## Speakers

**Dr Martin Becker**
Baxter Oncology

**Roland Koch**
Gasporox

**Felix Krumbein**
Head ECA Visual Inspection Group

**Christof Langer**
OSConsulting

# Container-/Closure-Integrity Testing

## Live Online Training on 24 October 2024


## Highlights

- Pharmacopeial Requirements for CCI testing
- Overview CCI Testing Technologies
- A CCI Qualification Concept
- Case Study: 100% CCI Testing of Ampoules
- Case Study: CCI Testing of Vials

# Objective

Different products and different container types require different testing methods: this event aims at giving an overview of the different CCI testing systems which are applied during production and as part of the quality control system. Apart from technical aspects the regulatory requirements on CCI testing will be highlighted as well as the applicability of inline and offline testing.

# Background

An intact container closure system, which is the sum of packaging components that protect the dosage form, is the pre-requisite for a safe and sterile drug product. The CC system protects the product from microbial contamination and also from exposure to gases or water vapour or the loss of solvent. Container Closure integrity testing is therefore a regulatory requirement and it is part of the whole life cycle of a sterile drug product.

Initially this testing was performed as part of the initial development of the packaging system and the system's suitability verified in stability studies including on-going stability. Over the years, the expectation was raised to perform batch by batch verification with latest trends to 100% inline or offline testing wherever possible.

We will discuss and answer questions like:

- What are the current and upcoming GMP- and compendial requirements in the US / EU / RoW?
- Will container closure integrity testing change to 100% inline testing?
- What does the Annex 1 require?
- How do we have to define 'tight'?
- How to set up and defend a CCI control strategy
- Which testing technologies are available and suitable?
- CCI testing of vials
- CCI testing of ampoules

# Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of systems for the container/closure-integrity testing of sterile medicinal products.

# Moderator

Christof Langer, OSConsulting

# Programme

## Container Closure Integrity Testing of Sterile Drug Products – Requirements, Expectations and Exaggerations

- Container Closure Integrity during development, qualification and stability testing
- Regulatory, Pharmacopoeial and GMP requirements
- System integrity versus container damages
- Patient risks – do we need batch by batch testing?
- Industrial best practices

## Overview of Container-/Closure-Integrity Testing Technologies

The presentation gives a complete overview of the different aspects of leak testing to do CCIT in the pharmaceutical production. The systems presented can be used for the CCIT of vials, ampoules, syringes, BFS, IV bags, blisters etc.

- Leak, leak rate and the relevant physical units
- Leak test methods
  - Pressure change methods (vacuum, pressure and LFC)
  - Head Space Analysis using TDLAS
  - Helium Leak Test and other Mass Spectroscopy Systems
  - High Voltage Leak Detection (HVLD)
  - Force Sensing Technology
- Capabilities and examples of the different methods
- How to select the right method
- How to generate positive controls

## Proposal for a CCI Qualification Concept

- Regulatory requirements
- CCI methods
- Composition and preparation of a qualification kit
- Execution and evaluation of the qualification

## 100% inline CCI Testing of Ampoules

- High Voltage inline testing: method description
- Integration in the production process
- Limits of the system
- Qualification of the system
- Validation
- Routine Operation

## Residual Seal Force (RSF) & Headspace (HAS) Testing of Vials

- Setup of the testing system
- Usage of HAS in product validation
- Statistical control by sampling RSF

# Speakers

Dr Martin Becker
Baxter Oncology

Dr Becker has many years of experience in the pharmaceutical industry. He has worked in analytical development, QA and production at IDT and Sandoz, among others. He was Head of Technical Operations at Siegfried Hameln GmbH and is now Director Manufacturing at Baxter Oncology in Halle.

Roland Koch
Gasporox

Roland Koch has 25 years experience in the development and implementation of technologies and systems for the GMP regulated industry (Differential Pressure Measurements, Tunable Laser Absorption Spectroscopy, HVLD, Force Sensor Technology and NDIR). He is at GASPOROX AB in Lund (SE) as a Senior Sales and Application Engineer.

Felix Krumbein
InspectifAI & Head ECA Visual Inspection Group

Mr. Krumbein studied optotechnics and image processing and initially worked on the development of GMP-compliant image processing systems. He was head of Inspections-Systems-Support at Roche Mannheim. Since 2022 he is Head of Visual Inspection at INSPECTIFAI / Körber AG, where he is responsible for the development of AI-based solutions for fully automated inspection machines. Mr. Krumbein is Head of the ECA Visual Inspection Group.

Christof Langer
OSConsulting

Christof Langer studied Biotechnology and is certified Risk Manager as well as a Lean Six Sigma Black Belt. He has been working as Managing Director at Baxter BioScience, responsible for Operations. Since 2009 he runs his own consultancy business.

## 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.


CERTIFICATE

- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

## This could be of interest for you as well

### Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control

### Why not online?
### GMP/GDP Training Courses/Conferences, Webinars and E-Learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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Reservation Form (Please complete in full)

## Live Online Training: Container-/Closure-Integrity Testing
## 24 October 2024

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

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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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
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 http://www.gmp-compliance.org/eca_privacy.html). 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 Live Online Training
Thursday, 24 October 2024, 09.00 – 17.15 h CEST

## Technical Requirements
We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 990
APIC Members € 1090
Non-ECA Members € 1190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

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

## 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.

## Conference language
The official conference language will be English.

## You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

## Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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