

FDA Warning Letter Excerpt: "...the documents..., should be organized based on the five modules in the CTD..."

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DATAFARM INC.
The eCTD From
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Information Agreement
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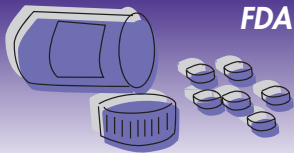
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FDA Warning Letter Excerpt: "...absence of electronic datasets in an acceptable format to permit review and analysis may be considered inadequate, resulting in a refuse-to-file decision ..."

DAY ONE
MONDAY, SEPTEMBER 17, 2007

7:45 REGISTRATION AND BREAKFAST

8:45 CHAIRPERSON'S WELCOME AND OPENING REMARKS

CASE STUDY

IN-DEPTH INTERACTIVE WORKSHOP

9:00 THE eCTD FROM START TO FINISH: WHAT IS IT?, WHAT IS THE IMPACT?, HOW DO I CREATE AN eCTD?, WHAT DO I NEED TO AVOID?

Shy (Shylendra) Kumar, President and CEO DATAFARM INC.

This workshop will provide a complete understanding of what the eCTD is and the requirements that you will really need to address. You will without a doubt walk away with the knowledge of and confidence of undertaking all aspects of the eCTD from start to finish.

This interactive workshop will take you step-by-step through the process of how to prepare, create and manage an eCTD. You will participate first hand in learning how to approach and control in detail the critical aspects of authoring, preparing compliant PDFs, and creating an entire eCTD along with its lifecycle.

You will learn that compiling an eCTD is only one step in process and gain the insight of what the real impact will be for you and your organization.

Throughout the workshop, you will also learn, based upon real life scenarios, where to invest your efforts and which of the many misconceptions and common pitfalls to avoid.

This will not be a high-level discussion of "backbone and leaves" so please be prepared to roll-up your sleeves to learn first hand how to take on the eCTD head-on.

- This workshop will provide the foundation for implementing your pre-eCTD business processes that support the compilation of a compliant eCTD.
- As part of the review of how to build an eCTD, regulatory expertise will be provided as how to compile your filings to multiple countries.
- This workshop will not only provide the necessary information of how to prepare, you will also learn how to execute an eCTD project.

About the workshop leader: Shy Kumar has a Masters in Public Health from Boston University. He has over 15 years of industry experience in IT, Clinical and Regulatory areas. His electronic submissions experience includes in the US, Canada, Europe and Japan. Mr. Kumar was involved with over 300 eCTD submissions projects that include the very first eCTD to EMEA via centralized process and the second eCTD submission received by the FDA.

12:00 LUNCHEON

CASE STUDY

HIGH LEVEL SESSION ON JUMP-STARTING AN eCTD PROCESS

1:00 GETTING A JUMP START ON eCTD SUBMISSIONS

Dominique LaGrave, Associate Director, Regulatory Operation and Innovation NOVO NORDISK

The session will highlight the benefits in taking an integrated approach to the eCTD, considering not only the publishing aspect of it but also the submission planning, tracking, management and viewing of eCTD. We will review the various steps taken by Novo Nordisk to move forward in the smooth adoption of the eCTD in the publishing department but also within the regulatory affairs department.

Highlighting the presentation will be information on:

- Examining success factors while transitioning to eCTD
- Leveraging eCTD to new perspectives
- eCTD case study examples

CASE STUDY

EXAMINING THE REGULATORY DIFFERENCES BETWEEN THE US, EU, AND JAPAN

2:00 STRATEGIES TO ENSURE THAT eCTD IS COMPLIANT AND USABLE FOR IMPLEMENTATION OF GLOBAL DRUG DEVELOPMENT AND SUBMISSIONS

Leyna Mulholland, PhD., Associate Director, Japan Pharmaceutical Development MERCK & CO.

The adoption of CTD has established a possible single global submission process and submissions in the CTD format became mandatory in EU and Japan since July 1, 2003 and more submissions are made by eCTD. This session will focus on

strategies to ensure that eCTD is globally compliant and usable for global drug development and submissions. Due to the differences in NDA filing and approval systems among three regions, the types of data included in the eCTD are different among regions and the global team needs to examine the content carefully to meet regulatory requirements. The use of eCTD enables the global team to review submission dossiers in a harmonized manner, however, the Japanese regulatory agency only accepts dossiers prepared in Japanese and this will create additional challenges for the global team as they review the eCTD in an expedited manner.

- How one organization establishes a global eCTD team
- Template driven process to streamline the eCTD preparation
- Simultaneous eCTD preparations/authorship and review process to capture and ensure regulatory compliance
- Dealing with regional differences

3:00 AFTERNOON BREAK – 7TH INNING STRETCH

3:15 INFORMATION AGREEMENT AND THE eCTD

Michel Vulpe, President
I4I, INC.

