JSS Academy of Higher Education & Research

JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Mysuru-570015

REPORT

Speaker: Dr. Subhash Malghan, Ex-Deputy Director, Centre for Device and Radiological Health [CDRH], US-FDA

Title: Medical Device Regulations and Artificial Intelligence

Date: 6th March 2023

Venue: Seminar Hall, JSSCP, Mysuru

Students of program: 1st and 2nd M. Pharm students and Ph.D. Scholars of Pharmaceutical Regulatory Affairs, JSS College of Pharmacy, Mysuru.

Dr. M. P. Venkatesh, Associate Professor, Department of Pharmaceutics introduced about the speaker to the students and delivered opening remarks.

Dr. Subhash Malghan illustrated about the developments of artificial intelligence in the field of health care and shed a light upon the fact that by the end of 2022 only 200 medical devices were being operated by artificial intelligence. Further, explained the difference between software and Artificial Intelligence as many have confusion on the functionality and mentioned on the questions and queries FDA receives even till now regarding the regulation of Artificial Intelligence.

Also, spoke about how FDA governs the medical device and added until now nanotechnology definition was entirely based on physics, but now FDA is working on improvising the definition based on the scientific work and discussed on how nanotechnology is helping to improve the health care industry.

Then discussed about the framework of FDA in approving the medical device. There was also a brief discussion regarding the classification of medical device, pre-market and post market inspections. FDA conducted workshops for the industries to discuss about the problems they are facing and solutions to those problems in accommodating similar products under 510(k) to make better regulation and framework.

Briefed how beneficial the telemedicine was during the pandemic and Artificial intelligence actions as an effective tool during COVID-19 in collecting all the data as quickly as possible and managing the workload of the hospital staffs.

Discussions:

1. What triggers recall of medical device?

Answer: Clarified by giving a case study about the premarket and post market inspection report and explained how the industry talks about the premarket requirements such as quality management system, FDA risk factors, network of hospital, physicians as well as the health sector.

The case study was about the maximum number of deaths in dialysis patients in a dialysis centre in the Northern States of America due to the climatic variations in the Northern region.

2. How do you think the Humanitarian Device Exemption pathway and its incentives in helping innovations in rare diseases treatment?

Answer: Explained that this will apply to the paediatrics most of the time and this incentive is useful for the company for manufacturing medical devices hence bulk purchases were made. One such company was MEDICARE which was the leading buyers in USA. Till now 65 Humanitarian Device Exemptions is available that is approved by FDA.

3. What were the reasons for recalling of product during pandemic?

Answer: Explained that during pandemic due to the emergency there was decrease in clinical trial testing and they mainly concentrated on providing safe and effective product. And since there was huge demand for the products, certain products were of low quality. This was the main reason for recall.

Conclusions:

Finally, concluded by saying the advantage of Artificial Intelligence in the health care sector and how to use them effectively by understanding the pros and cons of the technology.