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Section:	Page #:
Sponsors	2
Welcome	3
Agenda	5
Abstracts	6-8
Biographies	9-10
Moderator Bios	11
Acknowledgements	12



University I: All Sessions
Luncheon Workshop

University Foyer: Exhibitors, Refreshments &
Networking Reception



Welcome to the 2009 Applied Pharmaceutical Software Conference. Our organizers have gathered another excellent group of speakers for our second annual APS conference.

The program is arranged to incorporate extensive audience participation and discussion. We encourage attendees to take full advantage of the opportunity to engage in discussion in order to receive the maximum benefit from the APS experience.

Thank you for your participation.

APS 2009 Organizing Committee:

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Moderators:

Chris Kemper, Taylor Technology, Inc

Jeff Duggan, Boehringer Ingelheim

Steve Gorman, Cephalon

Tom Huggins, Proctor & Gamble

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Tom Huggins, Proctor & Gamble



2009 Conference

- 8:00 - 8:30 AM **Registration**
- 8:30 - 8:40 AM **Welcome Remarks**
Chris Kemper, Conference Chair
- 8:40 - 10:40 AM **Session 1: Implementation and Maintenance of Multisite LIMS**
Moderator: Steve Gorman, Cephalon
- 8:45 - 9:15 AM A Globally Harmonized Bioanalytical Data Management System - The Good, the Bad and the Ugly, *Kirk Cromer, Sanofi-Aventis*
- 9:15 - 9:45 AM T.B.D.
- 9:45 - 10:15 AM Multi Site Deployment of LIMS Software using Application Virtualization, *Bill Griffiths, Covance*
- 10:15 - 10:40 AM **Break**
- 10:40 - 12:15 PM **Session II: Electronic Notebooks**
Moderator: Tom Huggins, Proctor & Gamble
- 10:45 - 11:15 AM Electronic Laboratory Notebook Implementation in Bioanalysis – Successful Global Implementation in Less Than One Year, *Chad Briscoe, MDS Pharma Services*
- 11:15 - 11:45 AM Transitioning to the Next Generation of Bioanalytical Process and Data Management Through an Integrated Electronic Notebook, *Jianing Zeng, BMS*
- 11:45 - 12:15 AM Development of a Procedurally Driven ELN System for a High Throughput Bioanalytical Laboratory, *David Elgar, Boehringer-Ingelheim Pharmaceuticals*
- 12:15 - 1:15 PM **Luncheon Workshop Sponsored by**  **Agilent Technologies**
- 1:15 - 2:50 PM **Session III: Automated Report Generation**
Moderator: Chris Kemper, Taylor Technology, Inc
- 1:20 - 1:50 PM Custom Solutions for Automated Data Reporting, *Kristina A. Conceicao, Taylor Technology, Inc*
- 1:50 - 2:20 PM Regulatory and Scientific Requirements for Automated Report Generation: a Pharma Perspective, *Surendra Bansal, Hoffmann-La Roche*
- 2:20 - 2:50 PM PK Automation - Critical Requirements for Efficient Reporting Workflows, *Peter Schaefer, Pharsight*
- 2:50 - 3:15 PM **Break**
- 3:15 - 4:50 PM **Session IV: LIMS - Automation Integration**
Moderator: Jeff Duggan, Boehringer Ingelheim
- 3:20 - 4:05 PM Process Improvement and Increased Productivity Through the Introduction of Centralized Automated Sample Preparation into a Generalist Model, *Chris Holliman, Pfizer Global Research & Development*
- 4:05 - 4:50 PM Integrated Robotic Liquid Handling for Bioanalysis Using the Hamilton Starlet Interacting with Watson LIMS, *David Elgar, Boehringer-Ingelheim Pharmaceuticals*
- 5:00 - 6:00 PM **Networking Cocktail Reception sponsored by**

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A Globally Harmonized Bioanalytical Data Management System – The Good, the Bad and the Ugly, **Kirk Cromer**, Sanofi-Aventis

