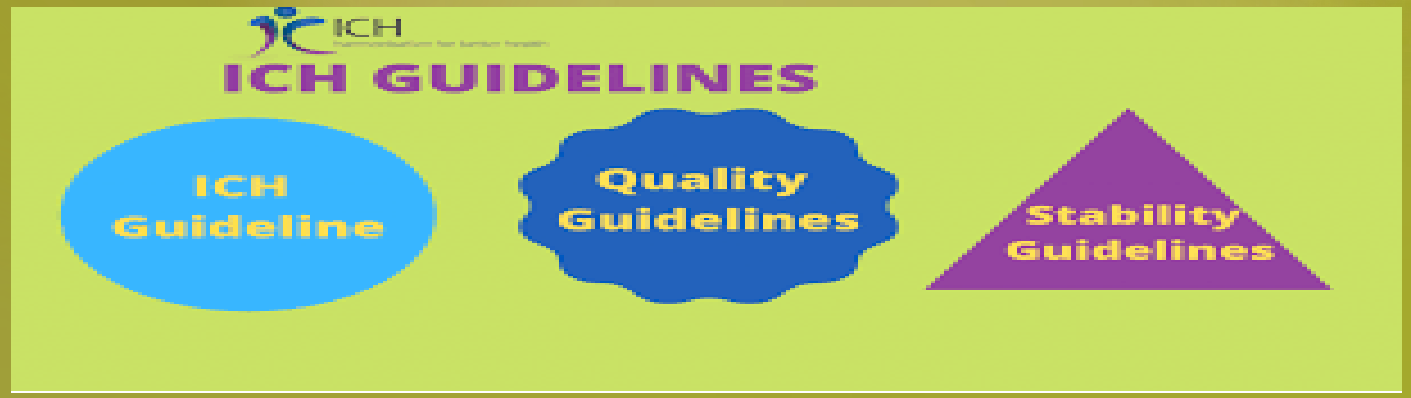
ICH Guidelines

Dr. Shashi Kiran Mishra
Assistant Professor
School of pharmaceutical sciences



Introduction

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

- Since its inception in 1990, 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.

- ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective and high quality medicines are developed, and registered and maintained in the most resource efficient manner whilst meeting high standards.

- Since its announcement of organisational changes in October 2015, ICH has grown as an organisation and now includes 19 Members and 35 Observers.
- ICH does not have "offices" as such, but ICH secretariat based in Geneva, Switzerland.

Need of ICH

Harmonization is beneficial to both regulatory authorities and the pharmaceutical industry, ultimately having beneficial impact for the protection of public health.

<u>The benefits of harmonization are given below</u>

- **To Promote international harmonization of technical requirements to develop safe, effective, and high quality medicines.**
- **Reduce the registration cost.**
- **Promote public health.**
- **Prevent the duplication of clinical trials in humans.**
- **Minimize the animal use without compromising in the safety, quality of the product.**
- **Promote international harmonization by bringing together representatives from the three ICH regions (the EU, Japan and the USA) to discuss and establish.**

Origin of ICH

- Harmonization of regulatory requirements was pioneered by the EU, Europe, in the 1980s as the Europe move towards the development of single market.

- The success achieved in Europe demonstrated that harmonization was feasible.
- At the same time there were discussions between Europe, Japan and the US on possibilities for harmonization.

- The birth of ICH took place at a meeting in April 1990.

- Topics selected for harmonisation would be divided into safety ,quality and efficacy to reflect the three criteria which are the basis for approving and authorising new medicinal products.

