3rd Statistical and Data Management Approaches for Biotechnology Drug Development

October 11-12, 2016
USP Headquarters, Rockville

Co-organized by IABS and FDA

This meeting is to bring together regulators, and scientists, or those interested in statistics from academia and industry, who have a background in statistics, to help resolve existing challenges in ensuring the quality of biotechnology medicinal products and to bring high quality medicines to patients. Guidance on how to use statistics for a variety of activities required during biotechnology product development such as method development, improvement and replacement, product comparability, biosimilarity exercises and stability program development will be provided by the speakers and panel members. In addition, the complexity of the types of data and the volume being analysed is ever increasing and how best to manage such data will be discussed. The meeting will bring the right experts together to discuss the issues and through roundtables attempt to reach conclusions that will be valuable globally to public health.

Scientific / Organizing Committee

Richard K. Burdick	Arizona State University	Thomas Parish	AbbVie
Robert Capen	Merck & Co., Inc.	Bill Pikounis	Centocor
Kedar Dave	Juno Therapeutics Inc.	Tim Schofield	GlaxoSmithKline
Abe Germansderfer	Novartis	Volker Schnaible	Roche
Kristi Griffiths	Lilly	Meiyu Shen	FDA
Walter Hauck	Sycamore Consulting LLC	Andrew Rugaiganisa	Pfizer
Tsai-Lien Lin	FDA	Yi Tsong	CDER / FDA
Anthony Lonardo	Lilly	Fei Wang	Genzyme
Tony Mire-Sluis	AstraZeneca	Harry Yang	Medimmune LLC
Julia O'Neill	Tunnell Consulting	Lanju Zhang	AbbVie

Day 1 – Tuesday, October 11, 2016

7:30am **Registration & Welcome Coffee**

8:00am Introduction to the meeting and IABS
Tony Mire-Sluis, Chair – IABS Human Therapeutics Committee

Session 1 – Biosimilarity, Equivalence Testing and Acceptance Criteria

Chairpersons: Meiyu Shen, FDA and **Andrew Rugaiganisa,** Pfizer

8:15am Statistical approaches to comparisons of product profiles
Lanju Zhang, Abbvie

8:45am Statistical assessment of biosimilarity
Florian Wolschin, Sandoz

9:15am Acceptance criteria for demonstration of analytical similarity
Harry Yang, MedImmune

9:45am **Coffee Break**

10:15am Sample size unbalance adjustment for analytical similarity assessment
Cassie Dong - presented by Yi Tsong, FDA

10.45am Statistical issues of correlated lot values in analytical similarity assessment
Meiyu Shen, FDA

11:15am Roundtable discussion
Chairperson: **Harry Yang**, MedImmune
Lanju Zhang, Abbvie; **Florian Wolschin,** Sandoz; **Harry Yang**, MedImmune; **Cassie Dong,** FDA; **Meiyu Shen,** FDA

12:00 noon **Lunch**

Session 2 - The use of Statistics in the Development Cycle, Process Performance Qualification and CPV

Chairpersons: Cassie Dong, FDA and **Fei Wang,** Genzyme

1:00pm Process capability and statistical process control
Stan Altan, Janssen

1:30pm Implementing a process performance program for a global manufacturing network
Dan Coleman & Theo Koulis, Genentech, The Roche Group

2:00pm Manufacturing profiles comparability study
Dan Obeng, Genzyme

2:30pm **Coffee Break**

3:00pm More effective monitoring techniques for biotech processes: moving beyond Shewhart charts
Brenda Ramirez, Amgen Inc

3:30pm Innovative statistical approaches to support accelerated approval pathways
Julia O'Neill, Tunnell Consulting

4pm Roundtable discussion
Chairperson: **Katherine Giacoletti,** Arlenda
Stan Altan, Janssen; **Dan Coleman & Theo Koulis,** Genentech, The Roche Group; **Dan Obeng,** Genzyme; **Brenda Ramirez,** Amgen; **Julia O'Neill,** Tunnell Consulting

5:00pm **End of Day 1**

Day 2 – Wednesday, October 12, 2016

Session 3 - The Use of Statistics with Analytical Methods and Testing

Chairpersons: Harry Yang, MedImmune; **Julia O'Neill**, Tunnell Consulting

8:00am Lifecycle approaches to bioassay analysis
Tim Schofield, GlaxoSmithKline

8:30am Acceptance sampling strategies applied to USP <790> visible particulates in Injections
Rick Burdick, Elion Labs

9:00am Bridging reference standards
Andrew Rugaiganisa, Pfizer

9:30 Statistical revelations when averaging across the rows of a bioassay plate
Stan Deming, Statistical Designs

10:00am **Coffee Break**

10:30am Statistical considerations on analytical method validation
Ruojia Li, BMS

11.00am Development of medium and large sample acceptance sampling plans from USP Compendia plans
Yi Tsong, FDA

11.30am Roundtable discussion
Chairperson: **Ian Yellowlees,** Quantics Biostatistics
Stan Deming, Statistical Designs**; Tim Schofield**, GlaxoSmithKline; **Rick Burdick,** Arizona State University; **Andrew Rugaiganisa,** Pfizer; **Ruojia Li,** BMS; **Yi Tsong**, FDA

12:00pm **Lunch**

Session 4 - Incorporating the latest statistical and data management approaches for Products and Processes within a regulated environment

Chairperson: Mark DiMartino, Amgen and **Rick Burdick,** Elion Labs

1:00pm New techniques for continuous automatic system revalidation
Ian Yellowlees, Quantics Biostatistics

1:25pm Some statistical techniques for the analysis of count data
Jose Ramirez, Amgen Inc

1:50pm Bayesian statistics: "Fit for Purpose" for the lifecycle approach to process validation
Katherine Giacoletti, Arlenda

2.15pm Optimized CPV of final product quality for biologic medicines
Jeff Gardner, DataPharm SDMS

2:45pm Roundtable Discussion
Chairperson: **Stan Deming**, Statistical Designs
Ian Yellowlees, Quantics Biostatistics; **Jose Ramirez,** Amgen Inc; **Katherine Giacoletti,** Arlenda; **Jeff Gardner,** Data Pharm

3:45pm Summary of meeting
Tim Schofield, GlaxoSmithKline

4:00pm **End of meeting**