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Hands-on Workshop on the Essential QbD Toolkit for the Pharmaceutical Quality System

Venue: GEA-NUS PPRL, Dept of Pharmacy, NUS

Programme:

5 - 8 Oct 2015: *Theory & Practice*

6 Oct 2015: *Complimentary Networking Dinner*

Objective:

Driven by the need to improve performance and efficiency, the pharmaceutical industry has adopted the **quality by design** (QbD) initiative for product manufacture. Implementing QbD requires both product and process understanding for the definition of a valid design space, control strategy and risk mitigation. The QbD approach utilizes a comprehensive tool set including multivariate data acquisition and modelling for understanding critical sources of variability; a modern control system to ensure quality product and process design space are maintained for materials, process and other factors to mitigate risks; and the control space for formulation and process. In this workshop, the QbD concept will be presented with hands-on practice in formulation design and the use of **process analytical technology** (PAT) for powder blending.

Who Should Attend:

Personnel involved in R&D and manufacture of pharmaceutical products:

- ✓ *Production*
- ✓ *Quality assurance/ Quality control*
- ✓ *Product formulation and development*
- ✓ *Contract manufacturing*
- ✓ *Pharmaceutical excipient marketers*

FOR MORE DETAILS & REGISTRATION:
www.geanus.nus.edu.sg

WORKSHOP PROGRAMME

Course Conductors:

Brad Swarbrick, *Quality by Design Consultancy*

Brad Swarbrick is the owner of Quality by Design Consultancy, which provides services in Asia for supporting pharmaceutical applications of Chemometrics, PAT and QbD for spectroscopic and process data. Brad has over 20 years of experience in the application of Chemometrics and DoE methods. Until recently, Brad was the Chief Operating Officer of CAMO Software and earlier, with the pioneering Pfizer PAT group. Brad has a unique combination of technical and business skills and is a globally recognized expert trainer in Chemometrics and Design of Experiment methodology. He is the current section editor of pharmaceuticals, for the Journal of Near Infrared Spectroscopy, and has written a number of chapters on NIR and Chemometrics, as well as a popular book "Multivariate Analysis for Dummies". Brad has a Bachelor of Science degree, majoring in Chemistry and has a post-graduate degree in Chemometrics.

Paul Heng, *National University of Singapore*

Paul Heng has a degree in Pharmacy and PhD in Pharmaceutics. He is currently teaching at the National University of Singapore and is the Principal Investigator of GEA-NUS Pharmaceutical Processing Research Laboratory. His research interest is in pharmaceutical technologies, with focus on encapsulation, specialized delivery systems, particle characterization and processing. He has over 240 international refereed research articles and several book chapters among others. He is the editor-in-chief of the Asian J Pharm Sci. and is on the editorial board of several journals.

Notes:

- Course materials will be supplied.
- Daily lunches and teas will be provided.
- Limited class size. Registration subjected to availability & on a first-come-first-served basis.

*** Highlights ***

- Use latest approved portable technology known as MicroNIR (by Viavi Solutions, formerly JDSU)
- Use best in class DoE software, Design Expert
- Use best in class MVA tools, Unscrambler by CAMO
- Hands-on workshop led by globally recognised industry expert in PAT/QbD
- Learn "How To" in theory and in practice

Theory:

Day 1: DoE for QbD

- Regulatory Guidance that supports the use of DoE for QbD.
- Designing Rational Experiments
- An Introduction to Design types and how they are used
- Optimisation Designs for Processes overview
- Optimisation Designs for Formulation overview
- Defining a Design Space to a Regulator

Day 2: MVA for QbD

- Regulatory Guidance that supports the use of MVA for QbD.
- Data types and how to handle them.
- Exploratory Data Analysis overview
- Regression Analysis overview

Day 3: PQS for QbD

- Regulatory Guidance that defines the PQS for QbD.
- Maintaining Design Space in a QbD environment
- Practical Implementation strategies for preparing a QbD submission for approval
- Conclusion and Discussion

Day 4: Debrief, Q&A (0900-1200 Hr)

Practice:

Day 1: Tablet formulation design and preparation using DoE

Day 2: Product characterization & analysis

Day 3: Blending trials with NIR

I hear and I forget. I see and I remember. I do and I understand.

Chinese Proverb



GEA-NUS PPRL

Department of Pharmacy, NUS

18 Science Drive 4, Singapore 117543

Contact: geanus@nus.edu.sg

Tel: (65) 6516-3933 Fax: (65) 6775-2265

Register: www.geanus.nus.edu.sg