CTIS Sponsor User Workshop

7 November 2023 | Mercure Hotel Amsterdam City

INSTRUCTORS

Fatima Pimentel
Associate Director, SSU & Regulatory
Syneos Health

Ruediger Pankow
Principal Consultant, Regulatory Affairs
Parexel International

Overview

The workshop aims to enhance knowledge and proficiency in managing applications in CTIS. Participants will engage in hands-on live system demonstrations under the guidance of experienced trainers. Functional principles of the dossier sections and dossier components, the management of applications under evaluation as well as substantial and non-substantial applications will be explained using examples of business situations. Alternative approaches will be presented and implications on documentation discussed.

Participants will have the opportunity to ask questions in order to gain a comprehensive understanding of the application functionalities under relevant business situations to ensure high-quality application dossiers and efficient application management in CTIS.

The workshop will not cover other CTIS areas such as user administration, notifications, annual safety reporting, ad-hoc assessments, corrective measure or results posting.

Who Should Attend

Sponsor workspace users (commercial sponsors, academia, CROs,) including SMEs wishing to enhance practical knowledge of the system functionalities.

REGISTER NOW

Workshop Venue

Mercure Hotel Amsterdam City
Joan Muyskenweg 10
1096 CJ Amsterdam
Netherlands

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.

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08:15 REGISTRATION AND WELCOME COFFEE

09:00 WELCOMING REMARKS AND INTRODUCTION

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09:15 SESSION 1

POPULATE APPLICATION DOSSIER INFORMATION EXCLUDING PRODUCTS

Instructors:
Fátima Pimentel, Associate Director, SSU & Regulatory, Syneos Health
Rüdiger Pankow, Principal Consultant, Regulatory Affairs, Parexel International

This session focuses on the application dossier sections "Form", "Part I excl. product", Part(s) II and explains dossier information and components with practical examples

Topics covered:

- Form section
- Part I data fields & sub-sections (Protocol, Sponsor, Associated trials)
- MSC and Part II data fields & sub-sections

Q&A

10:45 COFFEE BREAK

11:00 SESSION 2

ADD AND POPULATE PRODUCT INFORMATION

Instructors:
Fátima Pimentel, Associate Director, SSU & Regulatory, Syneos Health
Rüdiger Pankow, Principal Consultant, Regulatory Affairs, Parexel International

This session cover the practical aspects how to add a medicinal product section to the application dossier and populate the relevant information in line with its role in the trial (IMP, AxMP) and marketing authorization status. The precondition of a product record in the XEVMPD will be explained and the different product section approaches presented including related needs on data and documents for non-authorized and authorized medicinal products.

Topics covered:

- XEVMPD product master data record
- Add a non-authorised medicinal product
- Add an authorized medicinal product defined as actual product, as active substance, or via ATC code
- Create an IMPD-Q only clinical trial application

Q&A

12:30 LUNCH

13:30 SESSION 3

MANAGE SUBMITTED APPLICATION UNDER EVALUATION

Instructors:
Fátima Pimentel, Associate Director, SSU & Regulatory, Syneos Health
Rüdiger Pankow, Principal Consultant, Regulatory Affairs, Parexel International

This session provides practical guidance how to manage applications under evaluation and options how to RFI responses and discuss options to withdraw or resubmit an application

Topics covered:

- Response to RFI
- Application dossier change as part of an RFI response
- Withdrawal an application
- Resubmission of initial application

Q&A

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15:00 COFFEE BREAK

15:15 SESSION 4

MANAGE SUBSTANTIAL AND NON-SUBSTANTIAL MODIFICATIONS

nstructors:

Fátima Pimentel, Associate Director, SSU & Regulatory, Syneos Health
Rüdiger Pankow, Principal Consultant, Regulatory Affairs, Parexel International

This session covers subsequent change to the application dossier for certain business cases including implications on required dossier information and components

Topics covered:

- Non-substantial modification dossier update submissions
- Substantial modification applications (general principles, requests for trial status extensions, change of main sponsor)

Q&A

16:45 WRAP-UP AND CLOSING

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Fátima Pimentel, Associate Director, SSU & Regulatory, Syneos Health
Rüdiger Pankow, Principal Consultant, Regulatory Affairs, Parexel International

17:00 END OF THE WORKSHOP

REGISTER NOW

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on the DIA website, during and after the Workshop.

To access presentations, go to www.diaglobal.org and click on Sign in at the very top. Once you have successfully logged in, click on Welcome on the top, then My Account and on the left, go to My Events - Review Presentations.

No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with the presentation. Updated versions of the slides will be made available shortly after the conference.