North Jersey Chromatography Group

North Jersey Chromatography Group (NJCG) Symposium 2019

Method Lifecycle Management, Symposium, Exhibit, and More!

Register Today!

September 25th, 2019 (Wed.)

in Hyatt Regency Hotel, 102 Carnegie Center, Princeton, NJ 08540

Time	Moderator / Speaker	Title
12:30-1:00pm		Registration and Refreshments
1:00-1:05pm	Dr. Ying Hu Chair Ascendia	Welcome Remarks
1:05-1:15pm	Dr. Amjad Ali NJ-ACS Chair, Merck	NJ-ACS
1:15-1:45pm	Dr. Rosario LoBrutto Sandoz (Keynote)	Advancing Analytical Quality by Design
1:45-2:15pm	Dr. Peter Tattersall BMS	An Analytical Risk Assessment Program that Evolves During Clinical Development
2:15-2:45pm	Saji Thomas Par Pharmaceutical, an ENDO International Company	Impact of Method Transfers on Lifecycle Management (LCM) of Analytical Methods
2:45-3:30pm	Dr. Robert Menger Past Chair, Celgene	Vendor Show, Posters (refreshments will be served)
3:30-4:00pm	Dr. Jinjian Zheng Chair-Elect, Merck	Technology and Software Considerations to Enable Analytical Procedure Lifecycle Management
4:00-4:30pm	Margaret Maziarz Waters	Continued Performance Verification of Analytical Procedures Using Control Charts from Empower Chromatography Data Software
4:30-5:00pm	All Speakers Isabelle Vu Trieu	Panel Discussion
5:00-5:10pm	Dr. Ying Hu Dr. Jinjian Zheng Chair-Elect, Merck	Raffle Closing Remarks
5:10-6:30pm	Cocktail Hour	Sponsored by Waters Corporation

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Invited Keynote Presentation

Advancing Analytical Quality by Design

Rosario LoBrutto

Sandoz, Inc. (A Novartis Division)

Quality by Design (QbD) concepts can be applied in process development, formulation development and analytical development. Analytical quality by design (AQbD) has been an integral part of QbD and risk-based pharmaceutical development over the last decade. AQbD framework provides the basis for the development of robust analytical methods and for effective process control of high-quality pharmaceutical products and fit for purpose risk assessments to manage analytical methods over a product's lifecycle.

Implementation of Quality by Design in development allows for improved understanding of the analytical method focusing on robustness and ruggedness designed with end user in mind thereby facilitating methods transfer and provides opportunities for continual improvement. This allows for reduced chance of method failures during release/stability testing, aids OOS investigations, and ultimately increases quality and reduces costs.

When Quality by Design is implemented and integrated into the "DNA" of the development strategy the critical sources of analytical variability could be identified, measured, understood and controlled with an appropriate control strategy and monitored throughout the analytical method lifecycle (development, validation, technical transfer, production).

An overview of advances in AQBD application in the pharmaceutical industry will be presented.

ROSARIO LOBRUTTO, PH.D., Head of Scientific Affairs, Sandoz

Rosario has over 20+ years of experience in driving R&D, commercial, and operational excellence through business acumen and scientific leadership with roles of increasing responsibility in development, scale-up, transfer, and launch preparation of generic, complex generic and branded products as well as products following a 505b2 regulatory pathway at Merck, Novartis, TEVA and Sandoz. This includes development of active pharmaceutical ingredients and drug products including small molecules, synthetic polypeptides and proteins in various dosage forms (Parenterals, solid oral dosage forms, transdermals, films, etc) and drug-device combination products for a wide gamut of therapeutic areas.

Currently at Sandoz Rosario is Head of Scientific Affairs based in Princeton, NJ responsible for external partnership product development (NDAs, 505(b)(2)s, and ANDAs). Rosario oversees technical due diligence evaluating CMC and bio-analytical aspects of new product opportunities amenable to co-development, in-licensing or acquisition. Moreover, he advances pipeline strategy and leads team for identification, evaluation and prioritization of internal/external assets and robust tuneable technology platforms.

