

## GEA-NUS PHARMACEUTICAL PROCESSING RESEARCH LABORATORY

presents

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

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

#### Programme:

**28 - 30 Sept 2017:** Theory & Practice

**29 Sept 2017:** Complimentary Networking Dinner

#### Objective:

Following our very successful QbD Workshop in 2015, we have been strongly encouraged to provide an update. Along with the need to improve performance and efficiency in the pharmaceutical industry, many have 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 includes 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](http://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 had earlier worked 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 DoE 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 250 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 (Viavi Solutions)
- Use best in class DoE software, Design Expert
- Use best in class MVA tools
- Hands-on workshop led by globally recognized industry expert in PAT/QbD
- Learn "How To" in theory and in practice

#### Theory:

##### Day 1: DoE & MVA for QbD

- Regulatory guidance that supports the use of DoE for QbD.
- Designing rational experiments
- 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
- Regulatory guidance that supports the use of MVA for QbD.

##### Day 2: PQS for QbD

- Data types and how to handle them.
- Exploratory data analysis overview
- Regression analysis overview
- 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
- Discussion and conclusion

##### Day 3: Debrief, Q&A (0900-1200 Hr)

#### Practice:

- Tablet formulation design and preparation using DoE
- Product characterization & analysis
- Blending trials with NIR

*I hear and I forget. I see and I remember.  
I do and I understand. Chinese Proverb*

**Please note:** Information provided is only a guide for the workshop. Workshop content may be modified, in cases of unforeseen circumstances.



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