11th September 2023

REPORT ON GUEST LECTURE

"Emergence of Regulatory Affairs as a powerful function in the modern Pharmaceutical Industry"

Speaker: Mr. A Dhavaraj Soloman, Head – International Regulatory Affairs, Himalaya Wellness Company, Bengaluru

Faculty of the program:

1. Dr. T. M. Pramod Kumar, Professor & Principal, JSS College of Pharmacy, Mysuru.
2. Dr. M. P. Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.
3. Dr. Gangadharappa H. V, Associate Professor, Department of Pharmaceutics, JSS College of Pharmacy, Mysuru.

Students of Program:

1st and 2nd M. Pharm Department of Pharmaceutical Regulatory Affairs and Pharmaceutical Quality Assurance, PhD students of JSS College of Pharmacy, Mysuru.

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Discussion

Dr. T. M. Pramod Kumar, Professor & Principal, JSS College of Pharmacy, welcomed the guests and gave a brief note on the affiliation of the College and introduced Dr. Pushpalatha, General Manager, Himalaya Wellness Company and Mr.Mohd Rafiq, Himalaya Wellness Company, Bengaluru to the participants.

Speaker: Mr. A Dhavaraj Soloman

Mr. A Dhavaraj Soloman was the speaker of the lecture he spoke about the topic "Emergence of Regulatory Affairs as a powerful function in the modern Pharmaceutical Industry". The contents he discussed were, What is Pharma Regulatory Affairs? When and why regulatory affairs came into existence? Paracelaus and origin of regulations, Key regulatory agencies in the world, Major regulatory environment and guidelines, Evolution of regulatory affairs, Multifaceted role of regulatory affairs, Functions of regulatory affairs, what are all governed by regulations now, Major regulatory checks in each category, Career in regulatory affairs.

He explained about evolution of pharmaceutical regulatory affairs, and how to keep track on changing regulations and advice companies accordingly, also discussed on submitting dossiers to regulatory agencies and carryout any technical discussion if necessary to obtain or maintain

marketing authorization for the products concern also archiving the data with respect to product registrations.

Mr. Solomon explained when and why regulatory affairs came into existence i.e the critical incidents made us realize the importance of guidelines and regulations governing the use of medicines in modern era giving the examples of elixir sulphanilamide (antibacterial), Thalidomide (antiemetic) which killed/ harmed numerous people. Even today because of non-compliance many molecules launched are withdrawn from the market.

The speaker briefly explained about Paracelsus and origin of regulations/ regulatory bodies of modern era. He also told us about some of the key regulatory agencies in the world i.e US FDA, MHRA, ANVISA, WHO, EMA and shared about major regulatory environment, applications, and guidelines for NDA/ANDA, CTD, ASEAN CTD, ICH, and about good practices i.e GMP, GDP, GCP, GSP, GRP. The evolution of regulatory affairs as a function consisting of documentation cell, coordination department, registration department, regulatory affairs, regulatory compliance, and regulatory intelligence was detailed.

Mr. Solomon provided insights about major role played by regulatory affairs as law making, law enforcing, law advising in the field of pharmaceuticals and functions of regulatory affairs played in different sectors of pharma like involvement in pharmacovigilance, pricing, drug design, pre-clinical and clinical, quality assurance and quality control, manufacturing, safety, and compliance.

Further, what are governed by regulations like medicines, food, cosmetics, medical devices, biologics and biosimilars, herbals and animal products are discussed. He spoke about major regulatory evaluations for each category involving medicines- quality, safety, efficacy, toxicity. For food and food supplements evaluation for safety, ingredients, allergens; for cosmetics evaluation for carcinogenic ingredients, safety and injury causing factors for medical devices. Evaluation of potency, purity and sterile for vaccines and biologics.

The speaker gave an outframe of career in regulatory affairs and importance of knowing an additional foreign language like Spanish, French, Arabic and Latin.

In conclusion, the speaker highlighted the vital role of Regulatory Affairs in the pharmaceutical industry, addressing its evolution, functions, and importance. He emphasized the historical and contemporary reasons for its existence, key regulatory agencies, and the wide range of products governed by regulations. Additionally, he stressed the significance of language skills and discussed career prospects in this field. The learned speaker provided a concise overview of the emergence and significance of regulatory affairs in pharmaceuticals.

Figure 1: Session by Dr. Dhavaraj Solomon for "Emergence of Regulatory Affairs as a powerful function in the modern Pharmaceutical Industry

Figure 2: Felicitation to the guests.