EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instrument for Pre-accession Assistance (IPA) advanced EMA training on Quality and Inspections

15-16 June 2023 - Amsterdam

Chairs: Ivo Claassen, Martin Harvey Allchurch and Michiel Hendrix (EMA)

Programme

Day 01
15 June 2023
Room 1D / 09:15-17:00 CET

Registration and welcome coffee / 08:30-09:00

Official welcome and opening remarks
Ivo Claassen - EMA Deputy Executive Director / 09:15-09:30

Morning session

Chair: Ivo Claassen – Deputy Executive Director, EMA

Seminar 1 - Setting the scene: introducing ICH Q12 (Technical and regulatory considerations for pharmaceutical product lifecycle management)
Moderator: Brian Dooley, EMA
09:30-10:45

Coffee break / 10:45-11:15

Seminar 2 - Assessment of generics
Moderator: Jose Cozar, EMA
11:15-12:00

Lunch / 12:00-13:15

Afternoon session

Chair: Michiel Hendrix, International Affairs Officer, EMA

Seminar 3 - Inhalation products: In-vitro equivalence, PK and PD + Q&A change of propellants
Moderators: Claudia Vincenzi (EMA) and Sagrario Rey Torre (EMA)
13:15-14:45

Coffee break / 14:45-15:15

Seminar 4 - Plastic materials and extractables and leachables: current EU regulatory requirements, interface quality non/clinical and what's coming next
Moderators: Claudia Vincenzi (EMA) and Katrin Buss (BfArM - Germany)
15:15-16:45

Group photo
Networking event, EMA coffee lounge and terrace (3rd floor)
17:00-20:00

Day 02
16 June 2023
Room 1D / 09:15-16:45 CET

Registration and welcome coffee / 08:30-09:00

Introduction Day 2
Martin Harvey Allchurch – Head of International Affairs, EMA / 09:15-09:30

Morning session
Chair: Martin Harvey Allchurch – Head of International Affairs, EMA

Seminar 5 - Quality defects and recall: detailed EU procedures and practices
Moderators: Tom Brusselmans (EMA), Patricia Nagtegaal and Niels Speksnijder (Health and Youth Care Inspectorate, The Netherlands)
09:30-10:45

Coffee break / 10:45-11:15

Seminar 6 - Live biotherapeutic products: regulatory requirements
Moderator: Katrin Buss (BfArM - Germany)
11:15-12:30

Lunch / 12:30-13:30

Afternoon session
Chair: Martin Harvey Allchurch – Head of International Affairs, EMA

Seminar 7 - Good Distribution Practices (GDP)
Moderator: Barbara Henry (HPRA - Ireland)
13:30-14:45

Coffee break / 14:45-15:15

Seminar 8 - Sampling and Testing
Moderator: Ruben Lindo (EMA)
15:15-16:30

Closing remarks
Martin Harvey Allchurch, Head of International Affairs, EMA
16:30-16:45

About this event

This event is part of the European Commission funded Instrument for Pre-Accession Assistance (IPA) programme.

The main objective of this training is to prepare the integration of current candidate countries and potential candidates into the European Union regulatory systems by bringing them in closer alignment with the Acquis Communautaire in the field of medicines regulation.

About the European medicines regulatory system and EMA

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network makes the EU regulatory system unique.

The network is supported by a pool of some four thousand experts drawn from across Europe, allowing it to source the best possible scientific expertise for the regulation of medicines in the EU and to provide scientific advice of the highest quality.

EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers.

Venue

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How to find us

Welcome to EMA!