When it comes to a matter of communication, it all boils down to a language that has universally accepted. The content of CTD and e-CTD must be in the English language, being universally accepted, with the intention of minimising time and cost it takes for translation and linked activities. Only patient information leaflet (PIL) could be kept in local language (country-specific) from the customer or patient point of view. Braille language can be used for blind people across the globe.

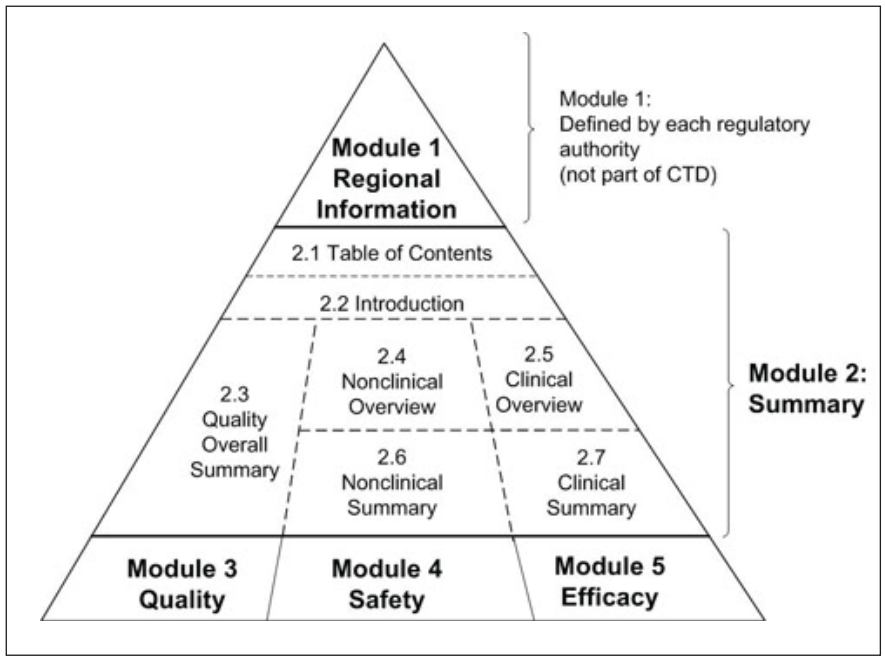
Also the content of Quality Module3-CMC i.e. each section and sub-sections for 'Drug Substance' and 'Drug product' should be harmonised for different range of products (for example, tablets, capsules, liquid orals, ointment-creams, parenterals etc).

Furthermore, there may be some documents that are generated externally in laboratories. For example, analytical reports, CoA, chromatographs, IR, NMR, DSC spectra, figures etc. It expects to have some definite guidelines for headers, footers, naming convention, scale etc for such documents. Additionally, as for the herbal products, veterinary products it can also be presented in the CTD and/or e-CTD format.

Until now, the discussion was based on the harmonisation of the common technical format and its content for product registration for every region in the world but apart from this there are few things that also need overall global harmonisation. Such as fees structure, approval timings, regulatory systems (US, EU, Japan, Asian countries (ACTD), Rest of the World (Row), different terminologies used for same types of applications (e.g. IND/IMPD, or ANDA/ANDS).

For getting a single drug product MA across the globe, an applicant has to go through various cumbersome filing and submission process along with country-specific requirements, form fee, agents fees, different formats, legal documentation etc which is really time consuming, costly and tedious. As we know the fact that US follows different regulatory systems for approval of IND/NDA/ANDA/BLA etc. whereas Europe follows national procedure, DCP, CP, MRP etc

Similarly South Africa follows MRF-1/2 process whereas Asian countries follows ACTD format along with their country-specific system and fees. UAE, follows their own MoH system, Japan (MHLW) whereas 'RoW = Rest of the World' follows different procedures.



Fees

In the ICH region also the fees structure is different for different countries but as for other areas there can be some difference. If we think of the regulation on the global level then the matter of the fees should also be taken into consideration. Whatever is the currency, fees can be determined according to types and timings of submissions. For instance, one particular fees structure for dossier submission, one definite fee constitution for further changes in the submission or late submissions fees etc. There can be a facility where an applicant can pay the full fees at their local point.

For getting a single drug product MA across the globe, an applicant has to go through various cumbersome filing and submission process along with country-specific requirements, form fee, agents fees, different formats, legal documentation etc which is really time consuming, costly and tedious

Specific time period for the approval

Above and beyond, the approval timings may vary from agency to agency but there must be some specific time period for the approval or its stages like starting from dossier review, Technical evaluation, validation, inspection until overall approval. That is the time between the dates imprinted on receipt and the date on the certificate or letter that permits the legal marketing authorisation.

Uniformity between RX and non-Rx drugs

One more thing that needs an emphasis is the uniformity of the prescription and non-prescription drugs. There are various types of drugs that have been banned in some countries and on the other hand, in some regions their use is still at full tilt. For example, certain pain killers. Hazardous side effects do not rely on specific atmosphere or people so the regulatory authority must keep an eye on such matters.

With all the above discussions; we would also like to suggest the term to be used as 'GTD = Global Technical Dossier' once we accept the harmonisation of regulatory system global.

Towards a GTD

In the nut shell, the ultimate goal of any health authority is to 'protect public health' and to check whether the drugs or drug products manufactured and distributed in any country are safe, of good quality and effective in whatever dose prescribed.

Nonetheless, for all this an applicant needs to submit an application along with dossier to different regulatory bodies with the necessary information as per respective country-specific format. Adopting the CTD and e-CTD formats along with uniformity in content, fees structure, filing and approval process, language would really help each country and region get the hassle free system which will eventually be safe, qualitative and effective for human beings.

Also it will help to save the time to reach the drug product to market and to patient.

Hence, experts from all regions should take a call on 'harmonisation of regulatory system across the GLOBE'. Also the term 'GTD = global technical dossier' could be used in future in ICH regions and by all other health authorities worldwide.

(The author can be contacted at rajashrio@gmail.com)