



# GMP Webinar

## Strategic Measures to Prevent Unconfirmed OOS Results in QC-Laboratories

The Key Question is: How to prevent Lab Errors?

Date:

Monday, 20 September 2021, 14.00 – 15.30 h CEST

Speaker:

Dr Karl-Heinz Bauer, Boehringer Ingelheim



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

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## Background

Laboratory tests are performed on active pharmaceutical ingredients, excipients and other components, in-process materials, and finished drug products. The investigation of out-of-specification (OOS) results is an important part of the work undertaken in QC-laboratories and continues to be a hot topic in authority inspections. The incorrect handling and investigation of OOS results are still frequently cited in FDA Warning Letters.

**Unconfirmed OOS results (= lab errors)** require a full and often time-consuming OOS investigation with a predefined procedure to find the root cause and to define CAPAs.

Against this background, it is essential to thoroughly investigate unconfirmed OOS results and make every effort to prevent the recurrence.

## Educational Objectives

In this webinar, you will get to know strategies to investigate unconfirmed OOS results and you will learn how to define strategic measures to significantly reduce the probability of such results.

The following topics are addressed:

- Terms, definitions and requirements to prevent errors in QC-laboratories,
- The role of quality risk management,
- Error sources and error analysis in the laboratory and strategic measures,
- Integrated error management and error culture,
- Tools for root cause analysis (Ishikawa, 5W, FTA etc.).

## Target Audience

This webinar is aimed at all levels of technical staff and managerial personnel dealing with OOS results. Those are for example persons working in

- Incoming goods control,
- Control of finished drug products,
- Analytical development,
- API and excipient testing,
- Contract laboratories.

## Speaker



### Dr Karl-Heinz Bauer, Boehringer Ingelheim

Dr Bauer holds a PhD in pharmaceutical engineering and has been with Boehringer Ingelheim for more than 25 years. He has held various senior management positions in quality assurance, quality control and pharmaceutical manufacturing.

During this time, he successfully introduced the Continuous Improvement Process into the quality department. In addition, he was responsible for the balanced scorecard of the quality unit.

Since January 2020, he has taken over a strategic, international quality management position. In addition to that, Dr Bauer works now for many years as a speaker, consultant and coach in the pharmaceutical industry.

## Fees (plus VAT)

Single participation: € 249,- for ECA Members

Single participation: € 299,- 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 € 254,15

11-20 Persons € 224,25

more than 20 Persons € 194,35

## Registration

By mail, fax, e-mail or online on the Internet at

<https://www.gmp-compliance.org>. 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 plug-in. 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

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[www.gmp-navigator.com](http://www.gmp-navigator.com)

## Do you have any questions?

For questions regarding content please contact:

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## Registration for the GMP Webinar:

**Strategic Measures to Prevent Unconfirmed OOS Results in QC-Laboratories on Monday, 20 September 2021, 14.00 – 15.30 h CEST**

**Speaker: Dr Karl-Heinz Bauer**

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 09.00 am  
on 20 September 2021**

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

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**E-Mail (mandatory for your registration)**

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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 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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