The eCTD is about to become a reality. The eCTD was specified in 2003; now five years later it appears that it will be a formal requirement in the 2008-2009 timeframe in the US and the European Union. Given that it takes on average 10 years to get from the laboratory to the NDA submission; this means that for an NDA expected to be filed in 2009 work on the eCTD should have started in 1999. This is because information to be provided in the eCTD reaches back to work done in the laboratory, and throughout the trials, where incidentally 20% of trial failures are attributable to poor documentation practices. That information should have been properly catalogued so the possible role in the eCTD is stated at the beginning of the process. As the understanding of the drug product evolves so does the information base, and when it finally comes time to submit, in principle the information base is current with the needs of the submission which is then created at the push of a digital button.

While it is unlikely complete accuracy will ever come to pass there are important reasons for striving to achieve this. The first and most obvious is that by starting at the beginning of the process rather than at the end, overall costs are better contained and managed and the last minute pressures that drive up costs are reduced. There is another important reason for starting at the beginning of the process; liability. Pressure for increased transparency of trials information is mounting. Regulators in the US and the EU have also signed information sharing agreements. It thus become vital that there be a strong level of information agreement in all the documents that make up or could possibly make up a submission. In order to achieve and maintain the proper evolution of the drug product information base, the data must be managed from the onset. Exposing gaps in the knowledge base is a liability risk.

The presentation will

- Review the reasons why ‘information agreement’ is critical and some of the measures that the organization can take to maximize it.
- Explore the role of authoring, document version sequencing and, metadata as tools to help the organization achieve information agreement in and around the eCTD.

4:15 INTERACTIVE PANEL DISCUSSION

INCLUDING ALL DAY ONE SPEAKERS

Lessons learned in protein development

- Paper vs. digital-is paper still more efficient?
- Is it important that authors and publishers learn XML ?
- How far away is eCTD as a common standard across all 3 ICH regions and Canada?
- Will the SAFE digital security and signature standard become a defacto standard? How safe is it?
- Questions and answers

5:00 END OF DAY ONE

DAY TWO
TUESDAY, SEPTEMBER 18, 2007

7:30 BREAKFAST

8:40 CHAIRPERSON’S OPENING REMARKS

IMPORTANT QUESTIONS AND ANSWERS ABOUT CDISC

8:45 CDISC: IS IT AN eCTD REQUIREMENT OR RECOMMENDATION

Michael Palmer, President
ZURICH BIOSTATISTICS INC.

The eCTD guidance specifies the CDISC standard for specific kinds of study data and metadata. Does this mean that study data submitted to FDA after January 1, 2008 should be in CDISC? That depends. Regulatory affairs professionals and their colleagues involved in submission planning and preparation will be called upon to read the CDISC tea leaves as that January 1, 2008 date draws near.

To read those tea leaves, you’ll need to know how to assess FDA’s accumulating revelations on how it sees CDISC and electronic submissions. You’ll have to understand CDISC’s current set of standards—which standards can be ignored, which can’t be ignored. And, you’ll want to assess your organization’s readiness to make a CDISC submission, if CDISC is what you need to do.

Knowledge and confidence are prerequisites to success in this new eCTD world, for study data as for other eCTD content. This presentation will give you knowledge of CDISC and FDA's reliance on it and confidence to help your organization succeed in the new eCTD world.

- Learn what FDA and CDISC require or recommend
- Understand why FDA is pushing industry to adopt CDISC for study data
- Acquire tools that you can use to assess your organization's

9:45 USING eCTD TECHNOLOGY TO STREAMLINE BUSINESS PROCESSES

Jay Smith, Director, Product Management
LIQUENT, THOMSON SCIENTIFIC

This session will focus on implementing eCTD in a global organization. It will highlight challenges and provide best practices in introducing the eCTD into an organization and discuss the advantages that can be gained by a harmonized, global approach and solution. It will discuss evolving standards and the need for adaptability to changing specifications, while ensuring validity of lifecycle management operations. The presentation will also include:

- Tips and tricks for planning, building and managing an eCTD over product lifecycle
- Considerations for global implementation of eCTD process and tools
- Understanding of the need for flexibility and adaptability of eCTD tools in light of evolving specifications and interpretation of Guidance vs. Regulations

10:45 MID-MORNING BREAK

11:00 eCTD IT IS ALL ABOUT PLANNING

Shy Kumar, President, CEO
DATAFARM INC.

Organizations are too focused on choosing a technical solution that provides them the capability to create eCTD submissions. A significant amount of time is spent on identifying the best solution that meets their business needs. The key to successful eCTD is the document and data within it. The preparation of documents and data is vital and may be overlooked in the mêlée of the eCTD implementation process. The purpose of this presentation is to highlight the importance of what goes into a submission and some of important activities one should consider while preparing an eCTD submission.

