

Lifecycle Management of the eCTD

Gain current regulatory and industry perspectives on best practice administration of the eCTD and management of eCTD lifecycles

12 – 13 October 2010 • NH Amsterdam Centre • Amsterdam • The Netherlands

EXPERT SPEAKERS

Regulatory Panel

- **Ricco van den Hoorn, MEB**, The Netherlands
- **Cécile Levy-Lombard, AFSSAPS**, France
- **Pieter Vankeerberghen, Federal Agency of Health and Medicinal Products**, Belgium

Industry Experts

- **Ashley Burt, Biogen Idec**, UK
- **Joerg Schnitzler, Astellas Pharma Europe B.V.**, The Netherlands
- **Christian Dinter, Bayer Schering Pharma**, Germany
- **Alastair Nixon, EFPIA**, UK
- **Geoff Williams, Roche Products Ltd**, UK
- **Kevin Wing, eCTD Consultancy Ltd**, UK
- **Carolline Petersen, Novo Nordisk**, Denmark
- **James Hendry, Pfizer**, UK
- **Laura Barrett, GlaxoSmithKline**, UK
- **Ferhad Farsi, Abdi Ibrahim**, Turkey
- **Suzie Horn Henderson, Besins Healthcare**, Belgium

BENEFITS OF ATTENDING

- ✓ **Discuss and solve eCTD lifecycle management issues** – use this opportunity to share your eCTD LCM problems and gain practical advice on issues such as granularity, metadata, navigation and baselines
- ✓ **Network with key EFPIA members** – find out the latest eCTD news and updates including the eCTD Next Major Version and implications for industry of the 2010 NeeS Guidance updates
- ✓ **Direct contact with regulatory agency representatives** – find out how to improve your submissions for more timely approval by the authorities
- ✓ **New Variations Guideline first hand experience** – hear about eCTD software updates and work practice changes required to accommodate the new guideline definitions

NEW
interactive
session

PLUS 3 GREAT LEARNING AND NETWORKING OPPORTUNITIES

Pre-conference workshop: Monday 11 October 2010

Introduction to the eCTD and Lifecycle Management

Led by: **Kevin Wing**, Senior Regulatory Operations Consultant, **eCTD Consultancy Ltd**, UK

Great for those new to the industry, and as a comprehensive refresher course!

Evening seminar: Tuesday 12 October 2010

Re-use of electronic dossiers for product registrations: Realising the global dossier?

Led by: **Kate Wilber**, Director of Regulatory Services, **ISI Europe**, UK

Post-conference workshop: Thursday 14 October 2010

Best Practice Lifecycle Management of Module 3

Led by: **Alastair Nixon**, EFPIA eCTD Topic Group Member, **EFPIA**, UK

A 'must attend' session for those involved in CMC and compiling module 3

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Pre-conference Workshop: Monday 11 October 2010

Introduction to the eCTD and Lifecycle Management

Led by: **Kevin Wing**, Senior Regulatory Operations Consultant, eCTD Consultancy Ltd, UK

Registration is at 09.00 for a 09.30 start. The workshop will finish no later than 16.30. Lunch, refreshments and workshop material will be provided.

Introduction

This workshop is aimed at those who have never worked with the eCTD or eCTD lifecycle management or those who have just started working with eCTD submissions. Participants will be provided with a comprehensive introduction to CTD and eCTD concepts. The workshop will introduce critical points related to lifecycle management of eCTDs including benefits, challenges and best practice based on current guidance and experience with multiple companies of all sizes.

Topics covered will include:

- Introduction to ICH, CTD, eCTD
- Granularity and authoring
- eCTD building/viewing software
- Principles of lifecycle management
- Impact of metadata
- Regional status
- Related standards (XML labelling, electronic application form)
- Future developments

Conference Day 1: Tuesday 12 October

08.30 Registration

Lifecycle Management of the eCTD for MRP/DCP, Centralised and National Licenses

09.00 Opening Remarks from the Chair
Alastair Nixon, EFPIA eCTD Topic Group Member, EFPIA, UK

09.10 **Successfully Managing eCTD Lifecycle in the Centralised Procedure**

- Progress to date with the e-submissions gateway
- Practical experience with the e-submissions gateway
 - Transition to the use of the gateway
 - Information requirements for Rapporteur, Co-Rapporteur and CHMP members
- Implications of central repository and EMA distribution

Ashley Burt, Associate Director, Regulatory Operations, Biogen Idec, UK

09.45 **Best Practice eCTD Lifecycle Management for the MRP and DCP**

- Problems encountered and how these were managed
- Feedback from various authorities about specific submission requirements

Ron de Boer, Regulatory Operations Manager, Astellas Pharma Global Development – Europe, The Netherlands

10.20 **Maintaining Lifecycles for a National Product License in a Number of Member States**