The Global Metabolism and Pharmacokinetics (GMPK) department at Sanofi-Aventis successfully implemented a Bioanalytical Data Management System (BADMS) at all ten of our global sites as of September 2007. The primary components of the BADMS are Thermo Fisher Scientific's Watson LIMS™ and Waters (NuGenesis) SDMS™. This system replaced three legacy LIMS used by the three predecessor companies that are now Sanofi-Aventis. The process that was used to achieve this harmonized, global system will be briefly reviewed, highlighting the challenges and the successes of the project. Once the system was in production, the new challenge was to put in place processes and procedures to maintain the harmonized use of this system while managing evolving requirements of not only the Bioanalytical group, but other groups and departments that are end users of the data in BADMS; as well as new Quality and Regulatory requirements. The key aspects of our approach to achieving this goal will be reviewed.

Multi Site Deployment of LIMS Software using Application Virtualization, **Bill Griffiths**, Covance

The deployment of LIMS Software using virtualization software, such as Citrix, increases flexibility when using the software at many sites across the globe. Citrix enables expedited deployment of a LIMS to a new site and reduces complexities inherent in any software upgrade. The Deployment using a Citrix environment also allows for a single database instance enabling workload sharing between sites and across business groups. This has allowed Covance to deploy a multi-site LIMS system faster and at a reduced cost.

Electronic Laboratory Notebook Implementation in Bioanalysis – Successful Global Implementation in Less Than One Year, **Chad Briscoe**, MDS Pharma Services

High throughput robotics and LC/MS/MS systems for the processing and analysis of clinical samples have created a bottleneck in the documentation and review of laboratory data. One of the solutions to this bottleneck is efficient, electronic systems for documentation. Laboratory information management systems are one tool for this documentation that has been used routinely in most bioanalysis laboratories for 5 years or more. These systems store primarily derived data that is necessary to build analytical run lists for instruments, to perform calculations on the data acquired from the instruments, and to organize data for reporting. Original, raw data documentation continues to be stored primarily in paper-based notebooks and binders. However, many companies are moving towards the implementation of electronic laboratory notebooks in order to gain additional efficiencies from the use of fully electronic systems. Advantages to these systems include increased availability of data, pre-defined workflows for data review and minimization of documentation errors through the use of bar-coded reagents, standards and equipment. The implementation of these systems is extremely labor intensive and often takes several years. At MDS Pharma Services we recently completed a major upgrade to our globally implemented LIMS system in less than 6 months. We were then able to learn from this experience in order to fully implement an electronic laboratory notebook globally (Lincoln, Montreal, Zurich) in approximately one year from approval of the project in corporate IT governance until full implementation. The IQ and OQ were completed in less than 4 months, implementation of the first module for the system was launched in 8 months and then phased implementation proceeded over the course of the next 4 months. In order to achieve this goal it was necessary to have total support and excitement for the project from the bench chemist to the corporate CEO. A very actively engaged project steering committee with broad representation across the global sites including operations, IT and QA was also a key component of this success. The project was broken down into small pieces where possible and the sub-project teams were allowed to operate independently and were given authority to make decisions in order to rapidly move the project forward. Also discussed are the challenges that were encountered along the way such as the need and desire to harmonize some of the very simple laboratory processes such as pipette calibration and understanding the global regulatory requirements to ensure the validation and use of the system would meet the expectations of all of the world's regulatory bodies to the best of our abilities. Further details of this approach including how these challenges were rapidly overcome in the implementation of this global system will be discussed as well.



Transitioning to the Next Generation of Bioanalytical Process and Data Management Through an Integrated Electronic Notebook, Jianing Zeng, BMS

Today's fiercely competitive pharmaceutical market, as well as a modernizing and challenging regulatory environment have prompted us to respond with innovative business practices that integrate new scientific and technological advances in order to raise productivity, lower the overall operational cost and maintain a sustainable growth rate. As a result, moving into the next generation of bioanalytical processes and data management systems via an integration of an electronic laboratory notebook (ELN) platform, LIMS and laboratory instrumentation seems both logical and an urgent requirement.