Creating the eCTD should not be the first step in the process – considerations must also include:

- Planning
 - Timelines
 - Team/Roles/Responsibilities
 - Process
 - Service Vendors - CROs

- Preparing your documents
 - Understanding the requirements – submission-ready documents
 - Authoring
 - Publishing
 - QA/QC
 - Life Cycle management
- eCTD Compilation
 - Application/Submission Information (Metadata)
 - Validation

12:00 LUNCHEON

eCTD AUTHORING STREAMLINED!

CASE STUDY

1:00 LEVERAGING eCTD TO STREAMLINE AUTHORING AND INFORMATION EXCHANGE

James Kelleher, CEO
GENERIS

The first generations of eCTD systems focused on creating the structure and XML output. To gain the maximum return on investment for implementing an eCTD system, however, a company should look to use the opportunity to integrate upstream processes from dossier planning through document authoring, review and approval to document re-use; as well as downstream processes such as submission and registration tracking, and even sales & marketing. This presentation will examine a number of examples from the industry for successful approaches, including some of the hurdles encountered and how they were overcome.

In particular this session will examine:

- How to use the eCTD structure to plan dossiers before content is even created
- How to streamline authoring processes, both in terms of creating content for use in eCTD but allowing co-authoring on a global basis including working with co-development partners
- How to enable non-document data to flow through from creation to inclusion in documents
- How to use the eCTD structure and metadata for submission tracking purposes

2:00 HOW TO EFFECTIVELY LEVERAGE eCTD WITHIN YOUR ORGANIZATION

Praveen Sofi MD, MBA, Principal, Healthcare and Life Sciences Consulting
Aatish Goel Consultant, Manufacturing and Supply Chain, Domain Competency Group
Murali Krishnan Sundararajan, Business Analyst, Pharma Domain Competency Group
INFOSYS TECHNOLOGIES LTD.

Faced with growing pace of innovation, complex regulatory compliance, extended development lifecycle and increased new product development cost, pharmaceutical and life sciences CxOs are looking to adopt newer ways to sustain growth and margins. One of the concerns being in the area of regulatory submissions, companies are struggling with solutions that allow them to capture critical documents and other sources of important data, and then control them. Companies are also looking at improving the regulatory submission process and eCTD is definitely being looked at as a driver to achieve this objective. Even though there are some geographical differences for instance- while US companies are aggressively persuading it and European companies are showing comparatively lesser interest, the underlying fact is that eCTD will become a vital factor for any organization's submission process.

This session will describe how the organizations need to manage regulatory submissions leveraging eCTD. The presentation will include the following areas:

- Challenges faced within the organization with respect to regulatory submissions
- Managing process, organization and technology changes in the organization in leveraging eCTD
- Handling dynamic regulatory variations
- Partnering with extended enterprise for eCTD submissions
- Experience sharing related to eCTD practices

3:00 AFTERNOON BREAK

CASE STUDY

OUTSOURCING eCTD SUCCESSFULLY

3:15 eCTD MADE EASY THROUGH PRODUCT INTELLIGENCE BUSINESS PROCESSES OUTSOURCING (BPO)

Michael Johnson, Senior Business Development Manager
Michele Pontinen, Senior Manager, Life Science Transformation Sector
CAPGEMINI

Today, XML and eCTD are generally not core competencies in most Life Sciences companies. FDA has adopted eCTD as their

standard for receiving electronic submissions and they of course expect industry to comply. eCompliance with eCTD will be expensive and time consuming to properly implement. Moving to eCTD is more than just XML, new hardware, software and services. It requires a complete business process re-engineering to achieve optimal capability for managing electronic data and knowledge throughout the record lifecycle. The process transformation to eCTD requires a re-tooling of some of your most valued knowledge workers.

Other US government regulated industries like aerospace have looked to business process outsourcing (BPO) as a cost neutral method to transform their legacy systems and processes to next generation XML Product Intelligence (PI) platforms. Although becoming commonplace in the global aviation industry, technical content BPO is relatively new in Life Sciences. During our interactive discussion you will learn how one of the world's leading regional aircraft manufacturers achieved a (40) % cost takeout and Federal Aviation Administration (FAA) compliance through Product Intelligence BPO.

You will learn about the successes in aviation and how the Life Science industry can quickly leverage these same outcomes through complete XML eCTD business process outsourcing. We will talk about the transformation from traditional clinical authoring to next generation Product Intelligence content creation, management and just in time delivery. We will discuss the business drivers and points of value associated with eCTD BPO. You will learn how to significantly reduce authoring, SPL and PIM costs while increasing global process standardization and knowledge transfer. We will explain how to reduce localization costs and achieve faster FDA compliant adoption of eCTD. Learn what Product Intelligence BPO can do to increase your company's earnings per share.

4:15 END OF CONFERENCE



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