Prior to joining Sandoz, Rosario worked at TEVA Pharmaceuticals as Site Head / Head of Development for Sterile Products in Pomona, New York. He also worked at Novartis as global project leader for API/drug product, Global Quality by Design Network Leader, and led various global teams: QbD training, Specification Setting Strategy and Regulatory CMC team focused on streamlining CMC processes for small molecules/ biologics development projects. In addition, he worked at Merck Research Laboratories API Division supporting the development of synthetic pathways and scale-up of chemical processes for early- to late-stage drug candidates.

Recognized for scientific innovation: 35 research publications, 100+ presentations, and book contributions on formulation, analytical and physical chemistry, process analytical technology (PAT), Quality by Design (QbD), and other topics. Co-Editor (Book): HPLC for Pharmaceutical Scientists.

Invited Presentations

An Analytical Risk Assessment Program that Evolves During Clinical Development

Peter Tattersall, Qinggang Wang, Li Li, and Brent Kleintop

Chemical Synthetic Development, Bristol-Myers Squibb

The analytical methods and related control strategy for a typical small molecule process typically evolve as they progress from early to late phase development. During the early stages of clinical development, when manufacturing processes and control strategies are evolving, analytical methods are employed to gather knowledge on synthetic intermediates, starting materials and reactions. Since processes evolve as more experience and knowledge is gained, methods are likely to change as well throughout development. As a result, a fit for purpose control strategy and method development requires a risk balanced approach that still ensures sufficient quality for clinical batches. To address this, we've recently established a risk

survey for the control strategy and methods to help both the development team and CMO partners better understand areas of concern when executing analytical methods whose robustness is less understood.
In later development stages, an analytical control strategy is finalized to ensure commercial-scale batches meet established quality standards. Expectations for method robustness are elevated both by health authorities and by commercial testing labs. As a result, these test methods require more detailed risk assessments. To satisfy these needs we have developed a risk assessment that focuses on each specific method. Here a small team of subject matter experts evaluate details from sample preparation to instrument conditions. The output of this determines the next steps that may include: further optimization; evaluation of knowledge gaps; risk mitigation; and clear communication of concerns.
In this presentation, we will provide an overview of how our risk assessment program evolves throughout the stages of clinical development and will:

- Describe how our 'Risk Survey' fits into our overall analytical risk program
- Explain the structure and tool utilized to assess risks
- Demonstrate the value added to projects by using examples

Author's Biography:

Peter Tattersall, Ph.D. is a Senior Principal Scientist in Chemical and Synthetics Development department within Product Development at Bristol-Myers Squibb Company in New Jersey. He received his BSc. and Ph.D. from the University of Manchester, UK. He previously worked in Analytical Development at AstraZeneca, Wilmington. He joined Bristol-Myers Squibb in 2003 where he is an analytical team leader within Chemical and Synthetic Development. He has worked at early and late stage leveraging innovative analytical approaches to solve challenging problems encountered in both API synthesis including in process testing and various types of drug product. More recently he has led analytical teams in NDA stage of projects validating and transferring robust methods to commercial sites around the world. He supervises a small group of analytical chemists working on method development, qualification and transfer in process support of drug substance synthesis.

Impact of Method Transfers on Lifecycle Management (LCM) of Analytical Methods

Saji Thomas

Par Pharmaceuticals

Once an analytical procedure is successfully validated and implemented, the procedure should be followed during the life cycle of the product to continually assure that it remains fit for its intended purpose. Trend analysis on method performance should be performed at regular intervals to evaluate the need to optimize the analytical procedure or to revalidate all or a part of the analytical procedure. Trend analysis of stability data should be done on an annual basis as part of APR. If the data points to a stability trend then the method should be assessed for robustness, accuracy and precision.

If an analytical procedure can only meet the established system suitability requirements with repeated adjustments to the operating conditions stated in the analytical procedure, the analytical procedure should be reevaluated, revalidated, or amended, as appropriate. Over the life cycle of a product, new information and risk assessments (e.g., a better understanding of product CQAs or awareness of a new impurity) may warrant the development and validation of a new or alternative analytical method. LCM can be addressed only if all the parameters that cause the variability in method are identified during the method development. This presentation will address how to identify the critical analytical parameters and addressing the LCM of legacy method and new methods under development.

