Both Big Pharma and small companies will be discussed.

Lean GMP Systems

Compliance – Efficiency – Quality

29 – 30 October 2013, Prague, Czech Republic

SPEAKERS:

Justin Barry
Midatech Biogune

Carmen Doran
Novartis

Afshin Hosseiny
Tabriz Consulting

Andreas König
Aenova Group

Linda Reijinga
Ferring

PROGRAMME:

- Efficiency without compromising Quality
- Modern Quality Management Systems (QMS)
- Managing Cost of Compliance
- Managing Compliance in a globalising World
- In Time Management of Quality
- Case studies:
  - Linking Lean and Quality
  - Managing Inspections
  - Reducing the Number of SOPs
  - Documenting Training
- Parallel Sessions:
  - Quality Risk Management (QRM)
  - Efficient Data Pooling
  - Challenges in small Companies

ECA ACADEMY

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

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Objectives

Learn how to design lean, efficient and compliant Quality and GMP-Systems that will support you in turning your quality goals into reality.

Background

The manufacture of medicinal products is strictly regulated. Manufacturer's struggle to comply often leads to a flood of complicated, inefficient systems and procedures. However quality related processes, procedures and their related documents should control and support, not constrain the true core competence of pharmaceutical companies: the manufacture of cost effective medicines and APIs at highest quality and in compliance with the regulation.

Properly implemented, Quality and GMP-Systems will support efficient the manufacture of safe and efficacious medicinal products of the required quality without creating an impossible burden on the company's resources. Quality Managers need to know how to fulfil the regulatory requirements efficiently and how to implement the necessary processes in a lean and cost effective manner that supports efficacy and safety rather than hinders it with unmanageable systems

Target Audience

Managers and Executives from pharmaceutical Quality Management and Assurance, Business Executives and Production Managers and those involved in continuous improvement projects. But also Quality and Business executives from smaller organisations with highly constrained resources

Moderator

Afshin Hosseiny

Programme

How to gain Efficiency in the Quality Unit without compromising Quality

- Systems to reduce deviations
- How do you measure quality?
- How to develop a control strategy
- How to facilitate quality based decisions using risk management techniques

Managing Compliance and the Cost of Compliance in a globalising World

- Intercultural compliance
- Supplier quality vs. quality excellence
- Cultural particularities in GMP understanding
- Import: CoA, CEP, GMP-certificate, audit – what to look for
- The Cost of Compliance

The modern QA Organisation

- Developing a QMS to support business objectives while remaining compliant
- Developing QA organisation to support seamless operations: How can QA manage
  - process validation
  - change management
  - batch disposition
  - inspection readiness

without reducing efficiency and increasing costs

In Time Management of Quality

- Working to avoid instead of repairing
- How to use PAT
- Risk Management
- Quick workflows

Parallel sessions (2 out of 3):

1. Risk Assessment/ Risk Management and GMP Compliance

2. Efficient Data Pooling: KPIs, PQR, APR, Management Review

3. Challenges in small Companies and how to deal with them

You will be able to attend 2 of these sessions. Please choose the ones you like to attend when you register for the course.

Case Studies:

Linking Lean and Quality in a global Company
- Introduction to the company's lean approach
- Driving quality via lean and lean via quality
- Examples and learnings from the journey so far

Preparing for and passing a regulatory Inspection in the mini-company Environment
- Managing a regulatory inspection with 10 people and a cat
- Building the quality system around the process
- Keeping the paper under control
- Managing the validation monster
- Fit for purpose SOPs

How to reduce the Number of SOPs while remaining in Compliance
- Rationalise the existing SOPs
- Reduce the total number
- Introduce an efficient SOP review process
- Remain compliant with the cGMP requirements

Efficient Training Documentation
- Determine initial situation and define the objective
- Clarify the process, content and responsibilities (commitment of management)
- Decide on an adequate software
- Adjustment / optimisation / Lean aspects / KPIs
- Verify substantial quality of training

Social Event

On 29 October you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Justin Barry
Midatech Biogune, Spain
Justin Barry is Managing Director at Midatech Biogune. He has more than 30 years experience in Biotechnology Quality and Quality Assurance with several years in Senior Management positions, including QA Director at GlaxoWellcome Biotech and General Manager for Genentech Spain.

Carmen Doran
Novartis Animal Health, U.K.
Carmen Doran is Head of Operations at the Novartis Animal Health site in Dundee. She joined Novartis in 2004 and has held various roles of increasing responsibility across Engineering, Operational Excellence and Production Management at both site and global levels.

Dr Afshin Hosseiny
Tabriz Consulting, form. GSK, U.K.
Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. and formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. Afshin is a QP with over 25 years experience and member of the ECA advisory board.

Dr Andreas König
Aenova Group, Germany
Dr Andreas König is Director Manufacturing & Quality at Aenova Holding GmbH. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was head of QC and QA at Fresenius Kabi and later Global Quality Director at Intervet.

Linda Reijinga
Ferring GmbH, Germany
As QA Manager, Linda Reijinga is responsible for GMP Training, Project Management and the reporting of Quality KPIs . She has more than 17 years experience in pharmaceutical industry with 10 years responsibility for training systems. Linda Reijinga has developed a Project Management and Training System which was rolled out within the Ferring Group.

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@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Lean GMP Systems
29 – 30 October 2013, Prague, Czech Republic
Please choose TWO sessions:

- ☐ Risk Assessment/ Risk Management and GMP Compliance
- ☐ Efficient Data Pooling: KPIs, PQR, APR, Management Review
- ☐ Challenges in small Companies and how to deal with them

☐ 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)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 %.

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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)! (As of January 2012)

Date

Tuesday, 29 October, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 30 October, 8.30h – 15.30h

Venue of the Course

Corinthia Hotel Prague
Kongresova 1
14069 Praha 4
Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

Fees

ECA Members € 1,490.– per delegate + VAT
APIC Members € 1,590,- per delegate + VAT
Non-ECA Members € 1,690.– per delegate + VAT
EU GMP Inspectorates € 845.– per delegate + 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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.

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Wolfgang Schmitt (Operations Director) at +49-62 21 / 84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21 / 84 44 51, or per e-mail at strohwald@concept-heidelberg.de.