FORUM

ExpertFORUM Pharmacovigilance 2018

The latest information | Social event in a unique atmosphere | Top speakers

Two days of intensive talks by and for drug safety experts!

What to expect:

- **Latest PV news**
- **New impulses for your work**
- **High-level discussion with colleagues and experts**

Your topics

- IDMP and SPOR: Consequences for pharmacovigilance
- Data protection: The new EU regulation and initial experiences
- Harmonisation of RMP by CMDh
- EudraVigilance and signal management
- Brexit countdown
- Mergers and acquisitions: A drug safety perspective
- Inspection readiness: An authority's perspective
- Liability issues in pharmacovigilance
- And much more

12 – 13 November 2018 in Frankfurt

Your programme on 12 November
Chair: Prof Burkhard Sträter

10:00

Prof Burkhard Sträter
Sträter Lawers,
Bonn, Germany

Welcome and introduction

10:15

Dr Norbert Paeschke
– requested –
Senior Expert Pharmacovigilance,
Bonn, Germany

Signal management: Transitional arrangements – initial experiences and outlook

11:00

Dr Melanie Ruppel
Boehringer Ingelheim International GmbH, Ingelheim, Germany

Head of Global Submission Services
Ingelheim

IDMP and SPOR: Impact on pharmacovigilance

- EMA master data management roadmap
- IDMP and SPOR concept
- Consequences for pharmacovigilance

12:00 Coffee break

12.15

Dr Fakhredin Sayed Tabatabaei
Medicines Evaluation Board,
Utrecht, The Netherlands

Epidemiologist,
Senior Assessor Pharmacovigilance

Harmonisation of RMP by CMDh

13:15

Discussion: Consequences of regulatory developments for the pharmaceutical industry

13:40 Lunch

14:45

Dr Kimberley Sherwood
Senior Expert Pharmacovigilance,
Bonn, Germany

Inspection readiness – an authority's perspective

- Current priorities of PV inspectors
- Typical findings in a changing regulatory environment

15:30

Prof Burkhard Sträter
Sträter Lawers,
Bonn, Germany

Partner

Impact of pharmacovigilance on early benefit assessment (§ 35a SGB V)

16:00 Coffee break

16:15

Horst Kastrup
Senior Regulatory Expert,
Muenster, Germany

and

Tobias Beer
European Medicines Verification Organisation, Brussels, Belgium

Head of Commercial & Partner Management

Looking beyond the horizon: Falsified Medicines Directive, February 2019 deadline

- Falsified Medicines Directive 2011/62/EU (FMD)
- Current state of implementation
- Link to IDMP and SPOR
- Risks due to falsified medicinal products
- Impact of the FMD on pharmacovigilance
- Role of pharmacovigilance in the anti-counterfeit company project
- Are today's processes appropriate for controlling the risks due to falsified and diverted medicines?

18:00 End of Day 1

18:30 Evening event

Your programme on 13 November
Chair: Dr Tanja Peters

09:00

Welcome and introduction

Dr Tanja Peters
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

Head PV Intelligence & Deputy EU-QPPV

09:15

BREXIT Countdown – Q&A with a focus on Pharmacovigilance

- State of Brexit negotiations and timelines
- Impact and challenges for Pharmacovigilance
- Q&A with the attendees

Dr Dr Adem Koyuncu
Law firm Covington & Burling LLP

Partner in the Brussels and Frankfurt offices, Lawyer and Medical Doctor. Licensed to practice in Brussels and Germany

10:00

Data privacy – The new EU regulation

- What's new and what are the major challenges?
- Challenges for pharmacovigilance

Daniela Fábián Masoch
FABIAN PRIVACY LEGAL GmbH, Basel, Switzerland

Attorney at Law & Privacy Professional

11:00 Coffee break

11:20

Mergers and acquisitions: A pharmacovigilance perspective

Dr Tanja Peters
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

Head PV Intelligence & Deputy EU-QPPV

12:00

Pharmacovigilance System Master File (PSMF) – Partner Audits

Dr Monika Manske
Mylan Healthcare GmbH, Hannover, Germany

Lead Quality Management Pharmacovigilance Safety & Risk Management

12:45 Lunch

14:00

Workshop: The role of the safety department in clinical development – service provider or development partner?

Dr Reinhard Fescharek
CSL Behring GmbH, Marburg, Germany

Senior Advisor to the Chief Medical Officer

15:00

Liability Issues in Pharmacovigilance and Safety Referral Procedures

- Offenses and civil liability
- Referral procedures and liability implications
- Relevance of PV inspections and PV audits
- Who can be personally liable: National PV Officer, QPPV, Managing Director, PV employees?
- Protection against liability cases and insurance questions

Dr Dr Adem Koyuncu
Law firm Covington & Burling LLP

Partner in the Brussels and Frankfurt offices, Lawyer and Medical Doctor. Licensed to practice in Brussels and Germany

15:45 Final Q&A session

16:00 End of conference

Aims and objectives

FORUM Institut and the conference chairs are pleased to welcome you to this year's ExpertFORUM Pharmacovigilance.

This conference has become a jour fixe for drug safety departments in the pharmaceutical industry. As always, we will highlight the latest regulatory developments and their implications for the pharmaceutical industry, and provide concrete suggestions for your daily work. We will also provide the latest information on current pharmacovigilance issues.

I look forward to meeting you personally in Frankfurt.

Kind regards,

J. Jegodka

Jessica Jegodka
Conference Manager Pharma & Healthcare
Tel. +49 6221 500-696
j.jegodka@forum-institut.de

Who should attend

The conference is primarily intended for drug safety managers, local drug safety representatives and QPPVs needing to be informed about current regulatory developments and operational implementation issues.

It is also aimed at senior executives at public authorities and research institutions, and in:

- Medical Affairs;
- Regulatory Affairs;
- Clinical Research; and
- Quality assurance

Your benefits

- Intensive discussion with pharmacovigilance leaders and authorities.
- Relevant expertise, including practical examples and projects.
- Sufficient time to address related issues.

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Registration: +49 6221 500 555 or email: service@forum-institut.de

Yes, I will attend the
☐ ExpertFORUM Pharmacovigilance 2018

☐ Yes, i agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone. I may withdraw my consent at any time

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +49 6221 500-500**
- **Conference-No. 18 11 201**

- **Date/Venue:**
12 – 13 November 2018 in Frankfurt
Le Méridien Parkhotel
Wiesenhüttenplatz 28-38 · 60329 Frankfurt
Tel. +49 69 2697-0 · Fax +49 69 2697-812

- **Fee:**
€ 1,790.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch, evening event and certificate.
Invoice and confirmation will be forwarded to you.

- **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