In the Bioanalytical Science Department at Bristol-Myers Squibb (BMS), the newly designed bioanalytical data management system is based on an ELN system that extends far beyond its traditional scope. We aim to take full advantage of the capabilities inherent in the new technology by configuring it to provide the framework for a new bioanalytical data environment that focuses on data quality, data sharing capacity, report capability and overall work flow efficiency. Rather than using the traditional model of individual scientist owned notebooks, our ELN is organized by project to allow scientists from different functional areas within the department to readily and flawlessly record, sort and organize data and results. The custom templates and validated calculation processes are designed to facilitate data collection, calculation and review, instrument management and automatic report generation. Integration of the ELN with the Watson LIMS system was a requirement to further streamline work processes and thereby decrease the cycle time for bioanalytical support. With quality functions and error checking considerations embedded at the beginning of the ELN design, "automated compliance" will help minimize accidental errors, reduce overall data reviewing time and lead to improved productivity. The project-centric structured data hierarchy should also allow more facile location of data for those less familiar with the project history and significantly shorten the time needed to prepare filing documents.

In conclusion, the new bioanalytical ELN at BMS is designed to harness potential synergies and foster collaboration and cross-functional integration. By taking into consideration both data generation and project documentation needs, a well-designed ELN can deliver significant improvements in laboratory efficiency and work productivity, and serve as an integral component of general bioanalytical data management.

Development of a Procedurally Driven ELN System for a High Throughput Bioanalytical Laboratory, David Elgar, Boehringer-Ingelheim Pharmaceuticals

Sample preparation and instrumental analyses, have until recently, been the rate limiting steps in sample throughput in the bioanalytical laboratory. The introduction of automated robotic sample preparation and techniques such as Ultra Performance Liquid Chromatography (UPLC) can dramatically increase sample throughput and data generation. However many aspects of the analytical process within the bioanalytical laboratory requires the use of paper based systems for recording information, necessitating lengthy data review procedures to ensure data integrity and compliance. This effectively transfers the rate limiting step to the data review process. The SmartLab ELN system allows the development of an integrated set of procedures that can be used to construct bioanalytical methods from libraries of previously described routines. Real time QC checking is built into the system, preventing the user from completing the execution of a procedure containing erroneous data, incorrect, or expired solutions. This allows a "review by exception" approach to be applied to the data. Development of this system will be discussed.

Custom Solutions for Automated Data Reporting, Kristina A. Conceicao, Taylor Technology, Inc

This presentation will highlight the advantages for a CRO of using custom software to support data reporting to a diverse set of clients. Using internally developed software enables the flexibility and responsiveness needed to support multiple, ever-changing reporting requirements. Additionally, applying the right software solution is important. Creating a separate push-button application for each data format is not practical from an ROI standpoint. Providing reporting staff with flexible LIMS export options and a strong set of data manipulation tools will allow them to support virtually any format. Once this infrastructure is in place, software development staff can concentrate on providing more comprehensive solutions for projects that warrant the investment



Regulatory and Scientific Requirements for Automated Report Generation: A Pharma Perspective, Surendra Bansal, Hoffmann-La Roche

Submission of bioanalytical method validation and analytical reports is a regulatory requirement. General guidance for documentation and report writing can be found in the FDA guidance for bioanalytical method validation (May 2001). Crystal City III whitepaper [The AAPS Jr., 2007, 9 (1), article 4)] provides further specific details on what is expected in such reports. The bioanalytical reports are for most part a compilation of the assay performance parameters and the concentrations obtained for study samples. These reports require only a limited discussion or interpretation, and therefore could be easily generated from the bioanalytical LIMS currently in use. While bioanalytical LIMS have been in widespread use for several years, the automated report generation seems to be in its infancy. The users spend hours or days in compiling the reports. The slow progress in automated report writing software may be partly due to varying user requirements, styles and interpretation of regulatory requirements. In this presentation we will try to review whether we have common regulatory and scientific requirements that could be utilized to generate automated reports. Automatic report or tables generation would not only save time, but also enhance regulatory compliance by providing a defensible means for representing accurate data in the reports.