- Points to consider when making the decision to convert from paper/NeS to eCTD for national licenses
 - Local legislation and base line requirements
 - Assessing level of granularity
 - Assessing finances for software, implementation and training
- Practical advice to successfully submitting your first eCTD dossier and subsequently maintaining the eCTD lifecycle

Suzie Horn Henderson, Regulatory Officer, Besins Healthcare, Belgium

10.55 Morning Coffee

11.25 **Industry Experience: eCTD Lifecycle Management in a DCP**

- eCTD Fundamentals/CMDh BPG on the use of the eCTD in MRP/DCP
- From the initial eCTD submission to the closing of the procedure
- Initial national translations, follow-up measures, PSUR, variations (incl. work sharing) and a new indication

Christian Dinter, Global Submissions Manager, Bayer Schering Pharma, Germany

12.00 **Managing the eCTD Lifecycle for Extra-ordinary Submissions**

- Issue/regulatory activity encountered not covered by the guideline
- How this was interpreted and managed in the submission
- Response from regulatory authority and final outcome

Gary Dodson, Manager, Regulatory Operations, Baxter, Austria (awaiting final confirmation)



12.35 **Presentation Hosted by ISI Europe**

For more information about this presentation, please refer to www.informa-ls.com/ectd

Kate Wilber, Director of Regulatory Services, ISI Europe, UK

13.10 Lunch and Networking

Review of NeS and Future Outlook for the eCTD

14.10 **European NeS Guidance and Validation Rules**

- Review of 2010 updates and implications for industry
- Building NeS ToCs – options and best practice
- NeS validation – why might agencies reject NeS dossiers?
- The future for NeS

Alastair Nixon, EFPIA eCTD Topic Group Member, EFPIA, UK

14.45 **Status Update on the eCTD Next Major Version and Regulatory Product Submission**

- Overview of the eCTD NMV and RPS projects, including:
 - Brief project background
 - Current status and expected implementation dates
 - Implications for industry and impacts on eCTD lifecycle management

Geoff Williams, e-Regulatory Liaison, Roche Products Ltd; EFPIA Deputy Topic Leader, ICH M2; and Project Facilitator, RPS R3, UK

15.20 **eCTD and Document Management Software: Considerations on Selection and Implementation to fit eCTD Lifecycle Business Processes**

- Overview of types of eCTD/document management software
- Submission and content planning
- Designing a helpful document management system
- Maximising transparency and minimizing rework
- Registration tracking possibilities

Kevin Wing, Senior Regulatory Operations Consultant, eCTD Consultancy Ltd, UK

15.55 Afternoon Tea

16.25 **Practical Session: Exchange of eCTD Lifecycle Management Experiences**

This interactive session, through means of group exercises and discussion, is designed to help delegates navigate the eCTD lifecycle by working through lifecycle management problems, including:

- Defining level of granularity and metadata for your submission
 - Pros and cons of grouping per product or strength in one application
 - Future implications of being very precise
- Accomplishing direct navigation
 - Hypertext link and bookmark requirements
- Advantages and disadvantages in submitting baselines

Joerg Schnitzler, Head of Regulatory Operations, Astellas Pharma Europe B.V., The Netherlands

17.30 Closing Remarks from the Chair and End of Day One

Evening Seminar: Tuesday 12 October 2010

Re-use of electronic dossiers for product registrations: Realising the global dossier?

Led by: **Kate Wilber**, Director of Regulatory Services, ISI Europe, UK

Registration is at 18.00 for a 18.15 start. The workshop will finish no later than 21.30. The seminar will include documentation and evening meal.

This interactive session will lead participants through a series of questions and scenarios to address the question, 'can the dream of using one dossier across multiple countries be realised?'

Topics of discussion will include:

Leveraging eCTD across ICH regions

- Primary points of differentiation
- Managing local differences

Leveraging eCTD across non-ICH/ROW/emerging markets

- ASEAN Countries
- Latin America
- South Africa
- BRIC (Brazil, Russia, India, China)

Key points of discussion within this session will include:

- Building a master dossier
- Paper and electronic requirements over these markets
- Working with partners and affiliates across these countries

Tracking your submission and managing eCTD lifecycle in a global market

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"Good conference on a dynamic and complicated topic"

(Genzyme, Delegate Oct 2009)

