DIA

DIA Eurasia
Implementing eCTD in the region

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Overview

The Eurasian Union is working to improve the submission process by implementing eCTD and also other ICH guidelines to support the aspiration to increase local manufacturing capacity. As the only public workshop in the region with international experts bringing their knowledge and experience, this is a must-attend for anyone who wants to stay abreast and implement the new requirements smoothly.

Key Objectives

- Inform about the regional eCTD implementation
- Hear and ask directly from the top regional regulators about current and future plans
- Learn from the experience from international experts
- Exchange and engage with your peers to broaden your professional network

Who Should Attend

- Regulatory reviewers and scientific administrators from Eurasian regulatory agencies
- Marketing authorization holders in Russia, Kazaksthan and Belarus
- Professionals working in regulatory strategy, regulatory policy or regulatory submissions
- Professionals involved with eCTD implementation projects

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

AGENDA

08:00 REGISTRATION

08:45 WELCOME NOTE

09:00 KEYNOTE

PATIENTS ARE WAITING - CONCERTED ACTIONS TO BRING INNOVATIVE PRODUCTS TO PATIENTS AROUND THE GLOBE

Moderator: Inka Heikkinen, Associate Director, Scientific Programmes, DIA EMEA, Switzerland

The EU regulatory framework enabling fast approvals of innovative products
Tomas Salmonson, former EMA CHMP Chairperson, Consilium Salmonson-Hemmings, Sweden

The role of the ICH and WHO driving regulatory convergence – high level overview of guidelines
Petra Dörr, former Vice-chair of the ICH Assembly, Petra Doerr Consulting Ltd, Switzerland

EAEU regulator presenting in their plans in regards to innovative products and engagement in global activities
Anna Kravchyuk, Deputy Head, Department of coordination of work in the field of circulation of medicines and medical devices, EEC

Discussion with speakers and Phillip Romanov, Director, Department of Medicines Regulation, MoH, Russia

10:45 COFFEE BREAK

11:15 SESSION 1

THE INTERNATIONAL ENVIRONMENT

Moderator: Hans van Bruggen, CEO and Regulatory Affairs Scientist, QDossier, Netherlands

Insights into ICH Q12 and impact on future submissions
Susanne Ausborn, Head, International Regulatory Policy, Hoffman-La Roche, Switzerland

eCTD implementation: how regional requirements can be aligned, steps for success, industry perspective & learnings from implementation in EU.
Alastair Nixon, **Director, Publishing,** GlaxoSmithKline, UK

Discussion with speakers and Konstantin Koshechkin, Head of IT-Development Department, FGBU NCESMP, MoH Russia

13:00 LUNCH - RESTAUTANT SAMOBRANKA - GROUND FLOOR

14:00 SESSION 2

TECHNICAL DISCUSSION ON eCTD

Moderator: Alastair Nixon, Director, Publishing, GlaxoSmithKline, UK

Comparison of eCTD and CTD and Preparing your company for electronic submission – required business process changes
Karl-Heinz Loebel, **Director, Principle Consultant Regulatory Operations, Pharmalex, Germany**

Case studies on eCTD review and validation and on eCTD lifecycle management
Marloes van der Geer, **Regulatory Affairs Scientist, QDossier, Netherlands**
Hans van Bruggen, **CEO and Regulatory Affairs Scientist, QDossier, Netherlands**

Panelist
Dmitry Rozhdestvensky, **Head, Department of coordination of work in the field of circulation of medicines and medical devices, EEC**

17:00 END OF THE WORKSHOP

Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.