PK Automation - Critical Requirements for Efficient Reporting Workflows, Peter Schaefer, Pharsight

Pharmacokinetics (PK) Automation is a technology that gives companies the means to vastly increase the productivity of their scientific staff while improving the quality and consistency of their PK analyses and reports. When the concept of PK Automation is applied to routine and repetitive analyses for the creation of presentation-quality PK tables, figures, and text output, it dramatically shortens the time to create intermediate and final reports and presentations – making time available that can be used for more and deeper analyses.

The presentation will discuss critical features that are required in a PK Automation application and will present how these features can be translated into product requirements that pharmaceutical companies can use to select or build an efficient and effective PK Automation solution that meets their needs.

Process Improvement and Increased Productivity through the Introduction of Centralized, Automated Sample Preparation into a Generalist Model, Chris Holliman, Max Tella, Christine Taylor, Julie Poe, Lisa Buchholz, Pfizer Global Research and Development

In the fall of 2007 Pfizer Groton made a significant procedural and cultural shift in the way quantitative bioanalytical support was provided for its discovery portfolio. The transition was initiated moving from a generalist model where each ADME scientist provided their own bioanalytical support to the creation of a centralized, dedicated bioanalytical support group. Agile System Thinking was used to evaluate historical processes, resources, and even instrument locations to optimize the new process and to achieve the transition to the new model without impacting the quality, quantity or turnaround times of the bioanalytical support. Integral to the successful transition to the new model was the development of a centralized sample processing group based on the liquid handling capabilities of the Hamilton MicroLab Star. In the new model, all in vivo sample processing is submitted to this team through a custom visual basic interface. Through this interface analysts direct all sample processing instructions (including creation of standards, quality control samples and sample dilutions) by the submission of a Watson LIMS analytical sequence. In this talk we will present the obstacles that were met and overcome by the deployment of this interface. We will share the technical attributes of the interface and our use of the Hamilton MicroLab Star system and provide the listeners with our system performance and utilization metrics.

Integrated Robotic Liquid Handling for Bioanalysis Using the Hamilton Starlet Interacting with Watson LIMS, David Elgar and Isif Yuabov, Boehringer-Ingelheim Pharmaceuticals

There are several increased productivity and data integrity improvements offered by integration of Watson LIMS to a robotic liquid handling system. By analyzing overall business workflow, leveraging inbuilt Watson functionality, expanding the use of Watson beyond the bioanalytical laboratory and utilization of additional software tools, these potential improvements can be realized and opportunities for further process improvements identified. This paper describes a multistage, multiphase approach to the integration of Watson LIMS to a Hamilton robotics system via a software utility developed in Oracle's Application Express tool. Some of the salient features include: the deployment of Watson LIMS into Toxicology, utilization of Watson's batch ID's as barcode identifiers for standard and QC samples, and reporting / interfacing with other laboratory systems. The architecture and advantages of this system will be discussed.



Surendra Bansal, Hoffmann-La Roche

Dr. Bansal is a Research Director in the Department of Non-Clinical Safety at Hoffmann-La Roche, Nutley, NJ. He has a Ph.D. in Biochemistry and MS in Computer Science. He did post-doctoral research at Roswell Park Memorial Institute, and has worked both in contract research organizations and Pharma industry (American Cyanamid and Roche). His responsibilities include Bioanalytical Methods development, validation and samples analysis from drug discovery to development in regulated (GLP) environment. He has published over 65 articles, book chapters and abstracts in subjects related to bioanalysis, drug metabolism and analytical instrument qualification. He has lectured at several bioanalytical conferences and has served as Chair of the AAPS Bioanalytical Focus Group.

