

## Seminar on Product Stability and Predictive Tools by GEA-NUS, Singapore & FreeThink, US

Thursday, 28 June 2018

| Time          | Activity  |
|---------------|---|
| 08:00 – 08:30 | Registration  |
| 08:30 – 08:40 | Welcome address   |
| 08:40 – 09:30 | Water sorption measurement and moisture in product stability (Tze Ning <b>Hiew</b> , GEA-NUS)   |
| 09:30 – 10:20 | Applications of vapour sorption with solid state emphasis (Likun <b>Wang</b> , HaiWei Technologies)   |
| 10:20 – 10:40 | Tea break   |
| 10:40 – 11:30 | Introduction to the Accelerated Stability Assessment Program (ASAPprime) and its use in setting shelf-life (Ken <b>Waterman</b> , FreeThink Technologies) |
| 11:30 – 12:20 | Packaging for stability (Ken <b>Waterman</b> , FreeThink Technologies)  |
| 12:20 – 13:40 | Group photo and lunch   |
| 13:40 – 14:30 | Formulation for stability: moving beyond excipient compatibility (Ken <b>Waterman</b> , FreeThink Technologies)   |
| 14.30 – 15.20 | Materials sciences for pharmaceutical packaging (Rangga <b>Pandyaprana</b> , Honeywell)   |
| 15:20 – 15:40 | Tea break   |
| 15:40 – 16:30 | Spray drying and coating: Methods for API stabilization (Dilwyn <b>Patterson</b> , GEA)   |
| 16:30 – 17:20 | Quality control solution for pharmaceutical packaging (Joe <b>Shek</b> , Labthink Instruments)  |
|               | End of Day 1  |

**Friday, 29 June 2018**

| Time          | Activity  |
|---------------|---|
| 08:10 – 08:30 | Registration day 2  |
| 08:30 – 09:20 | Novel high throughput protein formulation screening techniques for stabilization (Yogesh Kumar <b>Mishra</b> , Roquette)                      |
| 09.20 – 10.10 | Enhancing the stability of moisture sensitive active (Glenn <b>Russell</b> , Colorcon)  |
| 10:10 – 10:30 | Tea   |
| 10.30 – 11.20 | Stability of herbal products - A challenge facing the manufacturer (Minh Hien <b>Ha</b> , Institute of Drug Quality Control-Ho Chi Minh City) |
| 11:20 – 12:10 | Forced degradation (Likun <b>Wang</b> , HaiWei Technologies)  |
| 12:10 – 13:00 | Analysis of extractables and leachables (Lay Peng <b>Tan</b> , Agilent)   |
| 13:00 – 14:00 | Lunch   |
| 14:00 – 14:50 | Elemental impurity testing in relation to the new USP and ICH regulations (Steven <b>Pang</b> , Agilent)                                      |
| 14:50 – 15:40 | Oxidative instability and stabilization methodologies (Ken Waterman, FreeThink Technologies)  |
| 15:40 – 16:00 | Tea   |
| 16:00 – 16:50 | Biopharmaceutical and physical stability aspects of amorphous solid dispersions (Likun Wang, HaiWei Technologies)                             |
| 16:50 – 17:30 | Panel Discussion  |
|               | End of Day 2  |
| 19:00 – 21:00 | Networking dinner   |
|               |   |

## Saturday, 30 June 2018

| Time                      | Activity      |
|---------------------------|---------------|
| WORKSHOP                  | By allocation |
| 08:30 – 10:00             | Session 1     |
| 10:00 – 11:30             | Session 2     |
| 11:30 – 13:00             | Session 3     |
| End of Seminar & Workshop |               |
|                           |               |

### Notes on Workshop

In the Workshop, attendees will have the opportunity to learn about:

- Experimental design with known physico-chemical parameters,
- Analytical data input and degradation kinetics modelling,
- Packaging selection and shelf-life prediction, and
- Examples on drug potency and impurity kinetics will be examined

The Workshop will provide the opportunity to work on the ASAPprime® software, which can help to solve some of the most difficult stability challenges; able to help speed up product development and avoid unnecessary package screening. The typical accelerated studies can typically be completed in weeks instead of months, and result in remarkably accurate predictions.

