



Current Best Practices in International Good Manufacturing Practices workshop

22nd, 23rd, 24th Nov 2009, Dubai-U.A.E



International pharmaceutical regulations and cGMPs are complex and extensive “rules” that must be implemented effectively to maintain GMP licensing. Regulations and their interpretation differ between different regulatory agencies such as FDA, EMEA and PIC/s however over the last 5 years these have become much more aligned. This program will present the international best practice for several current GMP hot topics, such as quality management systems, control over critical utilities (HVAC and Water), effective cleaning validation and compliant laboratory OOS investigations.

***Under patronage of
Arab Union of the Manufacturers of Pharmaceutical and Medical
Appliances (AUPAM)***

Naratech and Seerpharma would like to invite you to attend this important course which will be presented as six workshop based modules:

- ▶ **International GMPs and Principles of Quality Management**
- ▶ **Documentation Systems and Practices - GMP Requirements & Control**
- ▶ **HVAC and Controlled Environments - control and qualification**
- ▶ **Pharmaceutical Water Systems: Design, Control & Validation**
- ▶ **Cleaning Validation**
- ▶ **Handling Out of Specification Conditions**

Course Objectives: On completion of these workshops participants will be able to:

- ▶ Describe and explain the historical development and current best practices in international cGMPs
- ▶ Prepare practical and compliant procedures and validation protocols
- ▶ Audit, validate and manage critical pharmaceutical systems such as HVAC and Pharmaceutical Water systems.
- ▶ Set up or evaluate environmental monitoring programs for cleanrooms
- ▶ Conduct compliant cleaning validation programs
- ▶ Successfully manage laboratory out of specification (OOS) conditions

Format

The course consists of a mix of expert presentations, case studies and interactive Q&A. An extensive participants manual including copies of all presentation slides and handouts will be provided.



Program details

Time	Presentation
Day #1 Morning	<p>International GMPs and Principles of Quality Management</p> <p>Regulators now expect that all companies have in place an effective quality management system (QMS) in compliance with the cGMPs applicable to their markets. This topic presents the historical evolution and current requirements in GMPs internationally.</p> <p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Describe the historical developments of cGMPs (FDA, PIC/S, EU/MHRA and ICH) and their evolution into international compliance programs. ▶ Explain the differences between regulations, codes of practice & guidance. ▶ Review fundamental requirements for GMPs & the obligations of manufacturers and managers. ▶ Interpret the requirements of different regulatory agencies
Day #1 Afternoon	<p>Documentation Systems and Practices - GMP Requirements & Control</p> <p>A fundamental cGMP requirement is that licensed manufacturers maintain documentation and records to support the compliance of manufactured products.</p> <p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Explain the structure of GMP documentation, expected format & control. ▶ Explain the relationship between Manuals, Policies, specifications, SOPs, Work Instructions, Records & other supporting documentation. ▶ Develop a model hierarchical documentation system based on ISO 9000. ▶ Link training plans and strategies to compliant documents ▶ Describe the importance of documents & records during GMP audits.
Day #2 Morning	<p>HVAC and Controlled Environments - control and qualification</p> <p>This module discusses best practice facilities design and operation, the standards for HVAC and cleanrooms and how products are protected from cross contamination.</p> <p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Explain key design requirements for controlled manufacturing environments ▶ Develop regulatory requirements for HVAC systems & environmental monitoring ▶ Successfully manage the validation of HVAC systems ▶ Explain the theory of particle filtration
Day #2 Afternoon	<p>Pharmaceutical Water Systems: Design, Control & Validation</p> <p>Pharmaceutical water systems are a critical utility that impacts the quality all products. Correct design, validation, management and monitoring are fundamental requirements in ensuring a compliant water system.</p> <p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Understand the requirements for design, validation & control of pharmaceutical water systems according to current cGMPs. ▶ Be familiar with water system validation guidelines, IQ, OQ & PQ requirements, current BP/USP standards & microbiological controls.
Day # 3 Morning	<p>Cleaning Validation</p> <p>Cleaning validation is one of the most difficult cGMP requirements to comply with. This topic includes a review of FDA and EU/PICs regulatory expectations. It discusses, with examples, current industry practices and compliance strategies.</p>

