

Free Seminar

Innovative approaches to Pharmaceutical & Biopharmaceutical Development and Manufacturing

GEA-NUS PP Res Lab,

National University of Singapore

April 20, 2009

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Process Analytical Technology (PAT) and Quality by Design (QbD) have been buzz words in the pharmaceutical and biopharmaceutical industries for a number of years now and based on the literature and guidance documents available, these initiatives are gaining real momentum. Fundamental to these initiatives are the basics of Multivariate Analysis and Design of Experiments. This seminar outlines some of the practical issues regarding the implementation of PAT/QbD and looks at the following topics.

- The pragmatic use of guidance to enable, not hinder, progress
- The multivariate nature of Design Space as stated in ICH Q8
- Historical vs. Designed data, challenges and opportunities
- Principal Component Analysis, the workhorse of multivariate methods
- Variability reduction and the use of Regression Modelling: The Concept of Smart Manufacturing and MAFSS
- Fundamentals of Multivariate Statistical Process Control (MSPC)
- Combining information from unit processes to form a process model. The HHL Model
- Putting it all On-line for real time analysis and regulatory guidance allowing such systems
- Question and Answers

All aspects will be discussed along with CAMO Software solutions (both old and new) for addressing these topics. Some strategic alliances with process monitoring technology and quality system vendors will be discussed. PAT and QbD, now more than ever, represents the future of global pharmaceutical development and manufacturing. Having the right systems in place with the right data analysis tools will mean the difference between a successful implementation and failure.

Speaker

Brad Swarbrick

Pharmaceutical Business Development Manager
CAMO Software

Brad Swarbrick has over 15 years experience in the use of multivariate data analysis methods in food, agriculture and pharmaceuticals. Prior to CAMO, he worked as part of the Pfizer PAT group, Sigma Pharmaceuticals and was an industry consultant with one of SE asia's largest pharmaceutical consultancies.

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