

Analytical Method Validation and Process Validation Seminar

Day 1 – 24th September 2014 (Wednesday)

PROGRAM

8:00 – 9:00	Registration
9:00 – 9:15	Welcome & Opening - by Mr Tan Ann Ling, Director of NPCB
9:15 – 10:15	Introduction on Analytical Method Validation (AMV) Documents Submission Guidelines and Common Problems - by Pn. Suhaili Binti Samad

SESSION 1: Analytical Method Validation – Chemical

Session Moderator: Ms Jaclyn Lee, PhAMA

10:15 – 11:00	Brief Introduction on Assay, Dissolution and Related Substance AMV Common Problems 1 - by Pn. Ooi Suat Hong
11:00 – 11:20	Coffee / Tea
11:20 – 12:05	AMV Common Problems 2 - by Cik Tan Shiau Yi
12:05 – 12:50	AMV Common Problems 3 - by Cik Ooi Wei Yen
12:50 – 2:20	Lunch
2:20 – 3:05	Q & A (Chemical) – All speakers from Chemical section

SESSION 2: Analytical Method Validation – Microbiological

Session Moderator: Ms Loh Kiaw Moi, MOPI

3:05 – 3:50	BET & Common Problems – by Pn. Latifah Binti Ahmad Zawawi
3:50 – 4:15	Coffee / Tea
4:15 – 5:00	Q & A – BET & Common Problems

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National Pharmaceutical
Control Bureau (NPCB)
Ministry of Health Malaysia

Day 2 – 25th September 2014 (Thursday)

SESSION 2: Analytical Method Validation – Microbiological (Continue)

Session Moderator: Ms Loh Kiaw Moi, MOPI

8:00 – 9:00	Registration (Morning Coffee / Tea)
9:00 – 9:45	MCT & Common problems – by Pn. Tan Chin Ling
9:45 – 10:10	Coffee / Tea Break
10:10 – 10:55	Sterility & Common Problems – by Pn. Tan Chin Ling
10:55 – 11:30	Q & A (All Speakers from Microbiological section)

SESSION 3: Process Validation

Session Moderator: Ms Chong Siew Mei, MAPS

11:30 – 12:15	Overview on ASEAN Guideline on PV Requirements Process Validation Scheme for Solid Oral Dosage Products (non-sterile products) - by Pn. Nasyrah Amalina Binti Sarginan
12:15 – 1:00	Process Validation Scheme <ul style="list-style-type: none">▪ For Aseptically Processed Products▪ For Terminally Sterilised Products - by En. Kok Chuan Fung
1:00 – 2:30	Lunch
2:30 – 3:15	General Considerations before submitting PV Data <ul style="list-style-type: none">▪ Checklist▪ Q & A of ASEAN Guideline on Process Validation▪ Case Study / Common Problems - by Cik Lim Jia Ai
3:15 – 4:00	Q & A (Process Validation)
4:00 – 5:00	Closing Coffee / Tea

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