# Global Generic Dossiers are not so Generic

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# Understanding available Regulatory Pathway(s)

- Major Agencies have a very well established regulatory framework
- Depending upon the situation, a regulatory pathway is decided for registering a generic product
- Data requirements, and timeline change significantly
- Pre-submission meetings are very common
- Agencies do communicate with the potential applicants to offer additional clarity, if needed

# Regulatory Pathways in US for registering Generic products

- **ANDA**
  - Pathway for registering a Generic that is similar to RLD
- **Petitioned ANDA**
  - Pathway when proposed Generic product differs from the RLD in its dosage form, route of administration, strength, or active ingredient (in a product with more than one active ingredient),and FDA has determined that safety and efficacy studies are not necessary for the proposed drug product

# Regulatory Pathways in US for registering Generic products

- **505(b)(2)**
  - Hybrid Pathway between ANDA and NDA
  - Applicant carries out some Clinical evaluation
  - To register new indications for existing approved products,
  - To register changes in dosage form, strength, formulation, dosing regimen or route of administration, New combination products, Prodrugs of an existing drug
  - In some cases, drugs with new active ingredients

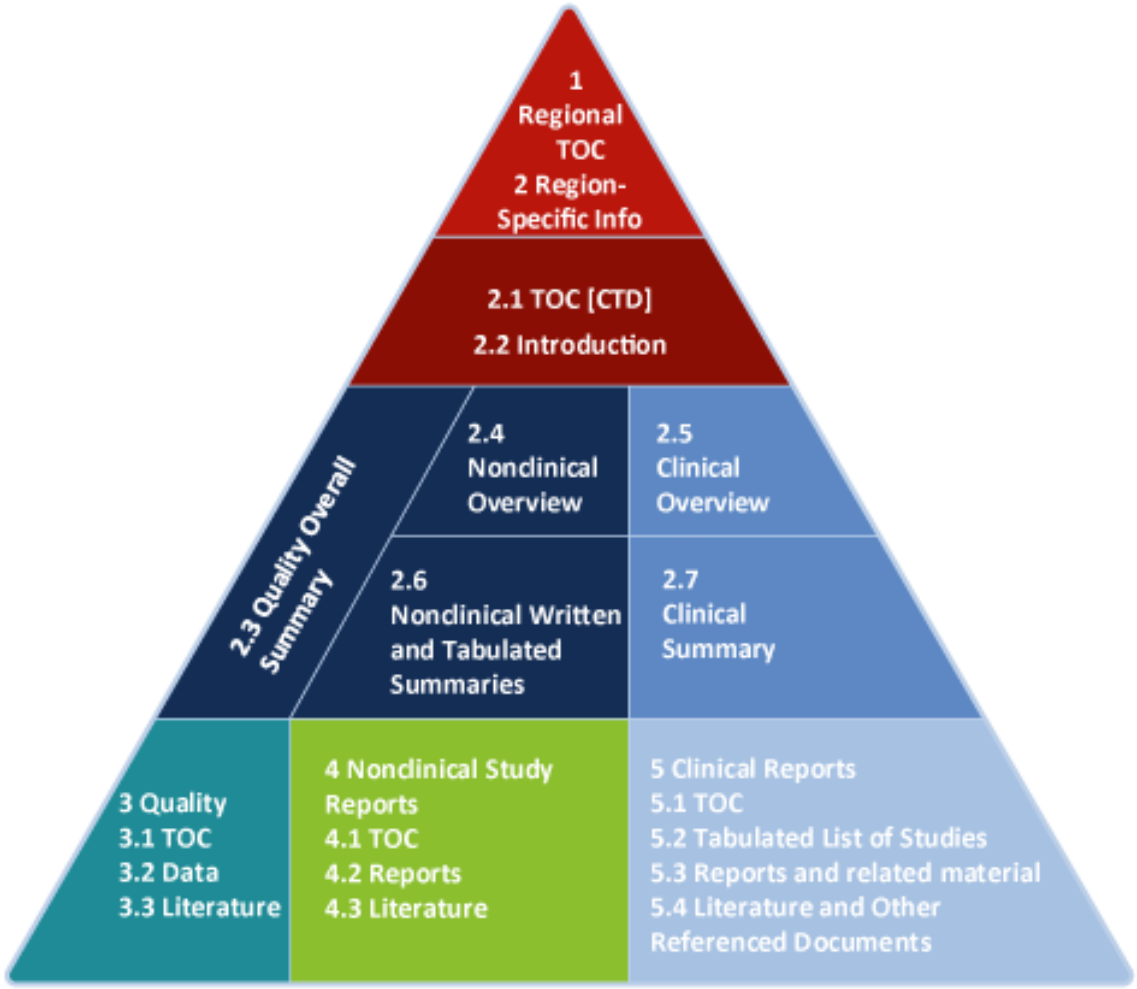
# Regulatory Pathways in EU to register simple Generic product

