Understanding Worldwide Regulatory Requirements

International Conference on Harmonization (ICH):

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together experts from the regulatory authorities and the pharmaceutical industry of Europe, Japan and the United States to discuss scientific and technical aspects of product registration. ICH strives to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

International Federation of Pharmaceutical Manufacturers Associations (IFPMA):

Represents the research-based pharmaceutical industry and other manufacturers of prescription medicines, worldwide channel of communication between this sector of the industry and the World Health Organization as well as other international organizations. The Federation has a central role in the exchange of information within the international industry and in the development of position statements on matters of policy.

Japan Pharmaceutical Manufacturers Association (JPMA):

A voluntary organization of research-based pharmaceutical manufacturers that contribute to society by developing new pharmaceuticals.The JPMA works in close cooperation with the International Federation of Pharmaceutical manufacturers Associations (IFPMA).

Pharmaceutical Inspect ion Convention (PIC), Pharmaceutical Inspection Cooperation Scheme (PIC/S):

PIC is a legal treaty, founded in October 1970 by EFTA (European Free Trade Association) with the objective to exchange such information as is necessary for the mutual recognition of inspections relating to GMP compliance of pharmaceutical products. PIC/S is a less formal and more flexible cooperation scheme was developed to continue and enhance the work of PIC. Instead of being a legal treaty between countries PIC/S is a cooperative arrangement between Health authorities. It commenced operating on 2 November 1995. PIC and the PIC/S operate together as PIC/S and provide an active and constructive cooperation in the field of GMP (Good Manufacturing Practice). The purpose of PIC/S is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors.

The Pharmaceutical Research and Manufacturers of America (PhRMA):

An association of US based pharmaceutical companies.

Qualified Person (QP):

EU requirement, a person who is held legally accountable for ensuring that all Quality conditions are met before releasing each batch of drug product.

Recall: A Major Quality Incident that leads to the removal of the entire affected batch or batches of material from the market or if clinical trials, from a study.

Seizure: An action by authorities, taken to remove a product from commerce because it is in violation of the law.