CONFERENCE

FORUM
40 JAHRE

ExpertFORUM Labelling

Essential trends in product information, digitalisation, patient accessibility, safety labelling & IDMP

TOPICS

- Implementation of IDMP – current status
- QRD Working Group update
- Electronic product information (ePI) and Germany's GI 4.0
- E-labelling projects and digitalisation
- Labelling compliance and pharmacovigilance
- Accessibility of product information

YOUR SPEAKERS

Dr Peter Bachmann
Senior Expert Regulatory Affairs, GERMANY

Berit Fasse, MDRA
Bayer AG, GERMANY

Dr Eva Göbgen
vfa Association of Research-Based Pharmaceutical Companies, GERMANY

Dr Thomas Grüger
Senior Expert Pharmacovigilance, GERMANY

Dr Niklas Jänich
Boehringer Ingelheim International GmbH, GERMANY

Karl-Heinz Loebel
PharmaLex GmbH, GERMANY

Kim Sherwood
Medical Products Agency (MPA), SWEDEN

Hjörleifur Thorarinsson
Icelandic Medicine Verification Organisation, ICELAND

Dr Anke Webler-Messenger
Boehringer Ingelheim International GmbH, GERMANY

18–19 MAY 2020 IN COLOGNE

MONDAY, 18 MAY 2020 FROM 09:00 - 17:00

YOUR SPEAKERS DAY 1

Dr Peter Bachmann
Bonn, GERMANY

Senior Expert Regulatory Affairs

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

She manages the project GI 4.0, the German pilot for digital patient leaflets.

Dr Niklas Jänich
Boehringer Ingelheim International GmbH, Ingelheim, GERMANY

Head of Global Reg. Affairs Processes/ Training/Compliance & Global Labeling Operations

Kim Sherwood
Medical Products Agency (MPA),
Uppsala, SWEDEN

Senior Expert Product Information Assessor, Department of Product Information

Hjörleifur Thorarinsson
Icelandic Medicine Verification Organisation,
Reykjavík, ICELAND

Executive Director

PROGRAMME DAY 1

Implementation of IDMP – current status
Karl-Heinz Loebel

- The development of IDMP and SPOR

QRD Working Group update
Kim Sherwood

- ePI and QRD templates – fragments, structures and XML
- Traceability of biologics
- Revision of the SmPC guidelines

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

E-labelling projects and digitalisation – Icelandic Medicines Verification Organisation (ICEMVO) update
Hjörleifur Thorarinsson

GI 4.0 – the German project
Dr Eva Göbgen

- Concept of the German ePI pilot project
- Source of information
- What happens next
- 'Rote Liste' in Germany

Labelling content management
Dr Niklas Jänich

- Overcoming the document paradigm
- Leveraging structured content management for the E2E labelling process
- Structured authoring tool development
- IDMP compatibility

TUESDAY, 19 MAY 2020 FROM 09:00 - 16:00

PROGRAMME DAY 2

Labelling compliance and pharmacovigilance
Dr Thomas Grüger

- Regulatory duty to update the package leaflet after signal detection following the PRAC decision
- Educational material as an authority requirement
- Variations submission and implementation
- Labelling as a trigger or part of PV inspections

Assuring labelling compliance in practice
Dr Anke Webler-Messenger

- Continuous updating of company core safety data and company core safety information, possible triggers and challenges
- Dealing with and avoiding local labelling deviations
- Roles, responsibilities and mechanisms to assure labelling compliance – governance bodies and decision-making
- Demonstrating labelling compliance during PV inspections

Patient communication beyond readability testing
Berit Fasse

Collecting, cleaning and structuring data in companies
Karl-Heinz Loebel

- … for IDMP
- … to improve labelling

PDF/UA: accessibility for people with disabilities using assistive technology
Karl-Heinz Loebel

YOUR SPEAKERS DAY 2

Berit Fasse
Bayer AG, Wuppertal, GERMANY

Senior EU Labeling Manager

Dr Thomas Grüger
Bonn, Germany

Senior Expert Pharmacovigilance

Karl-Heinz Loebel
PharmaLex GmbH, Mannheim, GERMANY

Director, Principle Consultant Regulatory Operations

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

Head of Regulatory Affairs CNS, Retinopathy and Emerging Areas

AIMS AND OBJECTIVES

This ExpertFORUM will provide a thorough update on current trends in product information and labelling. Authority and industry experts will talk about e-labelling, digitalisation and the identification of medicinal products (IDMP), and give you practical examples of labelling content management and compliance.

A discussion on the accessibility of product information to patients, including tips on how to optimise your labelling management, will round off the event.

TIME SCHEDULE

Monday, 18 May 2020
from 08:30 registration
from 09:00 - 17:00 conference

Tuesday, 19 May 2020
from 09:00 - 16:00 conference

WHO SHOULD ATTEND

This conference addresses the needs of individuals involved in product information in regulatory affairs, medical affairs and pharmacovigilance.

It will provide useful updates on the relevant trends in digitalisation, compliance and much more. A working knowledge of product information is a prerequisite.

YOUR BENEFITS

- First-hand information on e-labelling projects and electronic product information (ePI).
- Authority and industry experts will provide practical examples of labelling content management and aspects of safety labelling.
- The latest on the Quality Review of Documents (QRD) Working Group's activities and IDMP requirements.

REGISTRATION FORM

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Fee
1,890.00 (+German VAT)

CANCELLATION POLICY

Our general terms and conditions apply (as of 1. January 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.de/agb_en

ANY FURTHER QUESTIONS?

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