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

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

Common Problems - by Pn. Suhaili Binti Samad

11:20 – 12:05	AMV Common Problems 2 - by Cik Tan Shiau Yi
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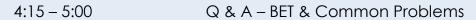
12:50 - 2:20	Lunch
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- All speakers from Chemical section

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 Zawa	
3:50 – 4:15	Coffee / Tea	







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Day 2 – 25th September 2014 (Thursday)

SESSION 2: Analytical Method Validation – Microbiological (Continue)

Session Moderator: Ms Loh Kiaw Moi, MOPI

8:00 – 9:00	Reaistration (Morning Coffee / Tea)
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- by Pn. Tan Chin Ling

10:55 – 11:30 Q & A (All Speakers from Microbiological section)

SESSION 3: Process Validation

Session Moderator: Ms Chona Siew Mei, MAPS

Process Validation Scheme for Solid Oral Dosage

Products (non-sterile products)

- by Pn. Nasyrah Amalina Binti Sarginan

12:15 – 1:00 Process Validation Scheme

For Aseptically Processed ProductsFor Terminally Sterilised Products

- by En. Kok Chuan Fung

1:00 - 2:30 Lunch

2:30 – 3:15 General Considerations before submitting PV Data

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





