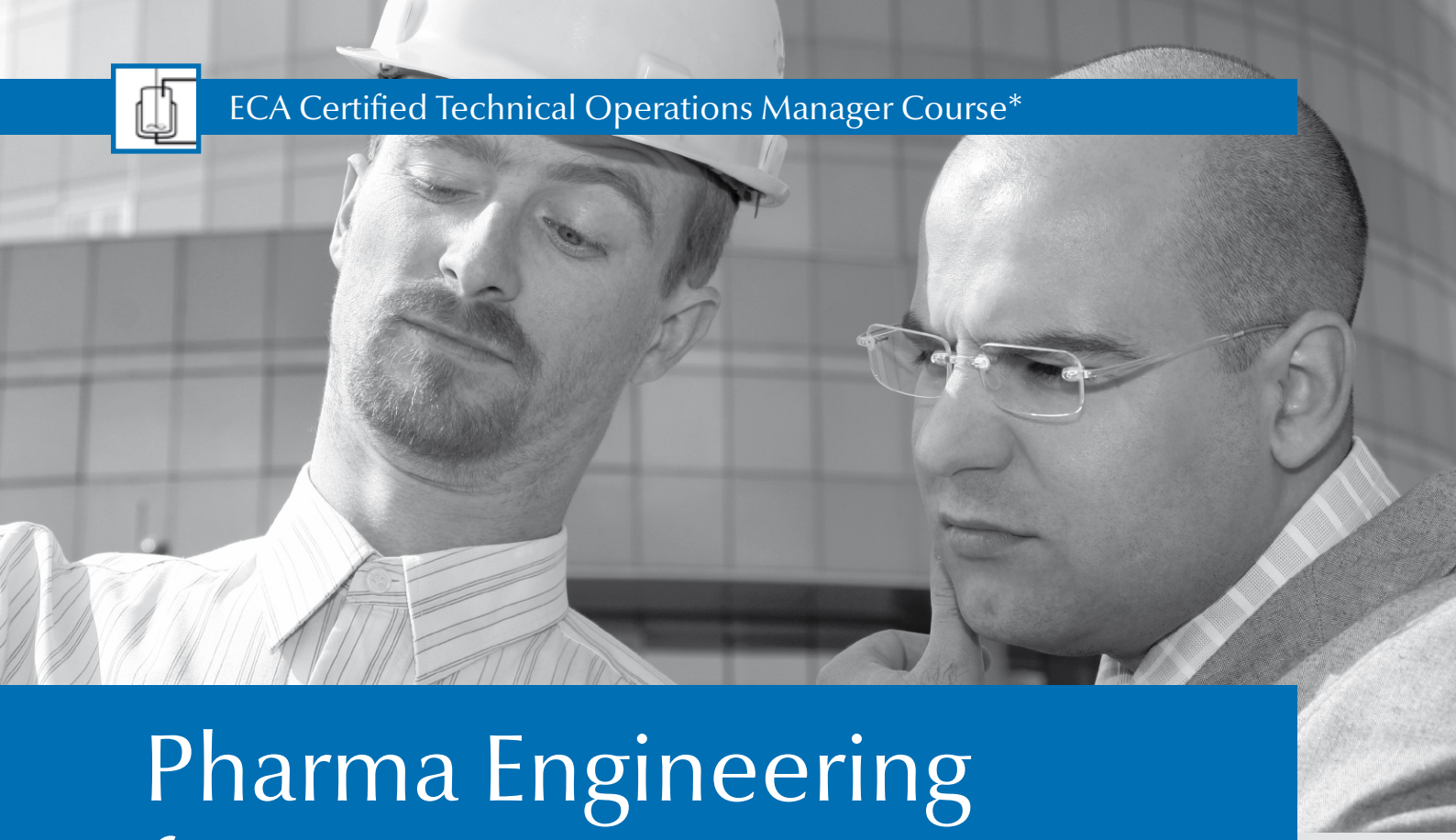
ECA Certified Technical Operations Manager Course*



Pharma Engineering for Non-Engineers

Pharmaceutical Utilities, Equipment, Facility

3 - 4 November 2010, Vienna, Austria

SPEAKERS:

Gordon Farquharson
Critical Systems Ltd.

