



# GMP Webinar

## Current Inspection Trends

Date:

Wednesday, 30 January 2019, 14.00 – 15.30 h CET

Speaker:

Dr Rainer Gnibl (GMP Inspector for EMA)



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

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## Background

GMP inspections by the supervising authorities are an important element in ensuring the quality of medicines. For the company, an inspection can have a decisive influence on the daily work and its economic future; for example, the issue or renewal of the Manufacturing and Importation Authorisations (MIA) requires a positive GMP inspection outcome. For a successful inspection it is essential to know the expectations of the authorities.

## Educational Objectives

The goal of this webinar is to give attendees a comprehensive yet compact overview of the current inspection highlights:

- What are the current hot topics?
- What are the inspectorates currently seeing as the biggest problems?
- What are the future developments?
- How do authorities co-operate?
  - Co-ordination of activities
  - Information Exchange
  - Mutual recognition of inspections
- What can the industry learn from this?

## Target Audience

The webinar is aimed at executives and employees from the pharmaceutical industry who want to get a compact and comprehensive overview of current inspection expectations.

## Speaker



**Dr Rainer Gnibl**  
**GMP Inspector, District Government of Upper Bavaria, Germany**

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

## 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  
11-20 Persons € 149,25  
more than 20 Persons € 129,35

## 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.

## Registration

By mail, fax, e-mail or online on the Internet 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,  
Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34  
[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de), [www.gmp-navigator.com](http://www.gmp-navigator.com)

## Do you have any questions?

### For questions regarding content:

Mr Wolfgang Schmitt (Director Operations)  
Telefon 0 62 21 - 84 44 39  
E-Mail: [w.schmitt@concept-heidelberg.de](mailto:w.schmitt@concept-heidelberg.de)

### For 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: "Current Inspection Trends" on

**Wednesday, 30 January 2019, 14.00 – 15.30 h CET,**

**Speaker: Dr Rainer Gnibl, GMP Inspector for EMA**

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

**Important:**  
**Deadline is 12 noon on**  
**29 January 2019**

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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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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

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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.