## **Biography of Speakers**

Minh Hien **HA**, Institute of Drug Quality Control-Ho Chi Minh City



HA Minh Hien has a degree in Pharmacy, a Master's degree in Pharmaceutical Science and a PhD degree in Drug Quality Control from University of Medicine and Pharmacy, Ho Chi Minh City. He is currently working at the Institute of Drug Quality Control in Ho Chi Minh City (IDQC-HCMC), Vietnam and is the Head of Traditional-Herbal Medicine Analysis Department. In 2007, he participated in the Study Programme on Manufacturing and Quality Control of Traditional Medicine held and sponsored by JICWELS in Japan. In 2010, he was awarded the Nagai Foundation International Fellowship to pursue his PhD research work in GEA-NUS Pharmaceutical Processing Research Laboratory-Department of Pharmacy-National University of Singapore.

Tze Ning **HIEW**, GEA-NUS PPRL



Hiew Tze Ning holds a degree in Pharmacy and graduated earlier this year with a PhD degree in Pharmaceutical Technology from the National University of Singapore. She is currently a post-doctoral fellow in GEA-NUS Pharmaceutical Processing Research Laboratory, where she continues to pursue her interest in improving formulation and process understanding. In her doctoral thesis, Tze Ning examined the effect of water activity changes on the performance of pharmaceutical excipients, and has research publications in peer-reviewed pharmaceutical journals. Her study on water activity has won her several regional and international awards, including the 2017 IPEC Foundation Graduate Student Award.

Yogesh Kumar **MISHRA**, Roquette Asia Pacific Pte Ltd



A Bio-pharmaceutical process development and manufacturing expert with over 10+ years' experience. Providing strategic and technical guidance related to technical development, scale-up, process characterization, technology transfer, analytical method development and validation for wide range of biologics. Strong understanding of technical and regulatory requirements of Biopharmaceuticals and Vaccines. Experience in purification and high throughput excipient screening, knowledge of various characterization/analytical techniques. Expert of using DOE & QbD principles to develop and optimize final downstream and formulation, extensive experience of different stress testing protocols.

Rangga **PANDYAPRANA**, Honeywell International



A young professional with an entrepreneurial mind and hands-on knowledge of new business and market development, corporate strategic framework, and financial modeling of a multinational company. A strategic thinker and problem solver with leadership quality for achieving challenges and goals, including managing multi-disciplinary, cross regional and cultural teams targeting for growth. Having +10 years experiences in multinational companies and now developing material sciences product for Honeywell into the market. Currently focusing to promoting Aclar solution for pharma industry as a moisture barrier solution which also brings total cost efficiency for pharma companies.

Steven **PANG**, Agilent Technologies Singapore



Steven Pang is presently Agilent's Spectroscopy Business Manager for Singapore and IDO. He joined Agilent Technologies in 2010 as an ICP-MS Applications Chemist. Steven has extensive work experience in the field of Instrumental Analysis, and has previously worked for a multinational testing laboratory, and prominent analytical instrumentation companies. Steven holds a B.S. (Cum Laude) in Biology and Chemistry from Campbell University, USA, M.Phil. (University Malaya), and M.B.A. (University of South Australia).

Dilwyn **PATTERSON**, GEA APC Pharma Solids



Dilwyn Patterson was educated at the University of Manchester, UK where he graduated with a PhD in materials science. He currently has the position of Senior Product & Process Manager, GEA APC Pharma Solids for batch granulation and coating technologies. He provides technical support for the design and operation of batch processing equipment and systems. The role also incorporates on site trouble shooting and providing assistance to optimise customers' processes. His previous jobs include Sales Manager the UK and Ireland, 1989 – 1994 for Asia and Australasia, 1994- 1999 and 2000 – 2017 for Japan, South Korea and Taiwan. From 2017 to date he is the Product Manager and Senior Process Specialist for batch granulation, coating and pelletising. Dilwyn has worked with the pharmaceutical industry for more than 25years supplying granulation, drying, pelletizing and coating equipment and systems and during this time has gained considerable experience in each of these technologies. He regularly gives lectures / presentations at seminars and academic courses.