Chad Briscoe, MDS Pharma Services

Chad received his Bachelor of Science degree in Chemistry from Alma College in Michigan and a Master's degree in Analytical Chemistry from the University of Michigan, with a focus in the use of LC-MS/MS in Protein and Peptide analysis. His PhD is from the University of Nebraska with a focus on studies of Protein Binding via affinity LC-MS/MS and computer simulations of affinity chromatography. Chad has been with the Lincoln site of MDS Pharma services since 1997 and has become well known in the bioanalytical community on such diverse issues as the use of advanced LC-MS/MS technology applied to high-throughput analysis, system suitability in high-throughput LC-MS/MS and bioanalytical software validation. He has recently been an invited speaker on these topics at the Land O' Lakes Bioanalytical Conference, the Applied Biosystems LC-MS/MS User's Meeting, and the 2007 and 2008 APA Meetings. Chad came to MDS Pharma Services from Dow Corning where he specialized in LC-MS/MS techniques and high-resolution MS and GC. While at MDS Pharma Services, Chad has advanced through various positions in which he was a Research & Development scientist, a Bioanalytical Principal Investigator, and finally the Associate Director for the R&D group prior to his promotion to Director. Chad has contributed to the development of industry standard processes for system suitability in LC-MS/MS, investigations in Bioanalysis and on-going development of risk-based software validation procedures.

Kirk Cromer, Sanofi-Aventis R&D

Kirk Cromer is the Global Ad1 administrator of the Bioanalytical Data Management System for the Metabolism and Pharmacokinetics department at Sanofi-Aventis R&D. Kirk has 25 years experience with the design, implementation and use of Data Management Systems as tools for the analytical chemist in the petroleum, environmental and pharmaceutical industries. After starting his career as an analytical chemist, he became involved with implementing early CDS and LIMS applications as tools to improve the efficiency and quality of his work as an analytical chemist. This gradually led to a career more focused on Data Management Systems for analytical laboratories, where his background in chemistry and data management provides an analytical chemists perspective in the planning and implementation of data systems. With the experience of working in multiple industries, including international postings, Kirk is able to provide a unique view of ways that these tools can improve analytical laboratory operations. In his current position at Sanofi-Aventis, Kirk managed the planning, selection and implementation of the Bioanalytical Data Management System, and is responsible for global management of this system, which includes supporting current operations and planning for future needs. Kirk has a B.S. in Chemistry from the University of Texas and has taken many graduate and industry-specific classes in the fields of analytical chemistry and data management during his career.

Kristina Conceicao, Taylor Technology, Inc

Kristina received a B.S. in Physics from Rutgers University. Her career in the pharmaceutical industry began in 1995 when she joined Taylor Technology, a contract Bioanalytical laboratory in Princeton, NJ. Kristina managed Taylor's reporting staff for over five years prior to joining the IT group. She has a wide range of experience with the extraction and reporting of data as both an end-user and IT professional. Throughout her time at Taylor, Kristina has been intimately involved with the administration and validation of the in-house-developed LIMS system. In her current position of Systems Developer, Kristina develops, validates and supports software used throughout her company.



David Elgar, Boehringer-Ingelheim Pharmaceuticals

Dave Elgar has nearly 25 years of experience working in bioanalytical laboratories in both the US and UK. In his role as IT application support, he is currently responsible for the upgrade and expansion of use of Boehringer Ingelheim's US bioanalytical LIMS, development of a pilot ELN and interfacing between the LIMS and a robotics system. Previous responsibilities at other companies have included: technical oversight and outsourcing of bioanalytical related projects, development and implementation of an integrated paperless laboratory system involving roll out, validation of Watson LIMS and interfacing between VelQuest ePMC, NuGenesis Vision, LIMS, inventory software and a variety of robotic and analytical instruments.