Dr Gerhard Hauser
European Hygienic Engineering and Design Group (EHEDG)

Dr Jean-Denis Mallet
Formerly Head of the French Pharmaceutical Inspection Department

Wolfgang Rudloff
GMP-Experts

LEARNING OBJECTIVES:

- Technical Documenation: Principles of P&IDs
- GMP compliant Equipment
  - Materials, cleanability & corrosion
  - Working principles of valves & pumps
- Filters and media
  - Specifications and maintenance
- GMP-compliant Water Systems
  - Manufacture of different qualities
  - Components of a water system
- Clean Room Technology
  - HVAC Working principles
  - Zone Concepts
  - Qualification
- GMP Facility
  - Clean room walls, ceiling and floor
- QA aspects of engineering
  - Quality critical areas
  - Auditor's expectations and findings

ECA
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

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Learning Goals

Auditors, QA and Production Manager will gain an intensive knowledge in Pharmaceutical Engineering and Technology. This course does not focus on how a qualification is set up, but on understanding the working principles of equipment which has to be qualified.

Background

Engineering and technology are no longer the sole fields of engineers. Today, it is daily business for production and QA units to deal with technology issues and to make decisions in engineering matters. For instance, technological details are viewed and challenged after an inspection of the quality system in an audit. The same matters are discussed in interdisciplinary qualification teams that have to find GMP compatible solutions. Another example for non-typical issues for the QA unit is the release of technical changes.

It is therefore very important to understand the technical fundamentals and GMP-relevant details. This is the basis for asking adequate questions, making the right decisions and for avoiding technically originated problems.

The training course gives answers to questions like

- How to produce water in different pharmaceutical qualities?
- How does a HVAC system work and when is recirculation or fresh air operation reasonable?
- How do pumps and valves work and how can they cause sterility problems?
- How to decide on the right material for pharmaceutical equipment and how should surfaces be treated?
- How to choose the right clean room walls, ceiling and floor?
- How often do air or gas filters have to be exchanged and how do they have to be maintained?
- How can inspection findings in the technical environment be avoided?

Target Group

This education course targets staff from production and QA units who are confronted with technical questions in projects or daily business. It aims at giving a basic understanding of pharmaceutical engineering and technology. Suppliers who have to meet the demands of their pharmaceutical clients are also targeted with this course as well as GMP Inspectors.

Moderator

Gordon Farquharson

Programme

Reading and Understanding of P&IDs

- Types of technical drawings
- Systematic of P&IDs
- Symbols used in P&IDs
- Examples

Mainly applied Materials

The knowledge of the most important metals, plastomers and elastomers is needed as basis to understand the requirements of hygienically designed equipment. This part will contain:

- Standardized names, composition, and important properties
- Effects of corrosion, failures, and damage
- Required roughness and cleanable structure of surfaces

For product contact areas in the pharmaceutical industry, the highest level of "Hygienic Design" will be required to avoid risks by unsatisfactory cleanability and to get clean areas for sterilisation. Therefore, it is evident, even for non-engineers, to know about the principal properties of materials and surfaces of equipment as well as of components like valves and pumps.

Design of valves:

Valves are the main elements to shut off, to divide and to adjust the flow of liquid products. This part will give an overall view of some important construction for sterile and non-sterile applications. An important aspect of cleanability is connected to the static and dynamic sealing. Particularly, the following types and aspects will be discussed:

- Butterfly valves
- Diaphragm and bellow valves
- Ball valves
- Block and bleed arrangement of valves

Construction of pumps:

Dependent on the properties of fluids different pumps are used in the pharmaceutical industry to generate the necessary pressure for flow. The design contains the different types of impellers, housings, and static and mechanical seals. The following types for different applications (e.g. low and high viscous fluids, non-sterile and sterile use) will be compared and their arrangement be discussed:

- Centrifugal pump
- Hose pump
- Excentric screw pump
- Rotary pump

Fundamentals of Water Treatment

- Influence of raw water
- Schematic water generation: Aqua Purificata, Destillation
- Components: working principles and hazards (Softening, EDI, RO,...)
- What to measure and to control (where and why)?

Storage and Distribution of pharmaceutical water

- Loop concepts
- What to measure and control (physical and chemo-physical)
- Modern sanitisation concepts, avoidance of biofilms
- Influence of water consumers
- How to handle OOS in a water system

Clean Media

- Steam, Gas, Air
- Filters and maintenance
- Condensables gases

Basics of ventilation and air-conditioning technology in the pharmaceutical industry

- Basics of cleanroom contamination control technology
- Protection concepts, types of air flows
- Cleanroom standards, cGMP Regulations, and their interaction
- Filter technology
- User Requirements - URS, Room parameters, design criteria
- Simulation of air flow - role of CFD
- Some HVAC system concepts-comparison fresh air / recirculating air
- Implementing the Design
- Qualification of facilities and Validation of processes.
- Practical examples will be used to illustrate the presentations.

