Conference

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Regulatory Leaders FORUM

Regulatory Intelligence and Regulatory Information Management

For all who carry responsibility in regulatory affairs

Your topics

- Regulatory pathways in the context of unmet medical needs
- Real World Evidence in the authority's approval
- From national to international: collaboration of authorities 2020
- Digital product information – Project GI 4.0
- eCTD and eSubmission – always and everywhere?
- SPOR and Regulatory Information Management

Your speakers

Dr Peter Bachmann
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Gesine Bejeuhr
German Association of Research-based Pharmaceutical Companies (vfa e.V.), Berlin, GERMANY

Dr Rüdiger Faust
Grünenthal GmbH, Aachen, GERMANY

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

Mickel Hedemand
Danish Medicines Agency, Copenhagen, DENMARK

Anne Lenihan
Pfizer Pharmaceuticals, London, GREAT BRITAIN

Dr Klaus Menges
Senior Expert Regulatory Affairs, Bonn, GERMANY

Georg Neuwirther
AGES, Vienna, AUSTRIA

Dr Isabelle Stöckert
Bayer AG, Wuppertal, GERMANY

Dr Maren von Fritschen
AddOn Pharma GmbH, Berlin, GERMANY

Martine Zimmermann
Alexion Pharma GmbH, Zürich, SWITZERLAND

28 - 29 September 2017 in Berlin

Chair, day one

Dr Maren von Fritschen
AddOn Pharma GmbH, Berlin, GERMANY

Managing Director

Your speakers, day one

Dr Peter Bachmann
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Bachmann has many years' experience in regulatory affairs. He made a significant contribution to establishing the European DCP System.

Dr Gesine Bejeuhr
German Association of Research-based Pharmaceutical Companies (vfa e.V.), Berlin, GERMANY

Regulatory Affairs/Quality

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

Owner

Anne Lenihan
Pfizer Pharmaceuticals, London, GREAT BRITAIN

Director Regulatory Affairs

Dr Isabelle Stöckert
Bayer AG, Wuppertal, GERMANY

VP, Head Regulatory Affairs EMEA

Martine Zimmermann
Alexion Pharma GmbH, Zürich, SWITZERLAND

VP Global Regulatory Affairs, Alexion Pharma International

Chair, day two

Dr Klaus Menges
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Menges is well experienced in the area of electronic submission and the electronically supported product information management. He is member of the EU-IT eSubmission Change Management Board.

Your speakers, day two

Dr Rüdiger Faust
Grünenthal GmbH, Aachen, GERMANY

Director, Regulatory Intelligence, Global Regulatory Affairs

Mickel Hedemand
Danish Medicines Agency Medicines Licensing & Availability, Workflow, Copenhagen, DENMARK

Special Adviser

Georg Neuwirther
AGES Austrian Medicines and Medical Devices Agency, Vienna, AUSTRIA

Head of IT Austrian Medicines and Medical Devices Agency

Your benefits

- Intensive discussion with regulatory affairs leaders and authority members
- Hands-on expertise, including practical examples and projects
- Regulatory intelligence and regulatory information management topics combined into one meeting
- Sufficient time for thorough discussion

Day one: 28 September
Regulatory Intelligence

09:00

Regulatory Leaders Think Tank – hot topics and challenges for 2020
Dr Maren von Fritschen

09:45

Collaboration of authorities in a globalised environment
Dr Peter Bachmann

- Information-sharing initiatives: assessment exchange and inspection exchange

10:45 Coffee break

11:00

Unmet medical needs and early access – suitable regulatory pathways and potential success
Dr Ulrich Granzer

11:45

Case Study: Real World Evidence for authority approval
Martine Zimmermann

- The global registry served as a data source for CHMP approval of an additional indication in a rare disease

12:30 Lunch

14:00

Continuous benefit/risk evaluation in drug development and the drug life-cycle
Dr Isabelle Stöckert

14:45

From junior to senior: how to form high-performance regulatory affairs teams
Anne Lenihan

- Training and coaching junior regulatory affairs specialists
- Suitable structures

