SUMMARY REPORT OF e-CTD (Electronic Common Technical Document) WORKSHOP

WORKSHOP- Conducted in JSS College of Pharmacy, Ooty

WHEN- February 13&14th

Speaker- Vijaykumar Srinivasan Sir

Topic- Overview and Global perspective of e-CTD

ABSTRACT

In view of the digital global agenda, time has come to update and revive the past to new way in making the mankind easier. e-CTD is one such interesting practice nowadays for a sponsor or manufacturer to submit the documents and dossiers. The e-CTD (Electronic Common Technical Document) is an **interface between industry and agency** for knowing and sharing regulatory information and at the same time taking in to consideration of creating, reviewing the lifecycle of submission. **e-CTD is an extension form of CTD** where structure is specified by XML based backbone (Extensible Mark-up Language).

The e-CTD submission requirement is definitely a great challenge to the industry and regulatory agencies. The regulatory professionals should know the standards and groundwork and be expertise in technology for submission globally, because of the cost effectiveness and continuous technology transformation over the industry person to agencies has made numerous regulatory agencies to adopt this process and made compulsive for any sponsor go through this process.

Keywords: e-CTD, Dossiers, Granularity, Regulatory validation.

UNDERSTANDING

What is e-CTD?

The e-CTD abbreviated to be Electronic Common Technical Document is electronic submission of dossiers and documents by a sponsor or industry person to the agency. They contain folders with XML based table of content. This submission is to gain approval of a drug product with and throughout the country. It should be compliant to 21CFR part 11.

Difference to Paper, NeEs and e-CTD?

Paper document- Contains one or more volumes with continuous table of contents. They are organized with paper and cover letters.

NeEs- Contains table with modules and global table of contents. PDF documents are published with folders containing modules and nodes.

Submission to different ganecies and their respective countries was learnt with "**Pharma Med**" portal were we are given chance to access and update through each of the modules.

This made to learn what are the specific requirements needed for each of modules and nodes.

Mistakes committed were rectified and thus submissions were re-done again.

Workshop Report

Firstly the overview of e-CTD was clearly explained differentiating the submission documents required for pharmaceuticals drug. The presentation covered wholly of Common technical document, starting with objective, purpose and agenda. Later switching over to the differentiation of Paper, NeEs and e-CTD submissions, which was to the point to understand giving different examples of what each module looks like and contains.

Later, the countries submission with their regulatory requirements was discussed along with the supporting links which guided through the respective websites showing what exactly the country regulatory body requires.

The foremost attractive thing throughout the presentation was Sir's presentation, his patience towards and dedication that showed in responding to all our questions. He was also even very keen in knowing if the points have been conveyed or no. I was not hesitant with the repeated slides, rather it only showed his dedication towards his job and responsibleness that he had.

As a regulatory student I had the projection towards the submissions of various documents. Where we were all given a turn to learn to do the submission of documents for different countries and how exactly the portal for submission guides one.

This also made to learn and overcome the mistakes done during the allotted turns given.

Thank You,

Aswini Sofia P I

REPORT ON THE e-CTD WORKSHOP CONDUCTED ON 13TH AND 14TH OF FEBRUARY 2017.

SUBMITTED BY:

T. VIDHYA LAKSHMI

I – M.PHARMACY

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

JSS COLLEGE OF PHARMACY, OOTY

FINAL REPORT:

The workshop was about the pharmaREADY software which is used for the electronic submissions of various kinds of dossiers to the regulatory bodies. The seminar was given by Mr. Vijayakumar Srinivasan from NAVITAS, conducted by JSS college of pharmacy, ooty on 14th and 15th of February, 2016. The seminar was conducted in two sessions.

The first session was about the complete theoretical explanation of the electronic common technical document. We were told about how important the dossier preparation and submission is in the pharma field and what are all the responsibilities of the regulatory affairs department. When, why, where, how and by whom the software should be used was rationalized. The actual regulatory pathway for the approval of any product was explained. The differences between the e-ctd and the other ways of submission like paper submission and non e-ctd electronic submission was clearly explained along with their advantages and disadvantages.

The reasons behind why the countries prefer e-ctd for dossier submission are as follows:

- Printing and shipping costs are eliminated
- Application can be submitted in multiple countries with relatively minor changes
- Reduce review times, increase the response times to Agency requests, and ultimately lead to a faster approval
- Access of the same documents can be done many times.
- Bookmarks and hyperlinks are present which makes a reviewer to easily jump to the paper just cited, the table just mentioned, or the validation report just referenced
- This submission will be easy for the regulatory agency to audit the company whenever needed.

We had an idea about the Electronic Submission Gateway (EGS). There was a complete description about the software and explanation for the new terminologies that were used in the software like granularity, checksums, Href pathways, xml back bones, attributes, study tagging files etc. We were also given an idea about the Regulatory Information Management System (RIMS) and the documents publishing softwares.

The complete procedure along with the description for each step was given and justified. It was only an oral explanation on the first day regarding the software.

The second day of the seminar was “HANDS ON TRAINING “on the software. We were given opportunity to work on the software individually. We were well trained on how to file

an NDA, ANDA and BLA application forms for different regulatory bodies like USFDA, TGA, and EMA. The documents to be submitted for different marketing authorization procedures like centralised, decentralised, national and mutual recognition procedure for the European Union were differentiated.

The country specific documents that are to be submitted in different countries were also identified. There is a provision to add any new country in the software to which the product is to be marketed. The attachments of the documents from various sources and the deletion or any substitution in the documents can also be easily made in the software.

We also got to know about the different software available and the basis for choosing the right one in the right step. Each step for dossier submission was clearly established along with a proper justification.

Module 1 is the important part of the software which is mandatory to be filled in the dossiers. For new drugs, all the modules to be should be present, but in case of generic products, module 4 is not required and module 5 should have the details about the BA/BE studies. After the uploading of the documents there is a tool called as “COMPILE” which is useful to compile all the documents in the single application. After compilation, the whole application should be validated and can be forwarded to the regulatory body only if there are no drawbacks or mistake in the application.

One sequence of the application can be sent to the regulatory body and the same format or the format with minor changes can be sent to multiple countries along with country specific documents. After the preparation of the application, the whole sequence of the dossier can be viewed as a summary and required corrections can be made if any.

It was a great opportunity to understand and the handling of the e-ctd software which will be very useful with respect to our career. We had a session for interaction where we were allowed to clear all our queries. All our doubts were clearly given justification. It was great to interact with Mr. Vijayakumar regarding the subject and we are thankful to him for sharing the useful website links and materials through mail.

REPORT ON WORKSHOP CONDUCTED ON E-CTD ON 13th AND 14th FEBRUARY 2017

The workshop was based on the e-ctd pharmaREADY software, conducted by JSS COLLEGE OF PHARMACY, OOTY. It was given by Mr. VIJAYA KUMAR from NAVITAS company.

The first day of the workshop dealt with the theoretical explanation of the e-ctd along with the details regarding how the software works. It had the difference between the paper submission, non-ectd electronic submission and the ectd submission. We learnt the different terms used in the regulatory field and in the software as well.

The second day of the workshop was "HANDS ON TRAINING" on the pharmaREADY software where each one of us got an individual opportunity to work on the software. We learnt in detail about how to file a NDA, ANDA and BLA for different regulatory authorities like USFDA, EMA and TGA. We understood what are the country specific documents required by the respective regulatory authority. We also learnt about different other softwares available and the basis of choosing the right one for right step. It was a great opportunity for us to interact with Mr. Vijaya kumar regarding the subject and we are thankful to him for sharing the links and websites that would be useful to us through mail.