Clean Room Walls, Ceiling and Floor

- Comparison of the different types of clean room wall systems
- GMP criteria for walls and ceilings
- Examples for qualification tests for clean room walls and ceilings

Pharmaceutical Engineering and the regulatory expectations

- Engineering Impact on GMP Compliance
  - Design of GMP Facilities and equipment
  - The roles of engineers and pharmacists in the qualification course
- Engineering GMP fundamentals in:
  - HVAC
  - Water Treatment
  - Utilities (Steam & Gases)
- Engineering and GMP Maintenance
  - Pharmaceutical process maintenance during operation
  - Instrument calibration, preventive maintenance, change control
- Points to consider during a GMP Audit
  - Inspection by wandering around
  - Examination of documents
- Conclusion
  - Examples & categorisation: minor, major, critical
  - Avoiding critical and major findings

Speakers

Gordon Farquharson, *Critical Systems Ltd.*
Gordon is a chartered consulting engineer with 30 years experience of quality & safety critical processes and facilities used by industries such as healthcare, life science, etc. Technology Division's global operation. In recent years he has focused on technologies such as isolators, barrier technology, and mini-environments, critical utility systems. He has been involved in the development of new regulatory standards, e.g. CEN/ISO cleanroom and contamination control standards, WHO GMP guidance and ISPE Baseline® Guides. He has recently worked with the EMEA in London to help update and improve the cleanroom classification and monitoring requirements in Annex 1 of the EU and PIC/S GMPs. Gordon is Managing Director at Critical Systems Ltd.

Dr Gerhard Hauser, *Formerly Technical University of Munich; Member of the EHEDG*
Dr Hauser was senior engineer at the chair of mechanical and plant engineering of Munich Technical University. He was also a member of the German mirror body for the European machinery directive (standardisation of hygiene and cleaning requirements on machines used in the food industry), member of the European Hygienic Engineering and Design Group (EHEDG), Chairman of the subgroup 'Design Principles'. Now he is still giving lectures on hygienic design at the University of Karlsruhe and at conferences. He has recently published 2 books on Hygienic Design.

Dr Jean-Denis Mallet, *Formerly Head of the French Pharmaceutical Inspection Department*
Jean-Denis Mallet is a Doctor Pharmacist, graduated in technological pharmacy (IPI) and management (ISMA). He is currently a consultant and a GMP auditor. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps). He also used to work in or with the pharmaceutical industry during 12 years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting.

Wolfgang Rudloff, *GMP-Experts*
Mechanical Engineer, legal expert in cleanroom technology and GMP-management, expert in Industrial Engineering, safety engineer, worked in technical and process lead positions within Warner Lamber - Gödecke in Freiburg. His qualification comprises lead auditor, head of construction management, process engineering, GMP consultancy. After the position as managing director of LSMW / Switzerland he became in 2001 managing director, senior consultant and senior auditor for PCS. Today, he is a freelance consultant and specialises in technical GMP management, GMP consulting, auditing and training for the pharmaceutical and API industry.

Social Event

On Wednesday 3 November you are cordially invited to a social event. This is an excellent opportunity to share your experience with colleagues from other companies in a relaxed atmosphere and to explore the beautiful city of Vienna

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

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CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

Pharma Engineering for Non-Engineers
3 - 4 November 2010, Vienna, Austria

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

Date

Wednesday, 03 November 2010; 9.00 – 18.30 h
(Registration and coffee 8.30 - 9.00 h)
Thursday, 04 November 2010, 9.00 – 15.30 h

Venue

RENAISSANCE WIEN HOTEL
Linke Wienzeile – Ullmannstrasse 71
1150 Vienna, Austria
Phone +43 1 89102
Fax +43 1 89102 – 300

Fees

Non-ECA Members € 1,490.- per delegate plus VAT
ECA Members € 1,341.- per delegate plus VAT
APIC Members € 1,415.- per delegate plus VAT
(does not include ECA membership)
EU GMP Inspectorates € 745.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention "VA 6447 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 22 September 2010. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language

The official conference language will be English.

Organisation and Contact

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