ICH – International Council for Harmonisation

Your Objectives:

At the end of the lesson, you should be able to summarise the role of ICH.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (hereafter ICH) is unique in that it invites the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines.

Since its inception in 1990, the ICH has gradually evolved to respond to increasingly global developments in the pharmaceutical sector, and these ICH guidelines are applied by a growing number of regulatory authorities, the aim being to achieve greater harmonisation worldwide so as to ensure that safe and effective, high-quality medicines are developed and that these be registered and maintained in the most vigilant yet resource-efficient way. Since its organisational changes, in October of 2015, the ICH has grown as an organisation and currently includes at least 17 members* and 32 observers*.

The ICH develops, under scientific consensus, standardized, commendable guidelines for the evaluation of the quality, efficacy and safety of medicines in a multi-stage process. These include Good Clinical Practice (GCP) guidelines for clinical trials of medicinal products, Good Manufacturing Practice (GMP) guidelines for a flawless manufacturing practice. Guidelines for the standardization of medical terminology (MedDRA) and information transfer (ESTRI) in the regulatory area are just two examples.

Also vital is a standardized format for the submission of documents for approval, known as the **Common Technical Document** (CTD) - see Image 2. Within the EU, the ICH guidelines are adopted by the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA).

Note that ICH guidelines, although they are not mandatory as such, a commitment to them and due implementation on a national or regional level does strengthen the ICH process. The guidelines, nevertheless, should only be deviated from in justifiable cases.

The ICH topics fall into four (4) categories of guidelines, and **topic codes** are assigned accordingly:

- Safety
- Quality
- Efficacy
- Multidisciplinary

Process of Harmonisation

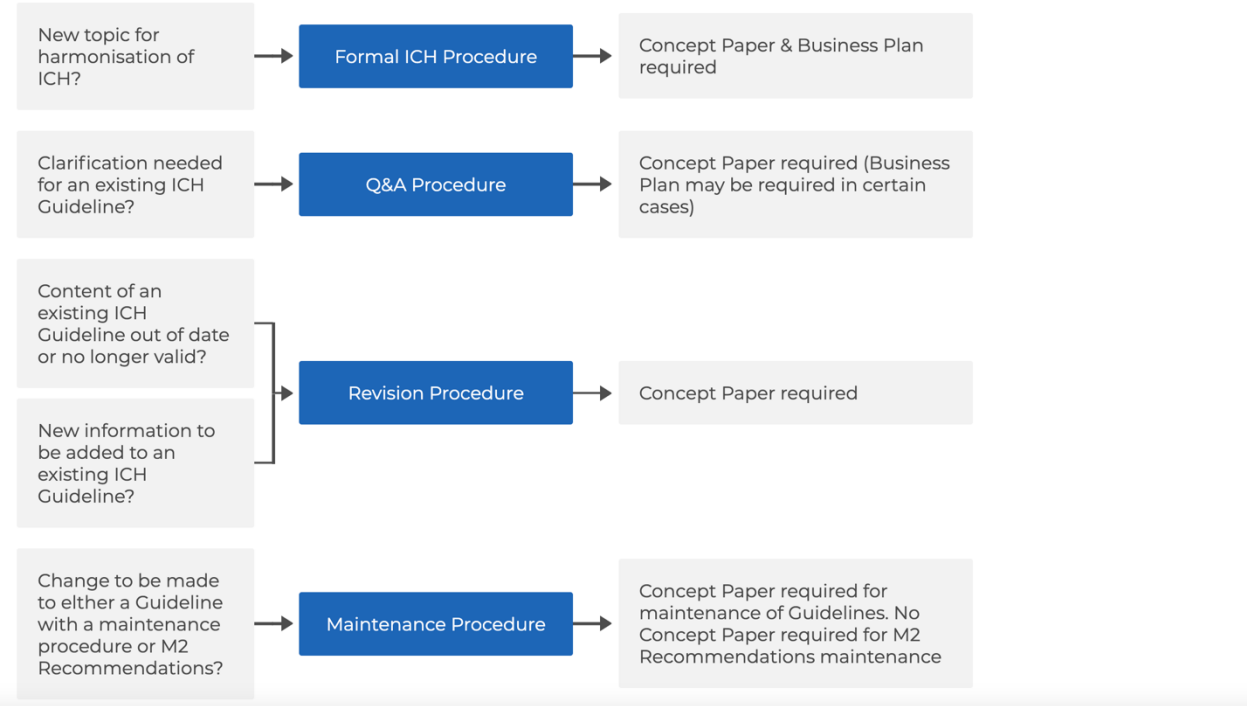
ICH harmonisation activities, too, fall into four (4) categories of procedures:

- Formal ICH,
- Q&A, (question & answer)
- Revision, and
- Maintenance, depending on the activity to be undertaken -see Image 1 on Page 2.

Each harmonisation activity is initiated by a **concept paper**, which is a short summary of the proposal. Depending on the category of harmonisation activity, a **business plan** may also be required. This would outline the costs and benefits of harmonising the topic proposed by the concept paper.

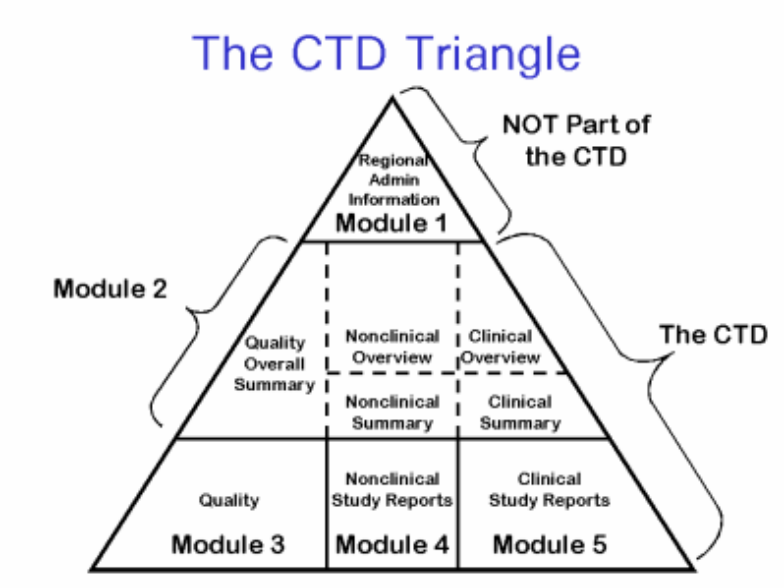
* For the list of founding and regulatory members and legislative and administrative observers, go here: https://www.ich.org/page/members-observers

Image 1:



source: https://www.ich.org/page/process-harmonisation

Image 2:



source: Wikipedia: https://en.wikipedia.org/wiki/Common_Technical_Document