- National filing is to register product in one single market
- Centralized Procedure (CP) is to register product in all EU member states
- Decentralized procedure (DCP) is to register product in multiple but select member states
- Mutual Recognition Procedure (MRP) to register product in multiple member states if the product is already approved in at least one member state
- Difference is intended markets, cost, review cycle, and approval timeline

# Different pathways, regulations, and requirements in harmonized format

- International Council for Harmonization (ICH)
- Multi regional organization dedicated to harmonize format and expectations of a regulatory dossier
- Formalized in 1990
- EU, US and Japan
- Collaboration among industry and regulatory authorities
- To minimize redundant research and standardize technical guidelines and requirements
- Harmonized Guidance documents for Safety, Quality and Efficacy
- Standardized dossier format--Common Technical Document  (CTD)

# Typical structure of a Dossier in CTD format

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# CTD Modules in a Dossier

- Complete Dossier contains 5 “Modules”
- Only Modules 2-5 are “CTD”
- Module 1-Region specific but always included in complete CTD structure
- Module 2-All summaries and Overviews
- Module 3- Quality (CMC)
- Module 4-Preclinical (Nonclinical such as PD, PK, ADME)*
- Module 5-Clinical

# Common Technical Document

- IT IS :

  -A common harmonized FORMAT for applications for preparing marketing authorizations

  -A TEMPLATE for presenting data in the dossier.

- IT IS NOT:

  -A statement of data requirements for applications

  -Data requirements market specific and specified by Health Authorities (Ex. FDA, TGA, EMA, ANVISA, COFEPRIS, Health Canada, MCC etc.)

  -Format is harmonized but contents of CTD sections may be market specific

# Highlights of CTD Format

- Developed by International Council for Harmonization (ICH)
- It is an agreed-upon common format for the “modular” presentation of data, summaries, and reports
- CTD is not a “Global Dossier”!
- CTD is organized into five sections

  -Organization of all “modules” are harmonized except Module 1

  -Module 1 houses region specific, mostly administrative information

# Advantages of submitting dossier in CTD format

- More “reviewable” applications due to standardization
- Complete, well organized submissions
- More predictable format
- More consistent reviews
- Easier exchange of information
- Facilitates electronic submission
- Reduced time and resources for submission

# Module 1- Administrative Documents

- Significantly varies from market to market
- Often a speed-breaker and can be a showstopper
- Requires careful strategic planning especially in emerging markets
- Upfront understanding of documents and lead time to procure, is a huge time saver
- Typical information includes
  - Forms and cover letters
  - Declarations
  - LOAs, LOCs, POAs (where applicable)
  - GMP certificates and manufacturing licenses (multiple)

# Module 1- Administrative Documents

- Labeling (proposed labels, comparative labels)
- Proposed Artwork (secondary packaging)
- SmPC
- Certificate of Pharmaceutical Product (CPP)
- Supply Agreements
- Samples and related documents

# Overall Organization of Module 2 in Generic Dossier

| | | |
|---|---|---|
| 2.1 | Table of Contents | |
| 2.2 | Overall Introduction to CTD | |
| 2.3 | Quality Overall Summary (QOS) | Main content of the Generic Dossier is Module 3-QOS is included |
| 2.4 | Non Clinical Overview (NCO) | Literature based NCO is required by EU, AU and some other agencies |
| 2.5 | Clinical Overview (CO) | Literature based CO is required by EU, AU and some other agencies |
| 2.6 | Summary of Non Clinical Study | Tabulated Summaries of non clinical studies by sponsor |
| 2.7 | Summary of Clinical Study | Tabulated Summaries of clinical studies by sponsor-included when BE studies are conducted by the sponsor |

# Questions??

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