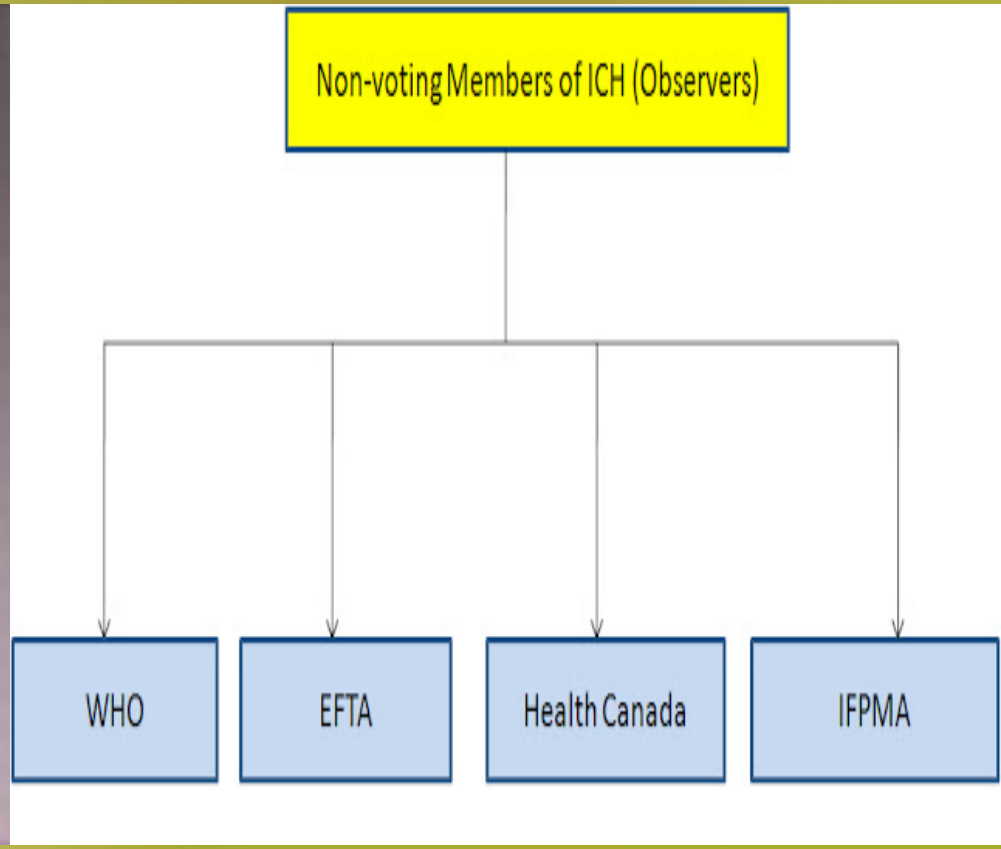
ICH GUIDELINES

Q	S	E	M
"Quality" Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance (Stability Testing, Impurity Testing, etc.)	"Safety" Topics, i.e., those relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.)	"Efficacy" Topics, i.e., those relating to clinical studies in human subject (Dose Response Studies, Good Clinical Practices, etc.)	"Multidisciplinary" Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories (MedDRA, ESTRI, M3, CTD, M5)

COMPONENTS OF ICH

Members of ICH

- ICH is comprised of representatives from six parties that represent the regulatory bodies and research-based industry in the European Union, Japan and the USA.
- In Japan, the members are the Ministry of Health, Labour and Welfare (MHLW), and the Japan Pharmaceutical Manufacturers Association (JPMA).
- In Europe, the members are the European Union (EU), and the European Federation of Pharmaceutical Industries and Associations (EFPIA).
- In the USA, the members are the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).
- Additional members include Observers from the World Health Organization (WHO), European Free Trade Association (EFTA), and Canada. The Observers represent non-ICH countries and regions.



Responsibilities of Non-voting members of ICH

- Provides support to the ICH Steering Committee.
- Documents the meetings of the Steering Committee.
- Promotes coordination between working groups.
- Provides information on the ICH guidelines and ICH process.
- Provides administrative support for MedDRA management board.
- Provides administrative support for global cooperation group

References

- https://www.ich.org/page/multidisciplinary-guidelines
- https://www.ich.org/page/process-harmonisation
- https://www.ich.org/
- https://www.slideshare.net/jayaprakash373/ich-and-ich-guidelines
- **Singh gajendra; Agarwal Gaurav; Gupta Vipul; Drug regulatory affairs; First edition 2015 reprint 2019-20; CBS Publishers & Distributors Pvt. Ltd.; Page no. 87-94.**