ECA ACADEMY

GMP Webinar
AQL in visual inspection

Date:
Thursday, 11 June 2015, 14.00 -15.30 h CEST

Speaker:
Dr Bernd Renger

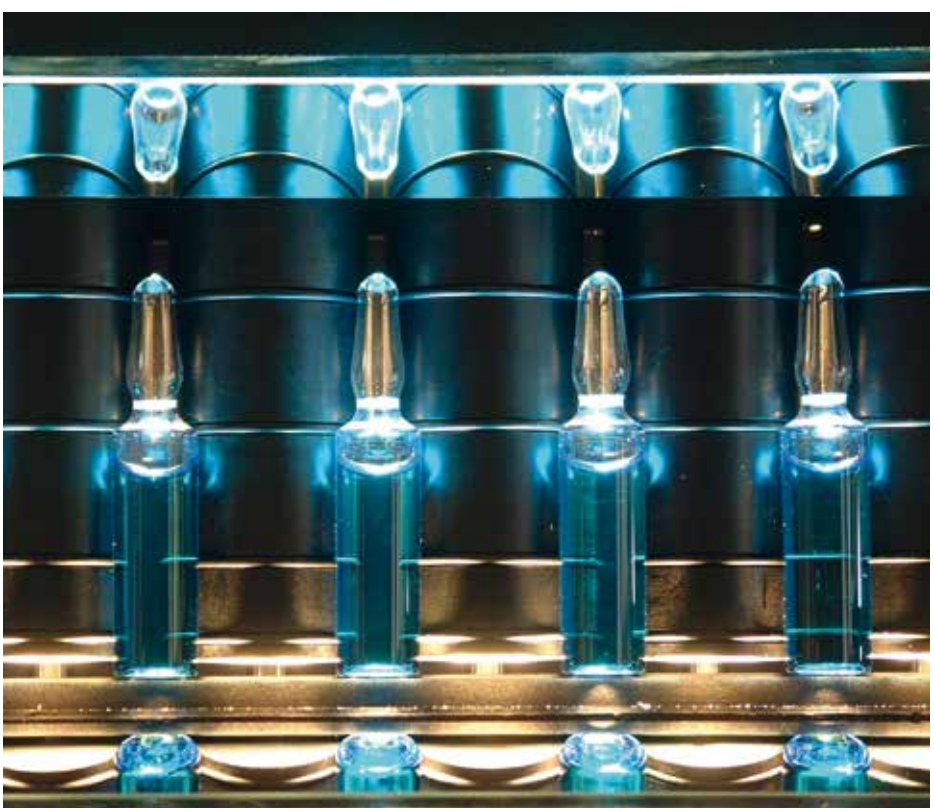

Image: Seidenader

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

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GMP-Webinar

AQL in visual inspection

Background

The requirement for injectables to be 'essentially' or 'practically' free of particles has been causing uncertainties for many years. On one hand 'essentially free' is not a measurable limit. On the other hand it is known that neither a manual nor an automated visible inspection is 100% free from error or defect. The implementation of AQL (Acceptable Quality Levels) testing as a part of the visual 100% inspection is a means of meeting the holistic approach of this control test. This is true for the manual as well as for the automated visual inspection.
Moreover, after the USP has included the AQL testing in chapter <790> Visible Particulates in Injections as part of the whole inspection system, it is likely that other pharmacopeias will follow.

Educational Objectives

AQL testing as part of the visual inspection process is not so common yet. But still, questions often arise also in sites where this second testing has already been implemented. It is the webinar's aim to provide assistance here and to explain the AQL testing concept.

- How mandatory is AQL testing?
- Is AQL testing part of production or quality control?
- How are quality levels determined and how is the number of units to be inspected calculated
- What does AQL testing look like for lyophilized products?
- What has to be done when AQL limits are exceeded?

Target Audience

The webinar targets executives and staff from production and quality units who are in charge of the visual inspection of parenterals. But also Qualified Persons, responsible for the review and release of products for injection are within the target group of this webinar.

Speaker

Dr Bernd Renger
Dr Renger is a Qualified Person and runs his own consultancy. Prior to that he was VP Quality Control at Vetter Pharma-Fertigung GmbH. He began his career at Hoechst AG in 1977 and has since held various management positions in the quality area at Mundipharma, Byk Gulden (today Takeda), as well as at Baxter BioScience AG in Vienna. Dr. Renger is a member of the Board of the ECA Foundation and the ECA Visual Inspection Group and Immediate Past Chair of the European QP Association.

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.

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.)

Group Participation (fee per person):
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

Technical Requirements

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.

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:
Dr Robert Eicher, phone +49 62 21 - 84 44 12,
E-Mail: eicher@concept-heidelberg.de,

For questions regarding technical aspects:
Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,
zimmermann@concept-heidelberg.de.

Registration for the GMP-Webinar: AQL in visual inspection
on Thursday, 11 June 2015, 14.00 -15.30 h CEST
Speaker: Dr Bernd Renger
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important:
Deadline is 12 noon on 10 June

Title, First Name, Last Name

Compamy | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

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 %, until 1 week prior to the conference 50 %, 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.
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)!