC-MS/MS analysis (dereplication), Pulsed Ultrafiltration (PUF)-MS and high resolution NMR. After 4 years at UIC, Young joined the DMPK group of GlaxoSmithKline in Collegeville, PA as an investigator/principal scientist, responsible for drug metabolism and bioanalysis of new chemical entities (NCEs) in drug discovery projects. He then joined the DMPK group of Genentech as a scientist in 2004. His contributions in Genentech include (1) Quantitation and metabolite identification of NCEs for discovery, early development and clinical programs using linear ion-trap MS, Orbitrap-MS and triple quadrupole MS etc, (2) the MALDI mass spectrometry-based tissue imaging for small molecules, (3) PK and ADME studies with ^{14}C nano-tracers using Accelerator Mass Spectrometry (AMS) and (4) Applications of *In silico* models for metabolic soft spot and permeability efflux-ratio predictions.

1989: BS in Pharmacy, Seoul National University, Korea

1991: MS in Pharmaceutical Analysis, Seoul National University, Korea

1997: Ph.D. in Pharmaceutical Analysis, Seoul National University, Korea

1997-2001: Postdoctoral Researcher, University of Illinois at Chicago, USA

2001-2004: Principal Scientist/Investigator, DMPK, GlaxoSmithKline, USA

2004-2010: Scientist, DMPK, Genentech, USA



**Intertek Pharmaceutical Services:
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