

present

Seminar on Product Stability & Workshop on Stability Prediction Tools

Venue: NUS, Singapore

28 – 30 June 2018

Objective:

The seminar and workshop will provide an opportunity for those involved in the design and manufacture of products to learn about quality-by-design (QbD) approaches for product substance stability in R&D from the experts. Topics related to moisture sorption, product stability and stabilization, packaging and testing will be discussed. The workshop will provide further hands-on experience with ASAP^{prime} software to predict substance and product stability, and packaging requirements in 2-4 weeks' test period. Collectively, participants will gain an in-depth understanding on the science of stability and tools to assess, protect and predict product stability.

Who Should Attend:

Personnel involved in R&D and manufacture of products – pharmaceuticals, herbal products, health foods, etc.:

- ✓ Early product development and preformulation
- ✓ Drug substance development and manufacturing
- ✓ Analytical development
- ✓ Production and packaging development
- ✓ Quality assurance/ Quality control
- ✓ Contract manufacturing
- ✓ Excipient marketers

Confirmed Seminar Presentations:

- Water sorption measurement and moisture in product stability
- Applications of vapor sorption with solid state emphasis
- Introduction to the ASAP^{prime} and its use in setting shelf-life
- Packaging for stability
- Formulation for stability: moving beyond excipient compatibility
- Materials sciences for pharmaceutical packaging
- QbD and FEM approaches for packaging design and development
- Spray drying and coating: Methods for API stabilization
- Novel high throughput protein formulation screening techniques for stabilization
- Enhancing the stability of moisture sensitive active
- Stability of herbal products - Challenges facing the manufacturer
- Forced degradation
- Analysis of extractives and leachables
- Elemental impurity testing in relation to the new USP and ICH regulations
- Oxidative instability and stabilization methodologies
- Biopharmaceutical and physical stability aspects of amorphous solid dispersions
& others

Speakers:

- Minh Hien HA, Institute of Drug Quality Control-HCMC
- Tze Ning HIEW, GEA-NUS PPRL
- Yogesh Kumar MISHRA, Roquette Asia Pacific
- Rangga PANDYAPRANA, Honeywell International
- Steven PANG, Agilent Technologies
- Dilwyn PATTERSON, GEA APC Pharma Solids
- Glenn RUSSELL, Colorcon Asia Pacific
- Joe SHEK, Labthink Instrument
- Lay Peng TAN, Agilent Technologies
- Likun WANG, HaiWei Technologies
- Kenneth C WATERMAN, FreeThink Technologies
& others

Programme:

Seminar

- 0830 – 1800 Hr, 28 – 29 June 2018

Workshop

- 0830 – 1300 Hr, 30 June 2018

Complimentary Networking Dinner

- 1900 – 2100 Hr, 29 June 2018

Scope of the Workshop:

The workshop will provide an opportunity to learn about ASAP^{prime}, the world's only commercial software for drug stability prediction:

- ✓ Experimental design & physico-chemical boundaries
- ✓ Analytical data input & degradation kinetics modelling with Monte Carlo simulations
- ✓ MVTR measurements for different packaging materials
- ✓ In-silico packaging selection & shelf-life prediction for varies storage conditions
- ✓ With hands-on examples on real-world drug potency & impurity data

Participants will be divided into small groups to attend the Workshop, lasting about 1.5 h per session.

Note:

- Course materials will be supplied.
- Daily lunches and teas will be provided on the Seminar days.
- Information provided is only a guide. Contents may be modified due to unforeseen circumstances.



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