



## 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

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

### Introduction to Statistics

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

### Sampling Plans

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

### Acceptable Quality Level (AQL)

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



### Q&A Session 1

### Defect Evaluation Lists

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

### Acceptance Sampling by Attributes (ISO 2859)

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- Use of ISO 2859

### Acceptance Sampling by Variables (ISO 3951)

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- Use of ISO 3951

### Other Statistical Tools

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- 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**



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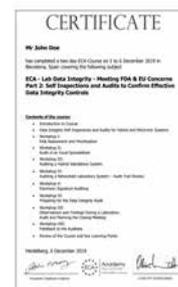
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## Fundamentals of AQL Testing in Packaging Control Live Online Training on 23 November 2023

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Date of the Live Online Training  
Thursday, 23 November 2023, 9.00 h – 16.45 h

All times mentioned are CET.

## Technical Requirements

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## Conference language

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## Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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