ECA Academy
Your GMP/GDP Information Source

Speakers

Torsten Kneuss
Bayer, Germany

Fundamentals of AQL Testing in Packaging Control

Live Online Training on 23 November 2023

Requirements, Challenges and practical Solutions

Highlights

- Introduction to Statistics
- AQL and Defect Evaluation Lists
- Sampling Plans
- Acceptance Sampling by Variables & Attributes
- Other statistical tools

Free download for seminar participants

Principles for the Defect Evaluation Lists for Packaging Material!

Objectives

In this live online training course, you will learn the fundamentals of AQL Testing in Packaging/Device Control. AQL testing as part of the incoming good inspection process is commonly used. But still, questions often arise. It is this online event's aim to aid here and to explain statistical fundamentals behind the AQL testing concept, like, for example:

- Definition of AQL – what does it mean in regard to the accepted lot? What is the level of possible defects?
- How to use defect evaluation lists?
- How are quality levels determined and how is the number of units to be inspected calculated?
- What does AQL testing look like for supplier and user?
- What has to be done when AQL limits are exceeded?

Background

Usually, the responsibility of ensuring the container/device quality upon delivery to users (e.g. pharmaceutical companies) rests with the manufacturers (suppliers) of packaging materials. However, users are held responsible by regulatory requirements to ensure suitability of containers/devices for their products. Therefore, users should conduct sampling of incoming packaging/device lots to confirm their acceptability according to predetermined quality agreements.

Expecting defect-free containers from a supplier does not eliminate the need for some degree of incoming and online inspection, as well as post-packaging inspection. However, acceptance sampling of incoming batches by users has its limitations. Care should be taken to understand the "risks" of the sampling plan and the defined defect class / **Acceptable Quality Levels** (AQLs). Every AQL testing contains the statistical possibility of accepting a lot that is "bad" or rejecting a lot that is "good" (consumer's and producer's risk).

Since it is not practical to inspect incoming lots to 100% and to expect container lots to be free of imperfections, it is important that users and suppliers consistently define sample sizes, attributes and AQLs. Defect evaluation lists containing sample sizes, defect classes (Critical, Major or Minor), attributes and AQLs can provide such consistency.

Target Audience

This online event is designed for all employees working in the pharmaceutical industry (including drug device combination products), for suppliers of packaging materials & devices and to all who have to deal with the manufacture, quality assurance/ control and release of packaging materials /devices.

Programme

Practical Challenges & Definitions

- Definition of lot size/batch size
- Distribution of defects
- Attributes testing vs. variable testing

Introduction to Statistics

- Probability calculus
- Define the confidence level (95%; 99%)
- Standard Statistical Distributions (Normal, Binomial)

Sampling Plans

- Methods to determine sample sizes (ISO 2859, ISO 3951)
- Single, Double, Multiple Sampling Plans

Acceptable Quality Level (AQL)

- Definition of AQL
- Producer Risk/Consumer Risk
- Operating Characteristic

Q&A Session 1

Defect Evaluation Lists

- General methods for Defect Evaluation/AQL assignment
- Public Defect Evaluation Lists

Acceptance Sampling by Attributes (ISO 2859)

- Use of ISO 2859

Acceptance Sampling by Variables (ISO 3951)

- Use of ISO 3951

Other Statistical Tools

- Significance testing
- Setting specifications (defining LSL/USL)
- Process capability (Cpk)

Q&A Session 2

Speaker

Torsten Kneuss, Bayer AG, Berlin, Germany
Torsten Kneuss has been working since 1999 with pharmaceutical packaging materials, medical devices and combination products, including several years within the field of quality control, development, operations, and pharmacovigilance. Since October 2020 he is, as a Quality Product Steward Medical Devices and Head of Project Office Medical Devices, responsible for devices and combination products within Bayer.

Agenda

09.00 – 09.15 h	Welcome and Introduction
09.15 – 09.45 h	**Practical Challenges & Definitions**
09.45 – 10.30 h	**Introduction to Statistics**
10.30 – 10.45 h	Break
10.45 – 11.15 h	**Sampling Plans**
11.15 – 12.00 h	**Acceptable Quality Level (AQL)**
12.00 – 12.30 h	**Q & A Session 1**
12.30 – 13.30 h	Break
13.30 – 14.15 h	**Defect Evaluation Lists**
14.15 – 14.45 h	**Acceptance Sampling by Attributes (ISO 2859)**
14.45 – 15.00 h	Break
15.00 – 15.30 h	**Acceptance Sampling by Variables (ISO 3951)**
15.30 – 16.15 h	**Other Statistical Tools**
16.15 – 16.45 h	**Q & A Session 2**

Your Benefit

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

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
- 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.

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)

Fundamentals of AQL Testing in Packaging Control
Live Online Training on 23 November 2023

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 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 %.

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 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 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
Thursday, 23 November 2023, 9.00 h – 16.45 h

All times mentioned are CET.

Technical Requirements
We use Webex for our live online training courses and webinars. At https://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 € 1,090
APIC Members € 1,140
Non-ECA Members € 1,190
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.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or at kuehn@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Maximillian Bauer (Organisation Manager) at
+49(0)62 21/84 44 25 or at bauer@concept-heidelberg.de.