Conference

FORUM

ExpertFORUM Labelling

Topics

- ePI – status of the EMA action plan
- Electronic formats – 'Alexa, read my package leaflet'
- Data integrity and trusted labelling
- Label changes after the PRAC decision
- End-to-end labelling solutions

Focus on data integrity, compliance, label change and electronic formats

Your speakers

Dr Peter Bachmann
Bonn, GERMANY

Dr Gesine Bejeuhr
vfa e.V.,
Berlin, GERMANY

Dr Rüdiger Faust
Grünenthal GmbH,
Aachen, GERMANY

Lynsey Flitton
AbbVie Ltd,
GREAT BRITAIN

Dr Nils Lilienthal
Bonn, GERMANY

Dieter Mößner
Edelmann GmbH,
Heidenheim GERMANY

Dr Juliane Rechsteiner
Bayer AG,
Wuppertal, GERMANY

Dr Anke Webler-Messenger
Boehringer Ingelheim
International GmbH,
Ingelheim, GERMANY

Dominique Westphal
Paul-Ehrlich-Institut (PEI),
Langen, GERMANY

15 - 16 May 2019 in Bonn

Your speakers day 1

Dr Peter Bachmann
Senior Expert Regulatory Affairs, Bonn GERMANY

He 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 Rüdiger Faust
Grünenthal GmbH, Aachen, GERMANY

Director, Regulatory Intelligence, Global Regulatory Affairs

Lynsey Flitton
AbbVie Ltd, GREAT BRITAIN

Associate Director, Global Labeling, Europe

Dr Juliane Rechsteiner
Bayer AG, Wuppertal, GERMANY

Labeling Manager & RA Packaging Manager, Regulatory Affairs

Day 1: 09:00 - 17:00

Electronic product information (ePI) in the EU
Dr Peter Bachmann

- Status of the EMA action plan and outcome of the EMA workshop
- Current QRD and upcoming electronic product information

Germany: Project GI 4.0 – electronic product information
Dr Gesine Bejeuhr

Digital formats for electronic product information in practice
Dr Rüdiger Faust

- 'Alexa, read my package leaflet'
- True electronic formats
- ePI and SPOR

Data integrity and trusted labelling
Dr Juliane Rechsteiner

- Structured labelling tools as a solution for assuring labelling compliance

e-labelling and patient focused leaflets from a pharmaceutical company perspective
Lynsey Flitton

- From SmPC to QR code sites – working with internal stakeholders on e-labelling sites
- e-labelling compliance
- Readability testing for the printed and electronic leaflets – should they differ?

How to use IT to improve the labelling business process
Dr Peter Bachmann

- Possible role of SPOR in the update and maintenance of ePI
- PMS and TOM PMS

Day 2: 09:00 - 16:00

PSUSA, label change after the PRAC decision and PV inspection findings

Dr Nils Lilienthal

- Assuring consistency in labelling from the signal to the artwork

End-to-end labelling from signal to inclusion in the patient information; practical challenges and possible solutions

Dr Anke Webler-Messenger

- The End-to-end labelling process
  - Compliance considerations and possible solutions
  - Interfaces
  - Tracking

Update from the QRD group

Dominique Westphal

- Revision of the QRD Template
- Mobile scanning and other technologies

Artwork Design: Layout changes due to serialisation, Tamper Evidence and antifraud – best practice

Dieter Mößner

- Technical and graphical changes to printed packaging materials
- Checklists, processes and items to be complied with
- Artwork checks and packaging qualification

Closing discussion

Your speakers day 2

Dr Nils Lilienthal
Senior Expert Pharmacovigilance, Bonn, GERMANY

Dieter Mößner
Edelmann GmbH, Heidenheim GERMANY

Project Engineer Pharma

Dr Anke Webler-Messenger
Boehringer Ingelheim International GmbH, Ingelheim, GERMANY

Head of Global Labeling

Dominique Westphal
Paul-Ehrlich-Institut (PEI), Langen, GERMANY

Your benefits

- Discuss issues with experts from the industry and the authorities
- Practical experience and industry solutions for data integrity, trusted labelling, electronic product information, end-to-end labelling, etc.
- Sufficient time for discussion guaranteed!

ExpertFORUM Labelling

Aims and objectives

This conference will provide you with a thorough update on the regulatory requirements and practical industry solutions for labelling. Nine experts will provide the latest information on electronic product information, regulatory compliance and data integrity challenges, SPOR requirements, end-to-end labelling solutions, safety labelling issues and much more.

After having attended this conference, you will be aware of your upcoming labelling duties and how to go about them with several practical industry examples.

Who should attend?

This conference will benefit anyone working in the field of product information, such as SmPCs, package leaflets, CCDS and drug information, and anyone who would like to have a detailed update on regulatory requirements and options in this field.

Members of the following departments will particularly benefit from this conference:

- Regulatory affairs and labelling
- Medical affairs
- Pharmacovigilance

Knowledge of the EU labelling system is a prerequisite for the conference.

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

Yes, I will attend

☐ ExpertFORUM Labelling

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content 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. 19 05 232**

- **Date/Venue:**
15 - 16 May 2019
Day 1: 08:30 registration; 09:00-17:00 conference
Day 2: 09:00 - 16:00 conference
Hilton Bonn
Berliner Freiheit 2 · 53111 Bonn
Tel. +49 228 7269-0 · Fax +49 228 7269-700

- **Fee:**
€ 1,890.00 (+ German VAT) incl. course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate.

- **Questions and information:**
Dr. Henriette Wolf-Klein
Department Manager Pharmaceuticals & Healthcare
Tel. +49 6221 500 680 · h.wolf-klein@forum-institut.de

- **Cancellation Policy:**
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