

HOLD YOUR DATES

CAPA, Failure Investigations

05-06, September 2011, Mumbai
08-09, September 2011, Hyderabad
Workshop Leader

- Karen Ginsbury
- Dr. Shailesh Nagarsenkar

Synopsis

In addition to the enforcement of QRM and ICH Q8,9,10, it is also now a mandatory requirement to establish CAPA procedures and a concrete CAPA System. This workshop aims to obtain clarity on practical aspects, on how to implement CAPA, establish a CAPA System and procedures in accordance with the revised regulatory requirements. In addition, participants will work in groups for the scope of measures, formality and documentation of the necessary CAPA measures as the result of risk assessment.

Critical Utility Systems : Water and HVAC Systems in Pharma Manufacturing

18-19, October 2011, Mumbai
21-22, October 2011, Hyderabad
Workshop Leader

- Paolo Curto
- Rasendu Shah

Synopsis

This Workshop will explore Pharmaceutical Air and Water, with an overview from the EU cGMP / EMEA, US cGMP / FDA/USP, as well as from international cGMPs / WHO and PIC/S. The objective of this workshop is to focus on Water, Steam and HVAC Systems as critical aspects impacting Pharma Manufacturing, with practical illustrations, real-life examples and case studies. The Workshop material is updated as per current 2011 Regulatory Requirements

Development and Validation of Analytical Methods

15-16, November 2011, Mumbai
18-19, November 2011, Hyderabad
Workshop Leader

- Raphy Bar

Synopsis

This course will concentrate on the design of analytical methods, and incorporating quality aspects into it for successful validation. The aim of the course is to learn how to develop a particular method and to bring it successfully to a "validatable" state. Participants will work on a live development and validation exercise thus getting a hands-on experience on implementing learnt principles at their workplace.

****Please Note :** The program topics and speakers were confirmed at the time of publication. However, circumstances may necessitate substitution, alteration or cancellation of program, speakers or topics, without prior notice.

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“MRP – DCP and CTD: Applications for Marketing Authorisations in the EU and US”

Re-scheduled to December 2011,
Mumbai, Hyderabad
Workshop Leader

• **Dr. Ahilan Nithiananthan**

Synopsis

Since Indian companies are already exporting heavily to US and EU, we are well aware and experienced in the regulatory requirements and procedures. However, the objective of this workshop is a brief revisit of essential principles; but more focus on practical issues, trouble-shooting, problem-solving, FAQs, Learning from common mistakes, real cases, examples, etc.

Process Validation : Understanding the Nuances

16-17 January 2012, Mumbai
18-19 January 2012, Hyderabad
Workshop Leader

• **Karen Ginsbury**

Synopsis

FDA's Center for Drug Evaluation and Research (CDER) has revised the Process Validation Guidance since January 2011. This course will attempt an in-depth understanding of the purpose of process validation, right from design control up to ongoing process and product performance monitoring; where process validation is headed – from the regulatory standpoint - and provide a roadmap for moving forward – from your perspective.

Excipients and Packaging Materials : Regulatory Updates and Compliance Issues

February 2012, Mumbai, Hyderabad
Workshop Leader

• **Allan Whiston**
• **Perviz Menesse**

Synopsis

The Pharmaceutical Quality Group UK (PQG) launched an updated standard PS 9000, on packaging materials in September 2011. In addition, IPEC Europe will launch ExiPack in January 2012. This will provide GMP and GDP annexes for ISO 2000 for manufacturers and distributors of Excipients. These are huge steps forward in bringing a standardised approach to Excipients and are widely supported by regulators worldwide, European as well as American.

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