A 2-Day Interactive & Practical Workshop

Interactive discussion is a key feature and input from attendees is encouraged

http://www.ibc-asia.com/processvalidation.htm

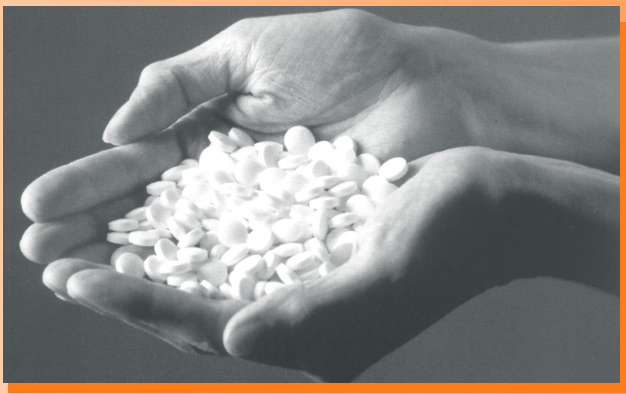
USA FDA's DRUG PROCESS VALIDATION & DRUG APPLICATIONS

Held At 2 Conveniently Located Venues

3 - 4 December 2001, Singapore ■ 6 - 7 December 2001, Hong Kong

OBJECTIVES

- LEARN the current OGD process validation requirements, practice and protocols for a successful product approval.
- GAIN an in-depth view of drug process validation principles & current concepts acceptable to the FDA for the Process Validation of Drug Products.
- OBTAIN a detailed knowledge on how to write a validation protocol and sampling plans
- ESTABLISH the procedures on how to create a validation report and the statistical comparisons the FDA expect to see
- ESTABLISH the key requirement of successful process validation technology
- PREPARE the Validation Test Results, Data Tables, and Validation Report to meet current FDA expectations.
- REVIEW Solid, Semisolid, and Liquid Validation written protocols and control procedures.
- DETERMINE Type of data needed to support any FDA drug submission
- ORGANIZE a successful drug submission
- OBTAIN detailed knowledge on how to write, prepare and assemble drug submission in line with FDA's expectations.
- IDENTIFY common mistakes made by foreign manufacturers in filing a drug submission with the FDA.
- REVIEW a model drug submission to understand why it is successful



WHO SHOULD ATTEND

Specially designed for drug manufacturing professionals who are involved in drug process validation and USA FDA drug product submissions.

- ✓ Manufacturers – Brand & Generic Pharmaceuticals as well as Traditional Medicine
- ✓ R&D Scientists For New Innovative Drugs
- ✓ R&D / QA / QC Process Validation Engineers Managers / Supervisors
- ✓ Heads/ Managers / Supervisors of Product Development and Production
- ✓ Regulatory Division, Heads and Managers
- ✓ Managers, Regulatory, Product and Analytical Development
- ✓ Documentation Managers, Supervisors and Technicians

will benefit the most from this workshop.

Organised by:

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WHY YOU SHOULD ATTEND

Drug Process Validation is a key requirement for drug submission to the USA FDA to obtain regulatory and marketing approvals. Since countries around the globe seek to adopt or adapt the high standards set by the USA FDA within their own regulatory systems, the knowledge gained in this workshop would help you prepare your plant for the time these standards become mandatory.

In addition, this workshop will also review the requirements for the different types of drug submissions and the series of supporting and collaborative documentation necessary for drug approval.

Attendees will gain knowledge through a hands-on approach in treating the subjects. Throughout the course, emphasis will be placed on interactive case studies and team role involvement in meeting the course objectives. The protocol writing session will allow you to master the salient aspects of drug process validation.

On completion of this workshop you will have gained an understanding of the most current FDA requirements and complexities of the US Drug Process Validation and Drug Application Process. You will fully appreciate the FDA requirement for process validation and recognize that there is no 'short cut ' in achieving drug approval.

ABOUT YOUR WORKSHOP DIRECTOR

Dr. Jeremy Block has over 30 years' of international experience in pharmaceutical industry with specialized knowledge in pharmaceutical drug development, analytical and process validation and US Drug Submissions. He qualified at Witwatersrand University with a B.Sc. (Ind. Chem.), M.Sc. (Pharm.), and D. Pharm. A prolific drug researcher in innovative and generic technologies, he has published the well known authoritative 24 Volume Handbook on Pharmaceutical Drug Development used globally in the pharmaceutical industry, Research institutions as well as graduate and undergraduate university courses.

He has established and directed Drug Development, QA, Production and Validation functions in industry.

Dr. Jeremy Block has published over a hundred original scientific papers in the areas of pharmaceutical drug development, process validation and drug application submissions.

As a former associate professor of pharmaceutics he has been an invited speaker at numerous industry and government symposia, conferences and workshops covering major aspects of industrial pharmacy technology, guidelines, scale-up and commercial processes. A fellow and founder member of several pharmaceutical association in RSA, UK and USA. He is presently President of IAGIM Drug Development Association and Chief Scientific Officer for Locum International Group, Basel Switzerland.

