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A Review on Regulatory Authorities & Standards Institutions and Self Auditing Consideration in Pharmaceutical Industry

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ABSTRACT

In the pharmaceutical industry the course is designed to give you the skills that have taken many experienced auditors decades to develop. It follows the auditing guidance of ISO-19011 and is a virtual audit of a manufacturing facility that makes a range of dosage forms. This allows you to plan and prepare audits of the supplier and your own supplier audit system. Throughout the course, there is personal practice with exercises and teamwork's in planning, preparation and performance that address WHO. The extensive of course notes and excellent lectures given by knowledgeable and professional tutors in pharmaceutical industry, The WHO was very easy to approach with any problems in during the course. The purpose of regulatory authorities to assess application for authorization to market products for human use and either grant authorizations to market each product or reject such applications and inspect the manufacturers and wholesalers of medicines for human use and either grant manufacturing and wholesale licenses or refuse such licenses. The international regulatory authorities under consideration are in this article WHO, USFDA, MHRA, and Australian TGA. The standard institutions give the economical background for development and transferring technologies, ISI, ISO, BISS and ASTM.

Keywords: Regulatory authority, WHO, Self-auditing, Standard institution

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INTRODUCTION

The Introducing first international pharmaceutical QMS auditor/ lead auditor certification (A17638). At NSF Pharma Biotech, in-house experts designed and developed the first internationally recognized and certified course for pharmaceuticals based on Good Manufacturing Practice (GMP) and auditing the quality management system. This course is certified by IRCA (the International Register of Certificated Auditors) and provides extensive practical support and training for the pharmaceutical auditor, including a practiced toolkit of skills [1-3]. This course has grown over the past few years with hundreds now trained and many companies requiring the training and certification of those joining their audit teams. The latest GMP regulations and expectations, and to work with them in the development, implementation, and verification of corrective action plans (CAPAs), that are comprehensive compliant and sustainable. We apply this same level of rigorous knowledge to the development and execution of our professional auditing training programmers offered globally [4-6].

International Drug Regulatory Authorities [1-2]

1. WHO
2. TGA (Australia)
3. MHRA (UK)
4. USFDA

THE WORLD HEALTH ORGANIZATION (WHO)

- The drug regulatory programmers' supports member states in their regulatory work with WHO guidelines and standards.
- The health assembly is composed of representatives from WHO's member states.
- The main tasks of the world health assembly are to approve the WHO programmed, budget and to decide major policy questions.
- The World Health Organization or WHO is the United Nations specialized agency for health. It was established on 7th April 1948.
- WHO's objective is the attainment of the highest possible level of health by all people.
- WHO is governed by 192 member states through the World Health Assembly.

Constitution of WHO

- The STATE parties to this constitution declare.
- Principles are basic to harmonious relations, happiness & security of all people.
- Promotion & protection of health.

- Healthy development of child.
- Provision of adequate health & social measure

Functions

- To act as directing & co-directing authority on international health work.
- To establish & maintain effective collaboration with united nation, government, agencies.
- To establish & maintain administrative & technical services.
- To provide information, counsel & assistance in the field of health.

THERAPEUTICS GOODS ADMINISTRATION

- The Therapeutic Goods Administration or TGA is the regulatory body for therapeutic goods in Australia.
- The TGA is responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard.

What are Therapeutic Goods?

A 'therapeutic goods' is broadly defined as a good which is represented in any way to be or is likely to be taken to be, for therapeutic use, unless specifically excluded or included under section 7 of the therapeutic good act 1989.

Therapeutic goods are a product and connection with:

- Preventing, diagnosing, curing, or alleviating a disease, defect or injury.
- Effecting inhibition or modifying a physiological process.
- Testing the susceptibility of person to a disease.
- Controlling or preventing conception.
- Testing for pregnancy.

