

Joint DIA/IMB Common European Submission Platform (CESP) Information Day

Event #13111

20 November 2013

DoubleTree by Hilton Hotel (formerly The Burlington Hotel)

Dublin, Ireland



Programme Chair

Pat O'Mahony

Chief Executive, Irish Medicines Board, Ireland

Programme Committee

Kevin Horan

Business Services Manager, Irish Medicines Board, Ireland

Suzanne McDonald

Director IT and Change Management, Irish Medicines Board, Ireland

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

About DIA

DIA is a neutral, global, professional and member-driven association of nearly 18,000 professionals involved in the discovery, development and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA is an independent non-profit organisation who provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well-being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland; Tokyo, Japan; Mumbai, India; Beijing, China; Washington, D.C.; and Latin America.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Overview

The joint DIA/IMB Information Day provides the latest information on the Common European Submission Platform (CESP). It focuses specifically on the use of this newly implemented solution designed to enable the simultaneous delivery of applications to the various EU regulatory authorities.

This Information Day provides a detailed view of the systems operation, together with information for organisations wishing to use CESP. Information on the level of usage will also be shared with participants, together with consideration of the benefits of using the CESP solution.

The session will be highly interactive enabling ongoing dialogue between the various stakeholders, and participants will have the opportunity to discuss issues and raise questions to which they can expect direct answers.

Key Topics

The conference will provide

- An overview of CESP operation
- Details of CESP usage levels and regulatory implementation across Europe
- Organisational requirements & training needs
- Potential organisational benefits arising from CESP

Objectives

To provide an opportunity for industry to evaluate CESP in the context of their own organisational needs

- To provide an update on recent changes to CESP operations
- To enable feedback on future considerations for the extension of CESP

Who Will Attend

This conference is aimed at intermediate and experienced professionals from

- The pharmaceutical industry, and regulatory service providers

For additional information about the event please contact kaija.kurki-suonio@diaeurope.org or call +41 61 225 51 51.

For more information about CESP please visit <http://cesp.hma.eu>

FINAL PROGRAMME



WEDNESDAY | 20 NOVEMBER 2013

12:00 REGISTRATION AND WELCOME COFFEE

12:45 WELCOME AND INTRODUCTION

Pat O'Mahony, Chief Executive, Irish Medicines Board, Ireland

13:00 Session 1

COMMON EUROPEAN SUBMISSION PORTAL – FROM CONCEPT TO REALISATION

Session Chair:

Kevin Horan, Business Services Manager, Irish Medicines Board, Ireland

Background to CESP

Andrea Johnson, Project and Training Engagement Manager, MHRA, UK

CESP Overview and Demonstration

Kevin Horan, Business Services Manager, Irish Medicines Board, Ireland

Industry Overview of Portals and Gateways in Europe

Remco Munnik, Regulatory Information Director, Asphalion S.L., Spain

Agency Use of CESP

Andrea Johnson, Project and Training Engagement Manager, MHRA, UK

15:00 COFFEE BREAK

15:30 Session 2

CESP – FUTURE POTENTIAL

Session Chair:

Suzanne McDonald, Suzanne McDonald, Director IT and Change Management, Irish Medicines Board, Ireland

Integrating CESP with Submission Systems

Christian Kaas, Director Development, Lorenz Archiv-Systeme GmbH, Germany

Future of CESP – Opportunities and enhancements

Kevin Horan, Business Services Manager, Irish Medicines Board, Ireland

Panel discussion with Q&A

17:00 END OF INFORMATION DAY

PRESENTATION ACCESS INFORMATION

As a benefit of registration, presentations will be made available on the DIA website from **Thursday, 28 November 2013**. Please log in to MyDIA and choose My Presentation Downloads, where you will be able to download all presentations that have been submitted by speakers.

Note: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use our Login Reminder.

After logging in to My DIA, you will see presentation PDFs from all the DIA offerings you have attended in the past 6 months. Simply choose the presentation you would like to view or download.

Please note that if a presentation is not available on the website, it is because:

- The presenter has not (yet) supplied us with a presentation file
- There was no slide presentation planned by the speaker
- The speaker did not agree to share it with other participants
- You have not yet paid the registration fee

CERTIFICATE OF ATTENDANCE

Pick up your certificate of attendance onsite! The DIA Team will print your certificate on request onsite at the Registration Desk. If you prefer to receive your certificate electronically after the conference, please email us on diaeurope@diaeurope.org or call +41 61 225 51 51.



DIA Mission

DIA fosters innovation to improve health and well-being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- Delivering customized learning experiences;
- Building, maintaining, and facilitating trusted relationships with and among individuals and organisations that drive and share DIA values and mandates; and
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.

DIA Vision

DIA is the global forum for knowledge exchange in the pharmaceutical sector that fosters innovation to raise the level of health and well-being worldwide

Unless otherwise disclosed, DIA Europe 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 Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.