William Griffiths, Covance

William Griffiths graduated from the University of Wisconsin-Oshkosh in 1997 with a BS in Chemistry and a minor in Mathematics. As a student at the university he worked as an undergraduate research assistant as for a physical chemistry professor and was a co-author on two papers. He joined Covance in 1998 as a Analyst in the Bioanalytical Chemistry group. In 2000 he joined a team at Covance to develop and deploy the Nautilus LIMS. In 2001 he took a newly created position in the Bioanalytical Chemistry group at Covance working on full time on computer software projects and administrating software used within the department.

Christopher Holliman, Pfizer

Chris Holliman leads the Non-Regulated Small Molecule Bioanalytical Research Group for Pfizer, Groton, Connecticut. His group sits within the Pharmacokinetics, Dynamics & Metabolism line and supports Groton's small molecule discovery portfolio. In addition to discovery support, his group is focused on small sample volume analysis and process continuous improvement through the development of bioanalytical automation, networking, and multiplexing. Chris received his Ph.D. in Analytical Chemistry in 1994 from the University of Nebraska where his doctoral research in Fourier-Transform mass spectrometry focused on ion-trap cell design and gas-phase ion neutral reactions. His graduate research was recognized in 1993 with an ACS Analytical Chemistry Division Fellowship. He served as a National Research Council Postdoctoral Fellow at the Naval Research Laboratory, Washington D.C. from 1994 to 1996 where he conducted FTMS-based research on the gas phase oxidative reactions of fullerenes and endo-metallic fullerenes. Following his post-doctoral position, Chris spent two years with Pharmacokinetics of Baltimore MD in support of GLP bioequivalence studies. Over the past ten years, Chris has held leadership positions in regulated and non-regulated bioanalytical groups for Pfizer and its legacy companies, (Searle, Pharmacia) where his groups have provided in-house bioanalytical support for Pharmacia's and Pfizer's microdosing efforts.

Peter Schaefer, Pharsight

Peter Schaefer is Director of Product Management at Pharsight, responsible for Pharsight's enterprise products – PKS, a clinical data repository, and AutoPilot, a PK Automation tool. During his career, Peter concentrated equally on modeling and simulation and software development and has applied his knowledge in very different industries ranging from automotive, to military and aerospace and to the pharmaceutical industry. For the last 4 years he has worked with Pharsight and its customers to develop software tools for more efficient PK data management and reporting that include automation and report creation and maintenance. Peter holds a Master's degree in Mathematics and Computer Science and a Ph.D. in Engineering from German Universities.



Jeffrey X. Duggan, Boehringer-Ingelheim Pharmaceuticals

Dr. Duggan received his Ph.D. from the University of Illinois at Chicago. Following two years of post doctoral research in photosynthetic pigment biochemistry, and then joined the Perkin-Elmer Corporation, later named ABI and ABI/Sciex, where he was involved in the development and support of fluorescence, HPLC and tandem LC/MS instrumentation.

In 1999, Dr. Duggan joined Searle Pharmaceuticals, later known as Pharmacia, in Skokie, Illinois as a Principal Scientist and Bioanalytical Team Leader where he performed LC/MS/MS training, software system validation and developed bioanalytical methods using robotic liquid handling devices. In 2003 Jeff joined Neopharm, a company in Waukegan, Illinois that developed liposome-based drugs, as the Assistant Director for Bioanalysis. Jeff was later employed by Midwest Bioresearch in Evanston, Illinois as the Vice President of Analytical Operations where he was responsible for all bioanalytical and analytical projects and personnel. He joined Boehringer-Ingelheim in June, 2005 as the Associate Director of the GLP Bioanalytical Group in the DMPK department, and he is now the Director of Bioanalysis and Clinical Biomarkers at BI, Ridgefield. Current projects of interest at BI include: integration of LIMS, data acquisition, and robotic systems for bioanalysis; UPLC methods for the GLP bioanalytical laboratory; and regulatory compliance for GLP bioanalysis. Jeff has published more than 25 scientific papers and has presented work at numerous symposia on scientific topics related to pharmaceutical and instrumental analysis.