Organization

- Business Management Group
- Executive Support Unit
- Office Of Complementary Medicine
- Office Of Devices, Blood and Tissues
- Office Of Laboratory and Scientific Services
- Office of Manufacturing Quality
- Office of Medicine Safety Monitoring
- Office Of Non-Prescription Medicine

Fees and Charges

From 1 July 1998, the TGA has been required by the government to fully recover its operating costs for all activities that falls within the scope of the act, including regulation of industry and TGA's public health responsibility. A list of fees is included in Schedule 9 of the Therapeutic Goods Regulation 1990.

THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe.
- The MHRA now also looks after blood and blood products, working with UK blood services, healthcare providers, and other relevant organizations to improve blood quality and safety.
- The MHRA regulates a wide range of materials from medicines and medical devices to blood and therapeutic products/services that are derived from tissue engineering.

History

The agency was formed on 1 April2003 with the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). It is an Executive Agency of the Department of Health.

Roles of the MHRA

- Operate post-marketing surveillance for reporting investigating and monitoring of adverse drug reactions to medicines and incidents with medical devices.
- Assessment and authorization of medicinal products for sale and supply in UK.
- Investigate internet sales and potential counterfeiting of medicines and prosecute where necessary.
- Regulate clinical trials of medicines and medical devices.
- Monitor and ensure compliance with statutory obligations relating to medicines and medical devices.
- Promote safe use of medicines and devices.
- Manage the General Practice Research database and the British Pharmacopeia.

Regulatory Program

- Assess application for authorization to market products for human use and either grant authorizations to market each product or reject such applications.
- Assess applications to undertaken clinical trials and grant, or refuse, permission.

- Inspect the manufacturers and wholesalers of medicines for human use and either grant manufacturing and wholesale licenses or refuse such licenses.
- Undertaken post marketing surveillance including

  Pharmacovigilance

  Quality defect monitoring

  Sampling and testing

  Product recalls

Monitoring of Safety and Quality Standards

The MHRA monitors safety and quality standards by:

- Regular inspections of good and safe practice, including
- Medicines manufacture and supply
- Medicines distribution and storage
- Clinical trials
- Auditing of clinical inspecting system for devices
- Laboratories testing medicines
- Auditing Notified Bodies

MHRA Governance

- The Agency Board is made up of a non-executive Chairman, six non-executive members and the Agency's Chief Executive Officer.
- The Agency's Chief Executive is responsible for service delivery and resources.
- The Executive Board, consisting of the Agency's directors.

Membership

- The Agency Board is chaired by the MHRA Chairman and consists of six non-executive directors and the Chief Executive Officer.
- The executive Board's primary responsibility are to ensure: -
  - The strategic direction set by the Agency Board is implemented and reflected in the day-to-day operations of the Agency.
  - Principles of good governance are followed.
  - The Agency is well managed financially.
  - Appropriate human resources (HR) policies are followed.
  - Reporting to the Agency Board on the operations of the Agency.

USFDA

- FDA ensures that food we eat safe &effective.
- Medicine, medical devices, radiation emitting consumer products such as microwaves oven safe &effective.
- FDA oversees feed &drugs for pets &farm animals. Authorized by congress to enforce the Federal Food, D&C Act & several other public health laws.

Staff

Chemists

Microbiologists

Scientist

Investigators & Inspectors

Objective of FDA

- To promote public health by efficiently reviewing clinical research.
- To protect public health by ensuring foods are safe.
- Participation.
- Harmonize regulatory requirements.

What FDA regulate?

Some of the agency's specific responsibilities include:

- Biologics product manufacturing licenses
- Safety of nation's blood supply
- Cosmetics safety labeling
- Drugs products approval
- Food product safety
- Medical devices

Standards institutions [3-5]

1. ISO
2. ASTM
3. ISI
4. BSS

ISO

- Largest developer of standards
- Principal activity development of technical standards
- Important for economic & social repercussion

ISO secretariat office:

ISO is a network of national standard institute of 146 countries, based on one member per country, with central secretariat in Geneva, Switzerland that coordinate system.

