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 Manufacturer's 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 Inspection 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.

Violative product: A drug product produced or manufactured in violation of the Federal Food, Drug, and Cosmetic Act.

Warning Letter: An official advisory notice to a firm communicating the FDA's position on a matter but does not commit FDA to taking enforcement action. The agency's policy is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.

Copyright©www.gmpsop.com. All rights reserved
Unauthorized copying, publishing, transmission and distribution of any part of the content by electronic means are strictly prohibited.

governments to encourage the safety and quality of imported products by ensuring that foreign standards are equivalent to those enforced by FDA.

Research
FDA's research activities provide the scientific basis for its regulatory decisions and the tools needed to identify and assess risks. The agency uses its research results to establish standards, evaluate new products, develop test methods and other support for product monitoring, and to study emerging risks.

Enforcement - Correcting Problems
When a problem arises, FDA can take a number of actions to protect the public health. Initially, the agency works with the manufacturer to correct the problem voluntarily. If that fails, legal actions can be taken which include asking the manufacturer to recall a product, having federal marshals seize products if a voluntary recall is not done and detaining imports at the port of entry until problems are corrected. If warranted, the FDA can ask the courts to issue injunctions or prosecute those who deliberately violate the law.

Current Challenges for the FDA
Today, more than ever, the FDA needs to respond to a rapidly changing world. There are many obstacles to overcome if the FDA is to continue its high standards of consumer protection. The most important of these challenges are:

- Ø Keeping informed about scientific breakthroughs. FDA scientists will need to keep up with rapidly advancing technologies in all product areas.
- Ø Understanding more sophisticated products. These “cutting edge” technologies will translate into products with new complexities and risks.
- Ø Planning for new public health threats. The FDA needs to be prepared to respond rapidly to unexpected health risks, such as tougher strains of antibiotic-resistant bacteria or more dangerous food borne illnesses.
- Ø Predicting the impact of international commerce. Monitoring of imports and cooperation with foreign regulators will become more important as international commerce continues to grow.
- Ø Providing consumers with the information they need. Today's sophisticated consumers and the wide availability of information about FDA-regulated products will challenge the FDA to ensure consumers are getting the information they need from the right sources.
- Ø Reducing risks to the public health. The FDA will continue to effectively manage product risks throughout their life cycle- from research and development through use/ consumption. Risk management decisions will be supported by rigorous scientific analysis that weighs, when appropriate, not only the risk-to-benefit profile of the product itself but also the risk versus the benefit associated with Agency actions.

The FDA/ORA Guide to International Inspections and Travel, is intended to assist in fulfilling FDA's overall mission of assuring that drug, medical device, biological and food products manufactured in foreign countries and intended for U.S. distribution are in compliance with the law and regulations; that non-compliance is identified and corrected; and that any unsafe or unlawful products are removed from the marketplace.

This guide provides FDA personnel with standard operation, inspection and investigation procedures to assure uniformity in the program. It contains instructions and references to assist investigators and analysts who conduct international inspections. It also provides information regarding authorities, objectives, responsibilities, policies and guides applicable to inspectional operations, administrative procedures, and the basic guidance necessary for FDA personnel who travel to foreign countries. This guide is not designed to be all-inclusive, nor unduly restrictive. The procedures and guides are designed to supplement the experience, skill and proficiency of investigators and analysts and serve as a reference.

Copyright©www.gmpsop.com. All rights reserved
Unauthorized copying, publishing, transmission and distribution of any part of the content by electronic means are strictly prohibited.

The Therapeutic Goods Act, Regulations and Orders establish the requirements for inclusion of therapeutic goods in the ARTG, including advertising, labeling, product appearance and appeal guidelines. Some provisions such as the scheduling of substances and the safe storage of therapeutic goods are included by the relevant State or Territory legislation.

Cooperative Arrangement between the FDA and the TGA

On October 11, 2000, the TGA signed a cooperative arrangement with the Food and Drug Administration (FDA), USA, regarding the exchange of information on current Good Manufacturing Practice (GMP) inspections of human pharmaceutical manufacturing facilities. Under this agreement the FDA and TGA expressed their intent to:

- Ø Provide copies of pharmaceutical establishment inspection reports (confidential information purged) and product sample results to one another, upon request, within certain specified time frames.
- Ø Notify one another when one authority plans to conduct inspections in the other authority's territory and be receptive to permitting joint inspections for the purpose of promoting better understanding of one another's inspectional programs and techniques.
- Ø Provide other GMP-related information such as recall information, adverse product trends, health hazard evaluations, and alert system information.

Both authorities agree to exchange appropriate information about manufacturers when shortage situations occur which involve medically necessary human pharmaceuticals. The information in the inspection report allows the FDA and TGA to make their own decisions concerning the compliance of manufacturers and appropriate follow up. Each agency may carry its own inspections in the other's territory if it deems necessary.

The agreement applies to GMP inspections of pharmaceutical facilities where the inspections have been conducted using the current FDA GMP requirements for drugs or the current TGA GMP Code for medicinal products.

TGA and EU

Australia has an MRA with EU, which means that the legislation and the way TGA works with regards to pharmaceuticals has been assessed and is considered equivalent to the EU system.

Australian Code of Good Manufacturing Practice for Medicinal Products

The Australian Code of Good Manufacturing Practice for Medicinal Products (16 August 2002), replaces the Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Products (August 1990), the Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Gases (July 1992) and the Investigational Medicinal Products Code of GMP (Annex 13, EC GMP Guide, 1997).

The new Code is based entirely on the international standard entitled Guide to Good Manufacturing Practices for Medicinal Products, PE 009-2, 1 July 2004, published by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S). The modifications to that Guide and its adoption as the Australian Code of Good Manufacturing Practice, is done so with the expressed permission of the PIC/S. It was enacted in August 2003 as the basis for the licensing of all Australian manufacturers of medicinal products.

Canadian Health Products and Food Branch Inspectorate (HPFBI)

When a product is offered for sale in Canada to treat or prevent diseases or symptoms, it

Copyright©www.gmpsop.com. All rights reserved
Unauthorized copying, publishing, transmission and distribution of any part of the content by electronic means are strictly prohibited.