USA FDA'S DRUG

3-4 December

http:/

Day One 3rd / 6th December 2001

0700 **Coffee & Registration**

0830 **Drug Process Validation Part I**

- Overview - The Process Validation System and acceptance criteria
- General Validation Principles and Guidelines – Validation Master Plans.
- The FDA Regulatory Environment and meeting the FDA expectations in Process Validation.
  The Validation Life Cycle.
- Brief Outline – of the different stages in Drug Process Validation from formulation to commercial manufacture.
- FDA's Principles and Regulation of Drug Process Validation Requirement
- Current Validation SOPs and content.
- Meeting the FDA expectations in Process Validation today.

1000 **Morning Refreshments**

1030 **Drug Process Validation Part II**

- The Installation , Operation , Performance Qualification.
- Validation of the HVAC system, Computers and High Purity Water Systems.
- Pharmaceutical Quality Control Laboratories and Analytical Validation
- The Validation Requirements and Specifications.
- **Case Study:**
  Retrospective Validation – Oral IR Tablet.
- **Case Study:**
  Concurrent Validation – Topical Semisolids.
- **Case Study:**
  A Prospective Validation – Modified Release Tabs/Caps.

1230 **Networking Luncheon**

1330 **Drug Process Validation Part III**

- Validation of Sterile and Non Sterile Drug Products.
- Major dosage form validation protocols and key differences.
- Validation Test Methods and Results.
- **Case Study:** - Validation Reports and Statistics.
- Analytical Validation requirements –
  Seven Essential elements.

- Cleaning Validation Requirements, Methodology, and Recovering Testing Techniques, How clean is clean – limits?
- Revalidation Requirements and Life cycles.

1530 **Afternoon Refreshments**

1600 **Drug Process Validation Part IV**
- Scale-up and Process Validation For Finished Pharmaceuticals
- Tablets, Capsules, Liquids, Suspensions and Semisolid Topical Applications
- ROLE PLAY :- Establish the key overall requirement for Finished Drug Products.
- **Case Study:** - Preparing written validation protocols and sampling plans Understanding Validation Test Results and how to present them to the FDA.

1730 **Q&A and End of Day 1**

Day Two 4th / 7th December 2001

8.00 **Registration**

0830 **Drug Process Validation Part V**
- The Test Data and Results – Out of Specifications and Impact.
- Technology Transfer Documents and Development Reports
  ROLE PLAY:- Interpreting the validation laboratory results and test data Compiling tables, graphs and reports.
- Do's and Don'ts in Drug Process Validation, using PV checklists.
- Tips and Traps & Past Industrial Process Validation Experience.

1000 Morning Refreshments
Drug Submissions I
- Current FDA Drug Regulations and expectations for file submissions
- Outline of the various application types and their content.
- Organizing and preparing successful submission presentations.
- The Drug Application submission similarities and differences.

1230 **Networking Luncheon**

1330 **Drug Submissions II**
- Key Requirements for:
- Investigational New Drug Applications (IND)
- New Drug Applications (NDA)
- Abbreviated New Drug Applications (ANDA) and Super ANDAs
- OTCs and Natural & Herbal Remedies
- Developing the CMC Sections of an IND, NDA, ANDA and OTC.

1530 **Afternoon Refreshments**

1600 **Drug Submissions III**
- **Case Study:**
  - Preparing a solid oral dosage Form drug submission for tablets and capsules.
- Tips and Traps on file submission - Past Industrial Experience.
- Essential submission data and supportive data that can be omitted from filing
- Establish the key requirement of successful ANDA.

ROLE PLAY:
- Do's and Don'ts in IND / NDA / ANDA / OTC drug submissions.
- Using Audit, Checklists and Flowcharts to monitor and evaluate completed drug submission files.

- Q&A and Conference Summary

1730 End of Workshop

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EARLY BIRD FEE (for registration and payment before 12 November 2001)	US$ 1295 / S$ 2272 S$2,340.16 (w GST)	US$ 1395 / S$ 2447
REGULAR FEE	US$ 1495 / S$ 2623 S$2701.69 (w GST)	US$ 1595 / S$ 2796

Fee is nett and exclusive of all taxes. Fee includes participation in all luncheons, refreshments and a complete set of workshop documentation. It does not include the cost of accommodation and travel.

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Third and subsequent delegates from the same company and billing address will receive a 20% DISCOUNT OFF REGISTRATION FEES

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Cancellations received in writing before 12 November 2001, will be refunded less **US$200/S$357** administration fee. Thereafter, cancellations are not refundable although participants may be substituted at any time.

HOTEL INFORMATION

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581 Orchard Road. Singapore 238883
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Contact Person: Terence Tan

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