Module 1: General Over view of Reg Affairs

Regulatory Overview

1. Regulatory Affairs department
2. Regulatory Authorities
3. Various Regulatory affairs department
4. Regulatory Tools
5. Clinical Studies stages

Module 2: Regulatory CMC Process Over View

Regulatory CMC Overview

1. Journey of Investigational products Up to IND
2. Forms Cover letter overview of Module 3
3. Content plan preparation and Project management
4. Module 3 drug substance
5. Module 3 Drug Substance
6. Module 3 Drug product
7. Module 3 Drug product

Regulatory CMC Overview

7. Guideline on stability
8. IND and IMPD
9. Development to IMPD
10. Regulatory CMC
11. Phase I IND
12. IMPD
13. CTA
14. Module 3

Module 3; Regulatory e-CTD Process Over view

Types of Submission

- Paper Submission
- Non – eCTD electronic submission (eNDA/eANDA)
- Electronic submission with eCTD

Why eCTD

- Lesser and lesser space at Agencies
- Handling paper an uphill task and quite subjective
- Electronic submission give more accountability and ease decision making process

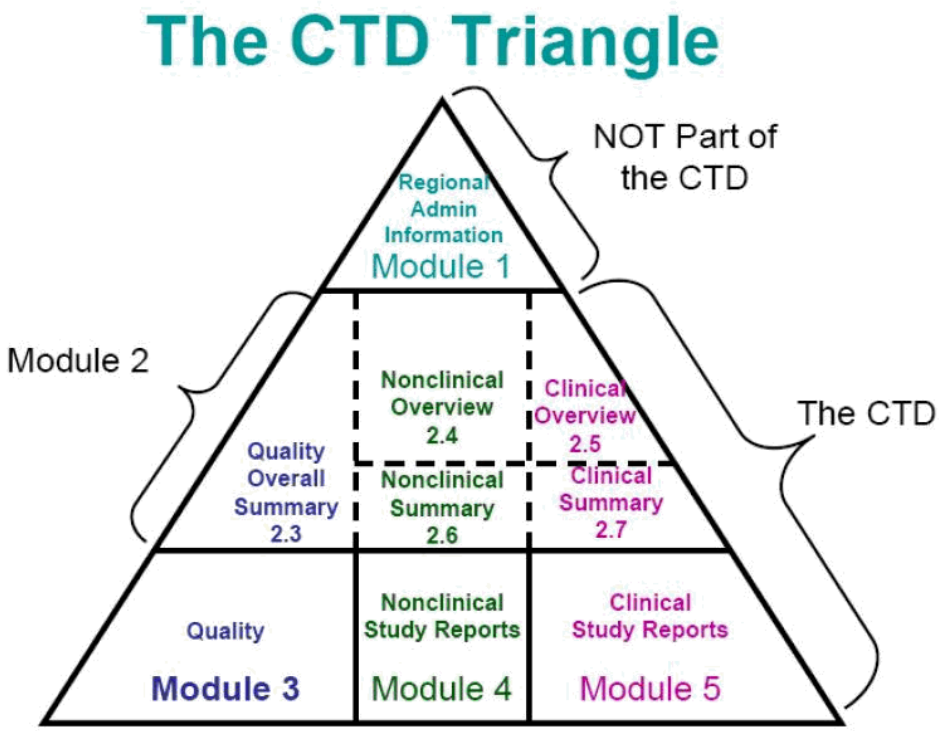
Why eCTD

- eCTD is a superior technology
- Establish a single application format for all applications
- Avoids expensive internal processes and systems for receiving and archiving applications

eCTD STRUCTURE

- XML backbone
- Modules
- Granules
- Leafs

A CTD TRIANGLE



eCTD FORMAT

- Module 1 : Administrative
- Module 2 : Summaries
- Module 3 : Quality (CMC)
- Module 4 : Non clinical study reports
- Module 5 : Clinical study reports

eCTD submission Checklist

- eCTD Software
- Software training and support from the supplier
- Compiling and eCTD
- eCTD hyper linking
- QC of eCTD
- Submit eCTD on CD/DVD or Use electronic gateway

Top eCTD Software Vendors

- Paraxel (Liquent)
- Extedo
- Lorenz
- GlobalSubmit
- eCTDExpress
- Medxview
- Freyr/ Pharmaready

Things to know before using eCTD software's

- eCTD knowledge
- General eCTD tool knowledge
- Document format types and editing
- Software functions and system requirements
- FDA ESG submission requirements
- FDA Guidance's

Advanced eCTD Submissions learning

- STAY TUNED

Thank You