

# PharmaFORUM

## Webcast International

Global Drug Safety & Regulatory Affairs

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### The upcoming webcasts at a glance

- Global CMC
- Global pharmacovigilance
- US-FDA requirements
- Russian and EAEU challenges
- Saudi Arabia's requirements
- Brazil's peculiarities

Please try us out:  
A free demo of marketing  
authorisation in IRAN is  
online available!

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### Your benefits

- One live webcast with international experts every two months
- Consolidated information in a short period of time at your work place
- Possibility to directly interact with the speaker via chat

## Concept

Do you work in international regulatory affairs or in pharmacovigilance? We would like to invite you to join us every two months for our live webcasts, where international regulatory affairs and vigilance experts will inform you of the latest news and trends in global marketing authorisation and drug safety within and beyond the ICH region.

You will meet our experts in a virtual conference room. Each meeting will be held as a 1.5-2 hour live webcast, presenting the latest news with supporting presentation slides (also for your personal download). Your practical questions will be addressed directly via the chat function coordinated by the meeting chairperson.

## Additional benefits

Are you unable to attend one of the webcasts? No problem! After each live meeting, you will be able to retrieve the recorded webcast from our e-Learning centre. This allows you to view each webcast at any time and as often as you like. An optional multiple choice test finalises each webcast, giving you the possibility to receive a personal certificate.

Get a first impression at [www.forum-institut.com/pharma-webcast-international](http://www.forum-institut.com/pharma-webcast-international)

## Your experts



**Dr Ulrich Granzer**  
Granzer Regulatory  
Consulting & Services,  
GERMANY

Owner



**Dr Edelgard Rehak**  
Dr Edelgard Rehak  
Consulting,  
GERMANY

Owner



**Dr Beatrix Metzner**  
Boehringer Ingelheim  
Pharma GmbH & Co. KG,  
GERMANY

Head of Global Tech RA



**Dr Mohammed Saleem**  
Boehmert & Boehmert,  
Representation Office  
Middle East and North  
Africa, JORDAN

General Director of SIPS  
(Science forum for Research & Consultancy)



**Anita Patel**  
PAREXEL Consulting,  
BRAZIL

Pharmacist, Manager Regulatory Affairs



**Dr Tiziana  
von Bruchhausen**  
Boehringer Ingelheim  
Pharma GmbH & Co. KG,  
GERMANY

Senior Safety Writer

<b>Your Programme</b>	<b>Date and Time</b>	<b>Your Expert</b>
<b>Global CMC requirements</b> <ul style="list-style-type: none"><li>■ Truly global CMC requirements versus regional trends</li><li>■ Global stability programmes</li><li>■ Global formats? CTD Module 2.3 and Module 3</li></ul>	17 <sup>th</sup> May 2017 14.00 (CEST)	Dr Beatrix Metzner
<b>Marketing authorisation in the US</b> <ul style="list-style-type: none"><li>■ Update on the procedures</li><li>■ Required marketing authorisation documents including pharmacovigilance requirements</li></ul>	5 <sup>th</sup> July 2017 14.00 (CEST)	Dr Ulrich Granzer
<b>Regulatory affairs and pharmacovigilance in Saudi Arabia</b>	20 <sup>th</sup> September 2017 14.00 (CEST)	Dr Mohammed Saleem
<b>Russia as part of the new EAEU – changes in RA and PV</b> <ul style="list-style-type: none"><li>■ A look at the changes in legislation for medicinal products</li><li>■ Changes affecting regulatory affairs and pharmacovigilance</li></ul>	15 <sup>th</sup> November 2017 14.00 (CEST)	Dr Edelgard Rehak
<b>PSURs &amp; RMPs – international markets</b> <ul style="list-style-type: none"><li>■ Global planning of PSUR schedules: solutions and strategies</li><li>■ How to ensure alignment of local RMPs with global RMPs</li></ul>	22 <sup>nd</sup> January 2018 14.00 (CEST)	Dr Tiziana von Bruchhausen
<b>Regulatory affairs and pharmacovigilance in Brazil</b>	6 <sup>th</sup> March 2018 10.00 (CEST)	Anita Patel

## Would you like to register?

Via Tel.: +34 91 372 83 99 or

email: [formacion@qualitecfarma.com](mailto:formacion@qualitecfarma.com)

### Registration

- Yes, I want to join the  
**PharmaFORUM Webcast International**  
(you will receive a confirmation email  
with your login details)

\_\_\_\_\_  
Name

\_\_\_\_\_  
E-Mail (required for your login details)

\_\_\_\_\_  
Position

\_\_\_\_\_  
Company

\_\_\_\_\_  
Street address

\_\_\_\_\_  
Postal Code/City/Country

\_\_\_\_\_  
Tel. No.

\_\_\_\_\_  
Date, Signature

### How to register

#### Conference-No. 18 03 214

##### Fee:

The fee per webcast is € 150 (plus German VAT).  
Membership of the PharmaFORUM Webcast International is only available for one year.

**The annual membership fee of € 900** (plus German VAT) for six webcasts is due upon registration.

Membership is automatically extended by one year, unless written notice has been submitted no later than six weeks before the end of the membership. A 12-month membership may be started at any time.

**If you are interested in a group account, please contact us.**

##### Benefits:

- Six live webcasts per year
- Recorded presentations available at our e-Learning centre
- Documentations for your personal download
- Multiple choice test and personal certificate after each webcast

##### Questions and information:

Mr. Pablo García  
Conference Manager (QualitecFarma®)  
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[formacion@qualitecfarma.com](mailto:formacion@qualitecfarma.com)

##### Cancellation Policy:

Our general terms and conditions apply (as of 01.01.2016) and are available upon request. We can send them to you anytime or you can find them online at [www.forum-institut.de/agb\\_en](http://www.forum-institut.de/agb_en)