Steven H. Gorman, Cephalon, Inc.

Steven H. Gorman is a Research Scientist III at Cephalon Inc. in West Chester PA. He received his B.S. degree in Biochemistry from the Pennsylvania State University in 1979. Mr. Gorman's focus has always been chromatographic assays, mainly in biological matrices. Before entering the pharmaceutical industry he held positions in academia (Jefferson Medical College and the University of Pennsylvania), and in a genetic engineering company (Genex Corporation). Mr. Gorman started his work in the pharmaceutical industry in 1986 at Rorer Central Research in the Drug Metabolism Department followed by employment at SmithKline Beecham in the Drug Analysis Section in 1990. Mr. Gorman has been in a supervisory position at Cephalon since 1993. He was originally brought in to develop and validate achiral and chiral bioanalytical assays in various matrices for Cephalon's lead compound, modafinil. In addition to developing assays, he took on management of bioanalytical outsourcing. Mr. Gorman further diversified by becoming involved with validation and administration of a client-server-based chromatography data system (CDS) and becoming Cephalon's primary programmer of the Watson LIMS. Mr. Gorman has also been a member of the Steering Committee of the Delaware Valley Drug Metabolism Discussion Group since 1993.

Thomas G. Huggins, Proctor & Gamble

Thomas G. Huggins, Ph.D. is Section Head, of the Trace Analysis Capability (TAC) at Proctor and Gamble in Mason, OH. A native of Iowa, he obtained a B.S. degree in Chemical Engineering in 1985 from Manhattan College. He received Ph.D. in Biochemistry (1990) under the tutelage of Professor John Baynes at the University of South Carolina. Dr. Huggins did his Post-doctoral research with Jack Henion at Cornell University from 1990 to 1992. He has held various positions at P&G including heading up the Mass Spectrometry Laboratory at the Norwich, NY facility and leading the Product Development method development/validation initiatives for LC/MS/MS based assays at the Mason, OH facility. Dr. Huggins is currently Section Head of the TAC Section at P&G where he manages a group of 26 individuals responsible for supporting the global Ligand Binding and Mass Spectrometry Trace Analytical needs of all the business units of P&G.

Christopher J. Kemper, Taylor Technology, Inc

Chris Kemper received his B.S. in Chemistry at Rensselaer Polytechnic Institute in 1979 and a Ph.D. in Pharmacology at the University of Louisville Medical Center in 1983. He has filled group leader positions in the DMPK departments of Wyeth Research and Johnson and Johnson. His area of expertise is in pharmacokinetics in general and modeling and simulation specifically. Currently, he is Director of Bioanalytical Services at Taylor Technology. He has been on the steering committee of the Delaware Valley Drug Metabolism Discussion Group (DVDMDG) for 19 years, 5 years of which as its chair and the last 7 as Communications Director. He has chaired and/or presented at dozens of symposia over the last 10 years with the DVDMDG, the European Bioanalytical Forum, The Bay Area Analytical Chemists (BAAC) Network, the Bioscience Forum, the Gordon Conference on Drug Metabolism, Honeycomb Webinars, and IIR. He is also co-founder of the RTP and New England DMDGs. He is currently working on a book chapter on bioanalysis in DMPK with Mitch Cayen as editor: the title "Strategic, Technical and Regulatory Requirements for First in Human Drug Submissions".

Acknowledgements



Thank you to all of our Organizers, Speakers, Sponsors and Attendees. Without your support, dedication and hard work this conference would not be possible.

We greatly value your comments regarding APS 2009 as well as thoughts or suggestions for improving future conferences. Please take the time to fill out our online survey at:
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