Conference Day 2: Wednesday 13 October

Regulatory Feedback on Lifecycle Management of the eCTD

- 09.00** Opening Remarks from the Chair
Murat Hamzakadi, Associate Regulatory Operations Director, **Astellas Pharma Global Development Europe**, The Netherlands
- 09.10** **Regulatory Perspective: eCTD @ MEB**
- Current situation of electronic submissions and the eCTD at the Medicines Evaluation Board
 - How case managers and assessors use the eCTD
 - Practical demonstration: MEB's enterprise content management system
- Ricco van den Hoorn**, Information Manager, **Medicines Evaluation Board**, The Netherlands
- 09.45** **Regulatory Perspective on the eCTD at the Federal Agency of Health and Medicinal Products**
- Current situation of the eCTD and lifecycle management
 - Feedback on submissions received: Common pitfalls and tips for success
 - Lifecycle issues encountered and potential solutions
- Pieter Vankeerberghen**, Head of ITC Development and Projects, **Federal Agency of Health and Medicinal Products**, Belgium
- 10.20** Morning Coffee
- 10.50** **Agency Requirements for Archiving eCTD Submissions**
- Archiving requirements at AFSSAPS to ensure your eCTD submission is approved
 - Overview of the national archiving survey and summary of individual agency requirements
 - Mapping of the practises in EU member states in regards of the overview archiving questionnaires
- Cécile Levy-Lombard**, Record Manager, **AFSSAPS**, France

11.25 Meet the regulators!

Topics of discussion will include:


- Overview of validation tool and criteria
 - Is there flexibility in interpretation?
 - How the criteria are technically validated
 - Digital signatures
 - How the Next Major Version will be incorporated
 - Harmonisation of eCTD lifecycle management
- To make the most of this opportunity, send your questions for the regulators to meera.byatt@informa.com

12.10 SPOTLIGHT SESSION

Raise your corporate profile by sponsoring or exhibiting at the Informa Life Sciences' Lifecycle Management of the eCTD conference. For details on speaking in this session or other sponsorship opportunities at this conference please contact: **Ben Edwards**,
Tel: +44 (0)207 017 4447, Email: ben.edwards@informa.com

12.45 Lunch and Networking

Lifecycle Management - Mergers & Acquisitions

- 13.55** **Maintaining eCTD Lifecycles during Mergers and Acquisitions**
- Implication and consolidation of multiple eCTD tools during a merger/ acquisition
 - How the eCTD lifecycle was maintained when eCTD tools were consolidated
 - Achieving an optimal process from differing organisational eSubmission practices
-  **James Hendry**, Senior Associate, Worldwide Safety & Regulatory Operations, **Pfizer**, UK

Industry Experiences with Lifecycle Management of the eCTD

- 14.30** **Publishing Electronic Submissions using the New Variations Guidelines**
- Upgrading the eCTD software - transitioning from EU m1.3 to m1.4
 - Key problems encountered
 - Training and communication
 - Work practice changes to accommodate new definitions
 - Initial experience with NeeS and eCTD
- Laura Barrett**, Supervisor Global Regulatory Publishing, **GlaxoSmithKline**, UK
- 15.05** **Transition of an Application to the Swiss eCTD Format during Swissmedic's Phase 2**
- Creating a "baseline" submission
 - International project team
 - IT set-up, validation and QC processes
 - Lifecycle learnings at this point
 - Going forward
- Carolline Petersen**, Publisher, **Novo Nordisk A/S**, Denmark
- 15.40** Afternoon Tea
- 16.10** **Lessons Learnt in eCTD Lifecycle Management**
- Converting existing application from paper/NeeS to eCTD
 - Key challenges
 - What sections were converted?
 - Baseline provided
 - How to avoid lifecycle problems and how these can be resolved
 - Dealing with specific regulatory authority eCTD submission and lifecycle requirements
 - Validation tools/criteria and how to interpret their results
- Murat Hamzakadi**, Associate Regulatory Operations Director, **Astellas Pharma Global Development Europe**, The Netherlands
- 16.45** **Generics Perspective on eCTD Lifecycle Management**
- Common eCTD lifecycle issues encountered and how these were resolved
 - Parallels and differences in eCTD lifecycle management for generics and innovator products
 - Regulatory questions and feedback for generic submissions
- Ferhad Farsi**, R&D Director, **Abdi Ibrahim**, Turkey
- 17.20** Closing Remarks from the Chair and End of Day Two

Post-conference Workshop: Thursday 14 October 2010

Best Practice Lifecycle Management of Module 3

Led by: **Alastair Nixon**, EFPIA eCTD Topic Group Member, **EFPIA**, UK

Registration is at 09.00 for a 09.30 start. The workshop will finish no later than 16.30. Lunch, refreshments and workshop material will be provided.

This workshop will guide you through the common issues arising from the lifecycle management of module 3 and CMC variations using practical examples and group discussion

Topics to explore will include:

- Defining the level granularity for module 3
- How to present changes in the lifecycle
- Handling multiple dosage strengths, dosage forms, manufacturers etc. and maintaining the lifecycle in this situation

- ICH CTD-Q guidance on use of m3 attributes
- Handling of compendial and non-compendial excipients
- Addition of dosage strengths in the middle of a lifecycle
- Changing from paper to eCTD in mid-lifecycle - benefits of baseline submissions
- Grouping and work sharing - new options and challenges for lifecycle management

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