ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Rainer Gnibl
District Government of Upper Bavaria, Germany

Katja Kotter
Vetter Pharma-Fertigung, Germany

Jean-Denis Mallet, PhD
Pharmaplan, France

Markus Roemer
Comes Compliance Services, Germany

Edel Ryan
Mylan, Ireland

Dr Anke von Harpe
QProgress, Germany

Distant Assessments/Remote Audits - what you need to know

Live Online Training on 17/18 May 2021

Preparation – Performance – Follow-up

Highlights

- Legal Background and General Aspects
  - Approach and Expectations of the Agencies
  - Methods and Tools
  - Pros and Cons
- Auditee's Perspective
- Auditor's Perspective
- Internal Remote Audits
- Case Studies
  - Experiences with various Inspectorates
  - How to make and rate Observations
  - SMF Assessment

Both aspects are covered: Role of Auditor and Role of Auditee!

Programme

Objectives

Get a detailed overview of the possibilities and limits of a Distant Assessment/ Remote Audit. Both perspectives will be considered, that of the auditor/ inspector and that of the auditee.

Background

One important part of a supplier qualification process is the performance of an on-site audit. Currently, because of the situation with the worldwide pandemic situation, site visits present a potential risk to all persons involved or might simply not be possible because of travel restrictions.

If an on-site audit is not possible, a risk-based supplier qualification process can be supported by a Distant Assessment. Such an assessment may be conducted through various communication channels such as video calls or other appropriate tools available.

Also many inspectorates from EU and other regions of the world have started to utilise Distant Assessment approaches.

But it needs to be well-prepared from both, the auditor and the auditee.

Target Audience

GMP Inspectors and GMP Auditors from Pharmaceutical and API Industry and those who are involved in preparing and managing Distant Assessments, audits and inspections.

Moderator

Wolfgang Schmitt
Concept Heidelberg (on behalf of ECA)

Programme

Approach and Expectations

- What are the regulations saying?
- Which inspectorates are currently performing distant assessments?
- Benefits, limits, risks
- Classification in the overall Supplier Qualification System
- Reliance of QPs on results of remote supplier audits for batch certification,
- Risk-based planning
- Which companies are suitable for a Distant Assessment?

Technical Background

- IT infrastructure
- Set-up of an online Meeting
- How to realise a safe document review
- How to realise a facility tour
- Data integrity

The Auditee's Perspective

- How to prepare customer Distant Assessments
- Tools needed
- Which documents can be provided upfront – and how
- What problems can occur and possible solutions
- Resources and time requirements

The Auditor's Perspective

- Communication upfront
- Document exchange upfront
- Which areas are suitable for a Distant Assessment?
- Integration of remote auditing into the customer's QA system
- Experience made and lessons learned

How to Perform/ Host Internal Remote Audits

- Initial preparation and planning
- Fully paper based and hybrid approaches
- How to support a virtual tour
- Sharing of documents

Case Studies: Experiences made with Various Inspectorates

- How to prepare and manage Distant Assessments by inspectorates
  - Russia (FSI SID&GP)
  - Germany

Case Studies: Would you Find This in a Distant Assessment?

- How to make and rate observations
- Examples

Case Study: How to Assess a Site Master File from Distance

- When to ask for the SMF
- What to focus on
- What questions to ask

The Follow-up

- How to reply to report and observations
- Dissent and dispute
- Proof of CAPA effectiveness
- Ensuring that measures are implemented company-wide
- What to do if a target date cannot be achieved

Speakers

Dr Rainer Gnibl
District Government of Upper Bavaria, Germany
GMP Inspector

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health.

Katja Kotter
Vetter Pharma-Fertigung, Germany
Vice President

Katja Kotter is Vice President Regulatory Affairs and Quality Compliance. She has broad experience in managing authority inspections and customer audits.

Jean-Denis Mallet, PhD
Pharmaplan, France
Former EU-GMP Inspector

Jean-Denis Mallet was the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (AFSSAPS). Currently he is working as a consultant for Pharmaplan.

Markus Roemer
Comes Compliance Services, Germany
Consultant

Markus Roemer is General Manager of comes compliance services, Germany. He was Senior Validation Consultant at Invensys Validation Technologies in Montreal, Canada and Director Compliance Services.at Systec & Services.

Edel Ryan
Mylan, Ireland
Director

Edel Ryan is Director, Complex Products Quality Operations. In this role she also supports CMOs in inspection readiness activities.

Dr Anke von Harpe
QProgress, Germany
Consultant

Dr Anke von Harpe started her consultancy business in 2018. Prior to that, she held various senior QA positions in the pharmaceutical industry, including QP and Director Quality Systems.

Your Benefits
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

Testimonials

“Variety of speakers and having both sides presented is very good.”
Dr. Timm Trenktrog, Alltimm GmbH | Switzerland

“Very professional & organised virtual training event.”

“The presentations were prepared well and very current meeting my expectations of the course. I certainly took away a lot of learnings which will enhance the way I prepare and conduct remote audits during these challenging times.”
Claire C., Sebela Pharmaceuticals | Ireland

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

Reservation Form (Please complete in full)

Distant Assessments/ Remote Audits - what you need to know
Live Online Training on 17/18 May 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Monday, 17 May 2021, 10.00h – 17.00h
Tuesday, 18 May 2021, 9.00h – 15.45h
All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 1,490.-
APIC Members EUR 1,590.-
Non-ECA Members EUR 1,690.-
EU GMP Inspectorates EUR 845.-
The conference fee is payable in advance after receipt of invoice.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon +49(0) 62 21 / 84 44-0
Telefax 49(0) 62 21 / 84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21 / 84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding organisation, please contact:
Rouwen Schopka (Organisation Manager) at
+49(0) 62 21 / 84 44 13 or per e-mail at
schopka@concept-heidelberg.de