ONLINE-CONFERENCE

FORUM

ExpertFORUM Labelling

Safety labelling, digital information tools

TOPICS

- From signal detection to labelling: The impact of PRAC recommendations on labelling
- UNICOM: Data as an enabler of patient empowerment
- The IMI Gravitate Health project: Digital information tools
- The EMA creation tool for ePI
- Readability testing and electronic product information

YOUR SPEAKERS

Dr Peter Bachmann
Senior Expert Regulatory Affairs, Germany

Dr Rüdiger Faust
UCB BIOSCIENCES GmbH, Monheim, Germany

Lynsey Flitton
AbbVie Ltd, Maidenhead, Great Britain

Dr Thomas Grüger
Senior Expert Pharmacovigilance, Bonn, Germany

Dr Nicole Kavanagh
Health Products Regulatory Authority, Dublin, Ireland

Dr Nathalie Lambot
Pharma.be, Brussels, Belgium

Prof Dr Anne Moen
Institute for health and society,
Faculty of Medicine
University of Oslo, Norway

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

Marie Vande Ginste
Pharma.be, Brussels, Belgium

20–21 OCTOBER 2022 – ONLINE

THURSDAY, 20 OCTOBER 2022, 9:00 am – 2:00 pm

YOUR SPEAKERS DAY 1

Dr Peter Bachmann
Bonn, GERMANY

Senior Expert Regulatory Affairs

Dr Thomas Grüger
Bonn, GERMANY

Senior Expert Pharmacovigilance

Lynsey Flitton
AbbVie Ltd, Maidenhead,
GREAT BRITAIN

Associate Director,
Strategic Global Labeling, Europe

Prof Dr Anne Moen
Institute for health and society,
Faculty of Medicine
University of Oslo, NORWAY

Director UiO:eColab

PROGRAMME DAY 1

UNICOM: Data as an enabler for patient empowerment and free movement in the EEA/EU
Dr Peter Bachmann

From signal detection to labelling
Dr Thomas Grüger

- The impact of PRAC recommendations on labelling
- Safety labelling and safety variations - a perpetual challenge

Labelling and the PV inspection
Lynsey Flitton

The IMI Gravitate Health project: Digital information tools that encourage the safe use of medicines
Prof Dr Anne Moen

FRIDAY, 21 OCTOBER 2022, 9:00 am – 1:30 pm

PROGRAMME DAY 2

The EMA creation tool for ePI - the first steps
Dr Rüdiger Faust

- From principles to action
- Creating an authoring tool to submit ePI

The e-PIL pilot project in Belgium and Luxembourg to test the use of electronic product information in a hospital setting: Interim analysis
Dr Nathalie Lambot, Marie Vande Ginste

Readability testing and electronic product information: How do they fit?
Kim Sherwood

Multilingual packages in a digitalised world
Dr Nicole Kavanagh

YOUR SPEAKERS DAY 2

Dr Rüdiger Faust
UCB BIOSCIENCES GmbH,
Monheim, GERMANY

Global Regulatory Policy and Intelligence Lead, Global Regulatory Affairs

Dr Nathalie Lambot
Pharma.be,
Brussels, BELGIUM

Advisor in public health, regulatory affairs and clinical trials

Marie Vande Ginste
Pharma.be,
Brussels, BELGIUM

Advisor in public health

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

Senior Expert
Product Information Assessor,
Department of Product Information,
member of the QRD group

Dr Nicole Kavanagh
Health Products Regulatory Authority, Dublin, IRELAND

Senior Pharmaceutical Assessor; CMDh member for Ireland

AIMS AND OBJECTIVES

This ExpertFORUM focuses on safety labelling and the digitalisation of product information.

European authority and industry experts will provide the latest on UNICOM, IMI Gravitate Health, e-PIL and other initiatives, and all you need to know for your digitalisation projects and fulfilling the requirements of product information, patient empowerment and safety labelling.

WHO SHOULD ATTEND

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

It provides useful updates on the relevant trends in digitalisation, safety labelling and much more. A working knowledge of product information is a prerequisite.

YOUR TAKEAWAYS

- You can meet leading authority experts
- You will get the latest information on digitalisation projects
- You will get firsthand information on safety labelling and PV inspections

REGISTRATION FORM

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Date
20 – 21 October 2022
Day 1: 9:00 am - 2:00 pm
Day 2: 9:00 am - 1:30 pm
You may dial in 30 min.
before the session begins

Fee
1,490.00 (+German VAT)

CANCELLATION POLICY

Our general terms and conditions apply (as of 1. November 2021) 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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