	<p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Interpret regulatory requirements and guidelines. ▶ Establish residue limits and calculate sample acceptance criteria to define clean. ▶ Select sampling and analytical methods to measure cleaning. ▶ Prepare cleaning validation protocols
Day #3 Afternoon	<p>Handling Laboratory Out of Specification (OOS) Conditions</p> <p>This module covers the cGMP requirements for managing laboratory out of specification conditions and includes a review of FDA and EU/PICs expectations.</p> <p>Learning outcomes and benefits: On successful completion of this topic, participants should be able to:</p> <ul style="list-style-type: none"> ▶ Explain the origin of out of specification rules ▶ Interpret accurately the FDA guidance for OOS situations ▶ Develop SOPs and records for OOS management ▶ Explain category 1 – 4 OOS conditions ▶ Effectively investigate OOS conditions

SeerPharma Pty Ltd*



Presenter: Steve Williams – Director SeerPharma Pty Ltd:

39 years experience in the Pharmaceutical, Biotechnology, and Medical Device industries in Quality Assurance, Manufacturing and Consulting. He has conducted numerous FDA and EU/ TGA/PICs compliance audits and gap analysis for many international companies as well as developed multiple training courses for GMP, GLP, Validation, Risk Management, HACCP and Quality Assurance. Steve also regularly presents at international conferences and seminars on a range of subjects relating to QA, Risk Management and GMP compliance. He is also the current serving chairman of the ISPE Professional Certification Commission (CPIP initiative).

Naratech Pharmaceutical Consultancy Est. **



Presenter: Dr. Nadia ARA Ghazal

Director Naratech Pharmaceutical Consultancy Est.

Holds a PhD degree in Pharmaceutical technology and masters degree in biotechnology from UK, and gathered 20 years of experience in pharmaceuticals manufacturing according to FDA, EU cGMP standards and in famous pharmaceuticals manufacturing companies. She has gained a track record for dynamic involvement in launching systems in pharmaceuticals finished products development business aligned to current EU/ FDA cGMP standards. Secured significant approvals related to pharmaceutical industry benchmarks. Involved in significant laboratory designs including the launching of validation protocols. Also, developed competitive pharmaceutical dosage forms of quality including super bioequivalent products.

Who will benefit:

The course is designed to service a wide range of participants from specific disciplines within the pharmaceutical industry. Participants wishing to enhance their professional development and advancement in pharmaceutical management are particularly encouraged to apply. Typically, participants will be biopharmaceutical managers who are responsible for **quality assurance, quality management systems, compliance programs, auditing and validation.**

This subject is specifically designed for participants who have prior knowledge in GMP compliance, quality assurance, validation and auditing practices, or those considering working in the pharmaceutical or biotechnology sectors.

More Information:

Call (0096265816575) **Fax** (0096265816871)

Payment Details/ Fees:

1. Registration fees: \$1150 / per person
2. Early bird registration (up to the 20th of October) \$990 / per person
3. Add 10% discount for 3 or more participants from the same company
4. 10% discount for AUPAM members
5. Fees should be paid in advance to confirm the registration
6. Dead line for registration: 10th of November.

Mail your check to:

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*SeerPharma is a global Life Sciences organization, with offices and affiliates in **Australia, Singapore, UK, Korea** and the **USA**. SeerPharma has successfully provided GxP related training and integrated consulting solutions to the pharmaceutical, biotechnology and medical device industries for over 20 years. SeerPharma is committed to enhancing the ongoing professional development of industry Quality and Compliance professionals and other stakeholders through expert professional short courses and post graduate accredited training programs. SeerPharma assures **Confidence in Compliance**.

** Naratech is a global Pharmaceutical consultancy firm based in **Jordan**, assisting Pharmaceuticals manufacturing facilities and drug distributors in MENA region and Gulf area in complying to FDA/Eu cGMP and GSDP practices and current global guidelines. We assist Pharmaceuticals manufacturers and distributors to deliver safe- effective drugs to the customers by adhering to higher global standards. We provide our customers with consistently high standards of performance in the area of cGMP, GSDP that add value to the quality of our customers products, and ensure safe, effective drug products in the hands of the consumer.