



GMP Webinar *Recording* **Semi-Automated Visual Inspection**

Speaker:
Dr Tobias Posset, Roche Diagnostics

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

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de



Abbildung: Seidenader

Background

Parenterals have to be 100% visually inspected. The semi-automated visual inspection is used for liquid and lyo vials and syringes since many years. Now, this type of inspection is getting more and more into the focus of GMP regulations and regulators. The requirements for manual or automated, camera-based inspections have become much clearer during the last 2-3 years with each relevant new chapter of the US and EU Pharmacopeias. But for the semi-automated visual inspection, being a hybrid of both methods mentioned above, this is not the case. Especially when it comes to inspection time per container, necessary computer validation and eye breaks etc. With this Webinar we want to show, how a GMP-compliant concept of a semi-automated inspection system and its qualification could look like.

Educational Objectives

Topics in this webinar cover conception, qualification and routine use of semi-automated visual inspection of parenterals.

- Qualification concepts for semi-automated 100% visual inspection including particle detection
- Dealing with particle detection and its probabilistic nature using semi-automated visual inspection
- A particle-threshold-study vs. particle detection using fixed predefined limits
- Qualification kits and defect libraries for the different qualification concepts
- Semi-automated visual inspection in daily business
 - eye breaks
 - inspection times
 - number of objects to be inspected
- Semi-automated visual inspection in compliance with USP<790>, Annex 1 and other cGMP regulations

Target Audience

The target group of this webinar are professionals in quality assurance, technology and production who are entrusted with the implementation or operation of a semi-automated inspection system or its defense during audits & inspections.

Speaker



Dr Tobias Posset, Roche Diagnostics

Tobias Posset studied Biochemistry and Chemistry. He is heading the Production Support unit in the Pharma Production at Roche in Mannheim. Herein he is responsible for the IPCs, the particle laboratory, the automated visual inspection and the coordination of the manual inspection operator training. He is also the chairman of the ECA Visual Inspection Group, member of the ECA advisory board and a member of the EDQM Group 12 advisory board from the European Pharmacopeia Commission.

Fees (plus VAT)

Single participation: € 199,- for ECA Members

Single participation: € 249,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at <https://www.gmp-compliance.org/about-the-academy>).

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.

Group Participation (fee per person):

3-10 Persons EUR 211,65

11-20 Persons EUR 186,75

more than 20 Persons EUR 161,85

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.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plugin. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Organisation/Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. 49(0)6221 / 84 44-0, Telefax 49(0)6221 / 84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content:

Dr Robert Eicher, phone +49(0)62 21 - 84 44 12,
Email: eicher@concept-heidelberg.de.

For questions regarding organisational aspects:

Mr Rouwen Schopka, Phone +49(0)6221 - 84 4413
Email: schopka@concept-heidelberg.de

Registration for the GMP Webinar Recording: "Semi-Automated Visual Inspection" of 16 June 2020, Speaker: Dr Tobias Posset, Roche Diagnostics
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Date on which you want to watch the recording online _____

Title, First Name, Last Name

Company

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)!

German law shall apply. Court of jurisdiction is Heidelberg.