15:30 Coffee break

16:00

Digital product information for ubiquitary patient access
Dr Gesine Bejeuhr

- Project GI 4.0 – electronic patient information leaflet

16:45

Conclusion and preview of day two
Dr Maren von Fritschen

17.15 End of day one

Day two (optional): 29 September
eSubmission and RIM

09:00

E-only in Europe – eSubmission of all regulatory information?
Dr Klaus Menges

- Has the EU roadmap been fully implemented?
- Is there acceptance by all authorities?
- Handling purely national marketing authorisations in Germany

10:00

eCTD for all submission types?
Mickel Hedemand

- eCTD prerequisites for variations filing
- Purely national variations: how to deal with them in Denmark

11:00 Coffee break

11:15

Current challenges using the eSubmission portals
Georg Neuwirther

- CESP and the eSubmission Gateway – current status
- CESSP – milestones in 2018
- The future of purely national portals
- Dealing with purely national marketing authorisations in Austria

12:15 Lunch

13:45

IDMP and SPOR – regulatory requirements and the authorities' duties
Dr Klaus Menges

- Timelines for iterative implementation
- Required content

14.45 Coffee break

15:15

Regulatory information management – major steps in pharmaceutical companies
Dr Rüdiger Faust

- SPOR data and its target operating model
- Preparing for the EMA SPOR initiative
- The impact on business processes and the need to establish data governance

16.15

Transition from xEVMPD to IDMP
Dr Rüdiger Faust

- How to maintain company data while preparing for IDMP
- Is reuse of xEVMPD data possible?

17.00 Conference end

My invitation

Do you have years of regulatory affairs experience and carry great responsibility in regulatory affairs? Then, you should not miss the Regulatory Leaders FORUM, where regulatory affairs experts from the industry and from European authorities will provide you with insights into their daily affairs, including practical case studies.

You will leave the conference with new ideas on how to successfully deal with upcoming challenges such as early access schemes, the inclusion of RWE data in marketing authorisations, digital product information and eSubmission requirements.

Since the requirements for eSubmission and IDMP/SPOR are especially challenging, day two will be completely dedicated to these issues. If these issues are not personal priorities, it is possible to attend only day one.

I look forward to meeting you at the conference.

Yours faithfully

Dr Henriette Wolf-Klein
Department Manager Pharma & Healthcare

Who should attend?

This conference addresses the needs of people working in the pharmaceutical industry who carry responsibility in a regulatory position. The meeting will mainly focus on EU regulatory challenges, but will also include global regulatory issues.

Day two focuses on eCTD, eSubmission, IDMP and SPOR, and can be booked separately.

Hotel accommodation

A limited number of rooms has been allocated for the nights of the 27–29.09.2017 at the following hotel:

Adina Apartment Hotel Checkpoint Charlie
Krausenstr. 35–36 · 10117 Berlin
Tel.: +49 30 200 767 0 · Fax: +49 30 200 767 599

These are subject to availability. The single-room rate including breakfast is €139.00 per night. The distance to the conference hotel is about 1.6 km.

Please book at least six weeks prior to the conference to obtain a hotel room at this discounted rate. All bookings should be made directly with the hotel, quoting FORUM Institut with the conference number as a reference.

Registration: +34 91 372 83 99 or email: formacion@qualitecfarma.com

Yes, I will attend the conference

☐ Day one: Regulatory Intelligence (28 September 2017)
☐ Day two: eSubmission and RIM (29 September 2017)

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

Registration: +34 91 372 83 99
Conference-No. 17 09 234

Date/Venue:
28 - 29 September 2017 in Berlin
NH Collection Berlin Friedrichstrasse
Friedrichstr. 96 · 10117 Berlin
Tel. +49 30 206266-0 · Fax +49 30 206266933

Fee:
One conference day €1,090.00 (+ German VAT)
Both conference days: €1,990.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch and certificate.
Invoice and confirmation will be forwarded to you.

Questions and information:
Mr. Pablo García
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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 on the internet at www.forum-institut.com/t&c