Role

- International standard which ISO develops are useful to industrial & business organizations of all types to government & other regulatory bodies, to trade officials, to conformity assessment professionals, to suppliers & customers of products & services in both public & private sectors.
- Make trade between countries easier & fairer.
- Aid in transferring technology.

Process of developing ISO standard

A) Consensus: The views of all interests are considered:

Manufacturers

Vendors & users

Consumer groups

Research organization

Testing laboratories

Government

Engineering professionals

B) industry-wide:

Global solution to satisfy industries & customer worldwide

C) voluntary:

ISO is market driven & based on voluntary involvement of all interests in marketplace.

ASTM

- Used for development of consensus standards.
- Organized in 1898.
- It is largest voluntary standard for developing organization.
- ASTM, a standard is a document that has been developed & established within the consensus principles of the organization & which meets the requirements of ASTM procedure & regulation.

ISI

- The BIS empowered through a legislative Act of Indian Parliament known as Bureau of Indian Standard Act, 1986.
- It operates a product certificate scheme.
- The certification allows the license to use ISI mark.
- It is quality program process.

Operational Areas

Textiles

Chemicals & Pesticides

Rubber & plastics products

Wood products

Building materials

Electronics products

Prerequisites for grant of licenses

Application

Recording

Preliminary Inspection

Certification system

Initial testing & assessment of a factory quality management system.

Its acceptance

Surveillance that considers the factory quality management system & testing of samples.

Objective

- The product certification scheme is basically voluntary.
- Aims of providing quality, safety & dependability to the customers.
- Standard mark on product.
- It is assurance of conformity to the specification.

BSS

- It is UK standards users' organization administered by BSI.
- Network of special interest groups
- These hold regular meetings & discuss current issues
- Publication:
- BSS issues guidance documents publish by BSI on application & management of standards.

Types

- All British standards use the product identification 'BS'.
- All British adoptions of European standards are identified with "BSEN".
- All international standards are identified with "ISO".
- All international standards adopted as British standard are identified with "BSISO".

III. Pharmaceutical GMP Audits and Self-Inspections [6]

This course is designed for auditors assessing:

- Manufacturing Operations
- Contract Manufacturing Organizations
- API Suppliers
- Excipients Suppliers
- Packing Component Suppliers
- Service Providers

These auditors could come from several pharmaceutical backgrounds including Qualified Persons, Quality Assurance, self-inspectors from QA and operations teams, virtual companies, and Quality Unit staff. The course has been designed to simulate the roles auditors face when auditing. Activities include group work, solo work, and feedback to a group of up to 20 trainee auditors. Attendees should have a working knowledge gained from ideally 3-5 years of experience or from the NSF Pharma Biotech four-day GMP course. They should be familiar with:

EudraLex Volume 4 Chapters 1-9 or CFR 210/211

ICH Q8, Q9, Q10

ISO 19011 (working copies are provided on the course

Table 1: a) FDA does not regulate following consumer products [5, 6]

Advertising	Alcohol	Consumer Products	Drugs of Abuse
FTC	TDBA, T.F.	CPSC	DEA

Table 1: b) FDA does not regulate following consumer products [5, 6]

Water	Meat & Poultry	Restaurants & Grocery Stores	Pesticides	Health & Insurance
EPA & FDA	US Department	Country health department	USFDA, EPA, USPDA	FDA Not Regulate

CONCLUSION

It is necessary that the self-auditing system practice all over the world be oriented toward al pharmaceutical companies and biotech companies. Guideline will provide manufacturer's

confidence to go for international marketing. This article provides the valuable information about the types and its classification, qualification, and critical factors to be considered while preparation of the bulk drugs. Now a day, regulatory guidelines are most important to assess and development for consideration. The international treaties are very important for regulation. Thus, impurity profiling can act as a quality control tool. There is strong requirement to have unique specifications/standards about self-inspection and regulatory guidelines in pharmaceutical auditing system.

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