



GMP Webinar

Statistical Fundamentals of AQL Testing in Packaging Control

Date:

Thursday, 1 December 2016, 14.00 -15.30 h CET

Speaker:

Prof Dr Karin Melzer



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

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GMP Webinar: Statistical Fundamentals of AQL Testing in Packaging Control

Background

Usually, the responsibility of ensuring container 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 for their products. Therefore, users should conduct sampling of incoming packaging 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.

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 / Acceptance Quality Limits (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.

In case of critical defects it is important to separate and know the difference between the goal of zero non-conformities and sampling plans where the criteria is Accept on zero, Reject on one.

Quality agreements between manufacturer and user (e.g. pharmaceutical company) should include consistent metrics (AQL specifications) based on the manufacturer's (supplier's) production capability and the user's reasonable expectations.

Educational Objectives

AQL testing as part of incoming good inspection process is commonly used. But still, questions often arise. It is the webinar's aim to provide assistance here and to explain statistical fundamentals behind the AQL testing concept.

- 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?

Target Audience

The webinar targets executives and staff from production and quality units (suppliers and users of packaging materials) who are in charge of inspection and quality control of packaging materials.

But also Qualified Persons responsible for the review and release of products are within the target group of this webinar.

Speaker



Prof Dr Karin Melzer
University of Applied Sciences,
Esslingen

Karin Melzer received her PhD at the University of Ulm. She worked as an actuary in the insurance industry and is a member of the German Actuarial Society. In 2008 she was appointed as Professor for Mathematics and Statistics at the Esslingen University of Applied Sciences.

Fees (plus VAT)

Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de** for details.

Group Participation (fee per person):

3-10 Persons € 169,15
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To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.

Your Internet browser must have following features to use the GMP Webinar system:

1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

Please read the detailed technical requirements in [this document](#).

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?

For questions regarding content:

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Registration for the GMP Webinar: Statistical Fundamentals of AQL Testing in Packaging Control, Thursday, 1 December 2016, 14.00 - 15.30 h CET

Speaker: Prof Karin Melzer

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important:
Deadline is 12 noon on
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