ICH Q14 is being developed to address the need for guidance on method development and method life cycle management.

Biography:

Saji Thomas M.Sc, Director, Par Pharmaceuticals (an Endo company), Spring valley , NY

Saji Thomas is currently Director at Par Pharmaceuticals. At Par his responsibilities includes raw material and finished product release, stability testing, process validation and lab automation. In his 25 years of industry experience, he has worked in the analytical R&D departments of Barr labs, Forest Labs and Purdue Pharma and P&G.

Saji has been a member of AAPS since 1993 and has been an active participant in APQ activities since 1994. He has been a member of the APQ program committee for the AAPS annual meeting since 2000. Saji is the past chair of the stability focus group and the generic focus group. He was the recipient of the 2007 APQ service award. He has organized and presented at numerous symposia, round table, sunrise sessions, short courses, open forums and hot topics for AAPS annual meetings. Currently Saji is AAPS a

representative on USP's PNP Stakeholder Forum Planning Committee. He is an invited speaker on a variety of CMC topics for pharmaceutical workshops and conferences in both the US and Europe and Asia.

Saji Thomas holds a B.Sc and M.Sc degrees in chemistry from the University of Kerala, India.

Approach Technology and Software Considerations to Enable Analytical Procedure Lifecycle Management

Jinjian Zheng

Merck

Analytical method developed based on quality by design (QbD) concept provides better method performance and enhanced method understanding, which leads to less method failures and better regulatory communications. Adopting the QbD concept requires us to change the workflow on method development and characterization, and thus posts some new challenges. Fortunately, there are some technology and software tools that can be used to facilitate the adoptation process. In this presentation, we will use HPLC methods as examples to discuss the application of these tools across all stages of the analytical procedure lifecycle. Specifically, we will discuss the following topics: 1) Understanding physico-chemical properties of analytes; 2) Screening of mobile phases and stationary phases; 3) Method optimization; 4) DOE method robustness evaluation; 5) Method transfer and 6) continuous method performance verification.

Biography:

Dr. Jinjian Zheng is currently a principal scientist at Analytical Commercialization Technology department of Merck. He obtained his BS and MS degrees in analytical chemistry from Xiamen University, China and Ph.D. degree in applied chemistry from The University of Tokyo. After graduation, he worked as a postdoctoral research associate at AIST-Japan and Ames Laboratory-Iowa State University before joining Schering-Plough (now a part of Merck & Co., Inc.) in 2003. He has provided analytical supports to the development of drug substances and drug products with increasing responsibilities. He has extensive experience in separation sciences including LC, GC and electrophoresis. He is especially interested in computer assisted HPLC method development using software simulation such as Chromsword, DryLab, ACD/Labs and Fusion. He is currently leading the efforts at Merck for analytical method development using quality by design (QbD) approaches.

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Continued Performance Verification of Analytical Procedures Using Control Charts from Empower Chromatography Data Software

Margaret Maziarz

Waters

The United States Pharmacopeia proposed a new general chapter: The Analytical Procedure Lifecycle <1220> to introduce a holistic approach to managing an analytical procedure throughout its lifecycle. The lifecycle approach is based on three stages that include design and development, performance qualification, and continued performance verification.

Continued performance verification evaluates how the method operates during routine use in a QC laboratory and confirms that the generated data continues to meet performance goals. Routine monitoring may include trending of the system suitability data, tracking analytical results of real samples or standards, out-of-specification or out-of-trend investigations, or stability trends.

In this presentation, we will discuss the use of Empower 3 Control Charts to facilitate the continued procedure performance verification stage of the analytical procedure lifecycle approach.

Margaret Maziarz, Principal Scientist, Scientific Operations, Waters Corporation

Margaret is responsible for analytical method development, validation and method transfer within the pharmaceutical applications development team, based in Milford, MA. Margaret specializes in the development of new applications on Waters ACQUITY UPLC, Alliance, ACQUITY Arc, ACQUITY QDa, Xevo TQ-S micro and related control software, generating technical seminar materials, webinars, marketing collateral and demo projects to support the sales and marketing organizations globally. Prior to joining Waters, Margaret worked at Boston Scientific and Purdue Pharma.