



# GMP Webinar *Recording*

## **Medical Software – Meaning of Apps, Websites and other Software for Pharmaceutical Companies**

Date of the recording: Monday, 7 December 2015

Speaker:  
Torsten Kneuss, Bayer Pharma AG, Berlin, Germany

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

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## Background

The increasing number of Apps for Smartphones and other software types developed and distributed by pharmaceutical companies to patients, physicians or other customers brings a new product class to the industry. This new product class – software – potentially falls under the Medical Device regulations. If its intended use is covered by the definition of a Medical Device it needs to be developed and operated according to the requirements for Medical Devices, and it also needs to have a regulatory clearance.

The goal of this webinar is therefore to provide you with an overview about Medical Software, allowing you to evaluate whether there is a need for actions in your company.

## Educational Objectives

The aim of the webinar is to provide you with an overview about relevant aspects of Medical Software:

- Introduction – Software distributed by Pharmaceutical Companies
- Medical Software vs. Promotional Software
- Overview about regulations for Medical Software (mainly in EU and US)
- Challenges with Medical Software

## Target Audience

The webinar targets executives and staff from quality and information technology units who are in charge of Software with Medical purpose (e.g. Mobile Apps, Desktop Software, Websites). It also addresses Qualified Persons, responsible for the review and release of Medical Software or Combination Products.

## Speaker



**Torsten Kneuss**  
**Bayer Pharma AG, Berlin, Germany**

Since 1999 Torsten Kneuss has been working with pharmaceutical packaging materials, including several years within the fields of packaging quality control and packaging development. Since November 2010 he has been Operations Manager, responsible for pre-filled syringes and medical devices. For the past two years he is also responsible for Medical Software, mainly the launch preparation of a system consisting of Patient Apps and Software for health-care professionals.

## 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.**

## 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 [http://www.gmp-compliance.org/eca\\_about.html](http://www.gmp-compliance.org/eca_about.html).)

## Group Participation (fee per person):

3-10 Persons EUR 211,15  
11-20 Persons EUR 186,75  
more than 20 Persons EUR 161,85

## 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](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.

## Do you have any questions?

For questions regarding content:

Dr Günter Brendelberger, phone +49 62 21 - 84 44 40,  
E-Mail: [brendelberger@concept-heidelberg.de](mailto:brendelberger@concept-heidelberg.de),

For questions regarding technical aspects:

Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,  
[zimmermann@concept-heidelberg.de](mailto:zimmermann@concept-heidelberg.de).

## Registration for the recorded GMP Webinar "Medical Software"

**Speaker: Torsten Kneuss, Bayer Pharma AG, Berlin, Germany**

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).

**Date on which you want to watch the recording online** \_\_\_\_\_

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## 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)!