A Brief Report on Alumni Interaction Series – Lecture 4

(Bridging the gap - Connecting to the World)

Name of the presenter:
Mr T Sathish
Vice President – Regulatory & Corporate Support
Tablets (India) Limited
Chennai

Date: 27.09.2021

Title of the presentation:
Pharmaceutical Regulations – Domestic & Global requirements

Program Organized by:
Dept. of Pharmacy Practice & Pharmacy Education Unit
JSS College of Pharmacy, Ooty JSS College of Pharmacy, Ooty

As a part of the Alumni interactions 2021, fourth in the series was held on 27.09.2021 by one of the proud Alumnus of Department of Pharmacy Practice, Mr T Sathish, Vice President – Regulatory & Corporate Support, Tablets (India) Limited, Chennai.

Mr T Sathish, had completed his M Pharm (Pharmacy Practice) at Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty in the year 1999 and had experience in Marketing and regulatory for the last 25 years. He started his presentation with the mention that, the quantum of experience he gained at public hospital at Ooty gave the strength and courage to take up the challenging marketing job in early days of his career.

His presentation was focused on three main domain such as drug regulation, food regulation and device / vaccine regulation in domestic and global requirement. As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, regulatory agencies are being established in various countries across the globe. Regulatory agencies and organizations play a vital role to meet the requirements of legal procedures related to drug development process in a country.

In the present scenario, pharmaceuticals are considered as the most highly regulated industries worldwide. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing and labelling of pharmaceutical products. USFDA (USA), MHRA (UK), TGA (Australia), CDSCO (India), HEALTH CANADA (CANADA), MCC (South Africa), ANVISA (Brazil), EMEA (European Union), SFDA (China), NAFDAC (Nigeria), MEDSAFE (New Zealand), MHLW (Japan), MCAZ (Zimbabwe), SWISSMEDIC (Switzerland), KFDA (Korea), MoH (Sri Lanka) are the few regulatory agencies and organizations established in respective countries.

World Health Organization (WHO), Pan American Health Organization (PAHO), World Trade Organization (WTO), International Conference on Harmonization (ICH), World Intellectual Property Organization (WIPO) are some of the international regulatory agencies and organizations which also play essential role in all aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual property protection.

The major challenges of these regulatory agencies and organizations around the world are to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedures related to drug development, monitoring and ensuring compliance with statutory obligations. They also play a vital role to ensure and increase regulatory implementation in non-regulated parts of the world for safety of people residing there. In his presentation, he described the brief review of various regulatory bodies of major developed and developing countries and the scope

and challenges of such regulatory organizations in drug development and delivery of safe and effective healthcare products to individuals around the world.

Challenges:

The major challenges of these regulatory bodies are

- To promote public health and protect the public from harmful and dubious drugs,
- To establish proper legalization covering all products with a medicinal claim and all relevant pharmaceutical activities, whether carried out by the public or the private sector.
- To increase worldwide regulatory growth to ensure safety of people.

Conclusion:

Regulatory agencies and organizations around the world need to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedures related to drug development, monitoring and ensuring compliance with statutory obligations. However the need of the hour is

- More centralized procedures in drug regulation
- Harmonization of regulatory norms
- Strengthening the regulatory authorities

After the presentation, question and answer session was organized. Further, he added his experience of establishing the corporate support and regulatory at his company, he shared.

Dr. S. Ponnusankar thanked the speaker for spending his valuable time with our staff and students.

S Ponnusankar