Glenn **RUSSELL**, Colorcon Asia Pacific, Singapore



Mr Glenn Russell graduated from University of Technology, Sydney, Australia in 1985 with a Degree in Applied Chemistry (First Class Honours). He was employed by Pfizer Australia for 13 years in the areas of quality control, product development and manufacturing (solid and liquid dosage forms). He joined Colorcon Asia-Pacific in 1994 as Area Technical Manager based in Singapore, providing technical support to the pharmaceutical industry throughout South-East Asia in the areas of film coating, modified release and core tablet formulation. In August 2006, Glenn was appointed as Technical Director, Colorcon Asia-Pacific, leading the technical team in the Asia Pacific region. He is currently based in Singapore and travels extensively throughout the Asia Pacific region.

Joe **SHEK**, Labthink Instrument, China



Labthink specializes in manufacturing of innovative material testing instruments used in packaging, pharmaceutical, food, daily chemical, since 1989. Our portfolio comprises of water vapor transmission rate tester, oxygen transmission rate tester, gas permeability tester, migration & non-volatile-matter content tester, tensile tester, heat sealer, headspace gas analysis, impact testing, compressive strength testing etc.

Lay Peng **TAN**, Agilent Technologies, Singapore



Tan Lay Peng is the Applications Chemist, for GC and GCMSD. She has been with Agilent since March 2000 and was working as a trainer until March 2008. She has delivered training courses on the operation, maintenance and troubleshooting of GC and GCMSD for customers. Previously, she was a Senior Chemical Engineer for Western Digital Singapore and was in charge of chemical analysis of incoming components for the hard disk drive. She graduated from the National University of Singapore with a Bachelor Degree in Chemical Engineering and a Master of Science in Materials Science & Engineering.

Likun **WANG**, Nanjing Haiwei Technologies, China



Likun Wang obtained his bachelor's degree from Zhejiang University and PhD from National University of Singapore. He joined Johnson & Johnson R&D in Belgium as Research Scientist in 2011 where he played key roles in designing and developing a number of successful drug products, apalutamide and ibrutinib among others. He then led the preformulation team in Johnson & Johnson R&D from 2014 as Senior Scientist and group leader. Dr Wang joined Jiangsu Hengrui Medicine Co. Ltd. as Site Director of Hengrui Nanjing Research Institute in 2015 where he successfully saw to the development of more than 10 NCEs and 5 super generics. Dr Wang has more than 30 peer-reviewed journal publications, several patent filings and had made many invited presentations. In 2018, Dr Wang founded Nanjing Haiwei Technologies, a company focusing on drug stability prediction, NCE feasibility and developability assessments.

Kenneth C. **WATERMAN**, FreeThink Technologies, USA



Ken Waterman received his B.S. degree with honors in chemistry from UCLA, his Ph.D. in physical-organic chemistry from UC Berkeley and conducted post-doctoral studies in physical and photo-chemistry as an NIH research fellow at Columbia University. Dr. Waterman worked 12-years at Polaroid (as a distinguished scientist) developing imaging products, then 13 years at Pfizer (as a Research Fellow) working on drug stability, drug delivery, biopharmaceutics and prodrugs. He is the author of over 75 publications and was made an AAPS Fellow in 2011. In 2011, he started FreeThink Technologies which both produces and licenses the accelerated stability software package ASAPprime® and is a CRO that has Connecticut-based laboratories specializing in stability for pharmaceuticals, generics, OTCs, nutraceuticals and consumer products.