



# GMP Webinar

## Data Integrity for Visual Inspection Systems

Date:  
Thursday, 16 May 2019, 14.00 – 15.30 h CEST

Speaker:  
Felix Krumbein, Roche Diagnostics



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

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## Background

The topic data integrity has been an integral part of numerous GMP inspections for several years. This involves ensuring and providing complete evidence that quality-relevant data from the manufacture or testing of a batch is correct and unadulterated. This is increasingly demanded also in connection with the data obtained in the automated visual inspection. Even if the systems work automatically, manual interventions and adjustments of inspection-relevant parameters such as lighting or mechanics may be necessary. To be able to prove with certainty in the case of a GMP inspection that the test data are nevertheless of integrity, a solid access management of the control system and an inspection-proof audit trail review concept are indispensable.

## Educational Objectives

- General requirements for data integrity
- Development of a suitable access control system
- Documentation of batchwise parameter adjustments in the inspection system
- Concepts for an inspection-proof audit trail review

## 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 automatic inspection systems or their defense during audits & inspections.

## Speaker



### Felix Krumbein, Roche Diagnostics

Felix Krumbein studied optotechnics and image processing and has been responsible for the implementation of GMP-compliant imaging-tools.

Now he is head of Inspections-Systems-Support at Roche Mannheim where he is responsible for the qualification of visual inspection systems.

## 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 [http://www.gmp-compliance.org/eca\\_about.html](http://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](mailto:schopka@concept-heidelberg.de)** for details.

## Group Participation (fee per person):

3-10 Persons € 169,15  
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## Registration

By mail, fax, e-mail or online at [www.gmp-compliance.com](http://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.

## Organisation/Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,  
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## Do you have any questions?

### For questions regarding content:

Dr Robert Eicher Phone +49(0)6221 - 844412,  
email: [eicher@concept-heidelberg.de](mailto:eicher@concept-heidelberg.de)

### or questions regarding technical aspects:

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

## Registration for the GMP Webinar: Data Integrity for Visual Inspection Systems, Thursday, 16 May 2019, 14.00- 15.30 h

### Speaker: Felix Krumbein, Roche Diagnostics

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

Please tick:

- Single Participation**
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  - 3-10 Persons
  - 11-20 Persons
  - more than 20 Persons

**Important:**  
Deadline is 12 noon on  
15 May 2019

Title, First Name, Last Name

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## E-Mail (mandatory for your registration)

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