JSS Academy of Higher Education & Research
JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Mysuru

Date: 5th August 2023

REPORT ON WEBINAR

"Recent updates on IVD Regulation and Business and Employment Opportunities in IVD's"

5th August 2023

Speakers:

1. Dr. Sella Senthil, ADC(I), CDSCO, New Delhi.
2. Mr. Manish Ragtah, Beckman coulter India Pvt. Ltd. Solitaire Corporate Park, 3RD Floor, BLDG NO.11, Andheri Ghatkopar Link (R), Andheri, Mumbai.
3. Mr. Hasmuk Rawal, Mylab Discovery solutions Pvt. Ltd. 5th Floor, Amar Paradigm, Survey No – 110/11/3, Baner Road, Pune – 411045, Maharashtra.

Faculty of Program:

Dr. K Bangarurajan, Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

Dr. M P Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

Students of Program:

1st year M. Pharm and PhD students of JSS College of Pharmacy, Mysuru.

Discussion

Dr. T M Pramod Kumar, Professor & Principal, JSS College of Pharmacy, welcomed the participants and introduced the purpose of the webinar.

Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics delivered opening remarks.

Dr. M P Venkatesh, Associate Professor, Regulatory Affairs Group, Department of Pharmaceutics gave an introduction of the speakers to the students.

Speaker 1: Dr. Sella Senthil

Dr. Sella Senthil, ADC(I), CDSCO was the first speaker of the webinar session spoke about the topic "Indian IVD Regulatory Landscape". He discussed about what are IVD's, definitions, what are they used for and how they differ from medical devices and Drugs. How IVD's are regulated under Drugs and Cosmetics Act 1940 and rules 1945 and what are notified and un notified IVD's and what are the Regulatory authorities in India. What are the roles of state licensing authority and central licensing authorities in IVD. He further gave a talk on how IVD's are classified in India, what does it mean by Low risk-Class-A, Low moderate risk Class-B, Moderate high-risk Class-C, High risk Class-D IVD's and what are they used for. What are the licensing authorities in India and how different classes of IVD's are licensed like for Class A, B, C, D. Where and how IVD's are evaluated in India, what are. He discussed about what are new IVD's and approved IVD's and their definitions. He further explained the specifications for each class of IVD's, what are the different central institutions and why outsourcing for evaluation is done in their evaluation, where to register and what are the checklists for the submission. How to access the CDSCO website for getting information on the banned, approved IVD's. He gave us a brief note on the IVD regulatory pathway in India, documents to be submitted, approval process through online portal, approval process for Class-A/B/C/D manufacturing license, approval process for post approval changes and retention of license. He also discussed on the import and manufacture license for the IVD, how many years it is valid and what is the retention time.

He further discussed on the regulations of COVID-19 IVD regulation kits, acceptance criteria and how fast track approval are done in India during COVID. Finally, he ended the topic discussing about the Post Market Surveillance in Indian markets, responsibilities of various parties in PMS, adverse event classification with examples, reporting process and road map of IVD's in India and what Phase-I, Phase-II and Phase-III are and how India is successfully in implementing those phases. He concluded his session by giving a brief on what are recently banned IVD's in India.

Speaker 2: Mr. Manish Ragtah

Mr. Manish Ragtah, Manager, Beckman Coulter India Pvt. Ltd was the second speaker of the webinar. His talk was focused on "Regulatory Requirements of IVD instruments and softwares". He covered the aspects of what are IVD devices and gave us a brief on different components like analyzers, reagents, equipment, and apparatus, IVD softwares, their intended use. He gave us information on reagents tested on analysers and type of analyzers i.e., open and closed analyzers, why companies prefer closed type of analyzers and also explained how Immuno-Histo chemistry works. He also explained about the registration process for licensing of class A and B and approval process for class C and D manufacturing license. What are the documents required for registration. Regulatory status and requirements for analyzers and instruments in different countries like USA, European Union, Australia, Canada, Japan, Singapore, India. He explained the process and phases of medical. What are the legal documents, registration documents, registration fee, device master file, plant master file, what

are the mandatory labelling requirements. What are the new IVD regulations inn EU and its transitions. How hardware life cycle is assessed and why it is done.

He ended the topic by further discussing on what is an IVD software, how they are regulated. what are the labelling and regulatory requirements for the IVD software's, comparison on regulatory requirements between different countries. What are audit reports and how audit reports can affect the product license.

Speaker 3: Mr. Hasmuk Rawal

Mr. Hasmuk Rawal, Managing Director, Mylab Discovery solutions Pvt. Ltd was the final speaker of the webinar. His speech was focused on "Business and employment opportunities in IVDs". This topic covered what are the business and job opportunities in the field of IVD and what are all needed for a company for its smooth and efficient operations. He gave us a brief about each and every role in business and how one can explore different opportunities like manufacturers. Business associates and how they can help improve the business. Liaison associates and their role in submission of documents for state and licensing authorities. Who are logistic partners, what are the challenges faced in the logistics of IVD's and how logistics can improve company maintain its market presence. Packaging material manufacturing and why IVD's need specific packing requirements. What are pre analytical instruments manufacturing and why they are used in analysis of IVD reagents for instruments. Biosafety/segregation partners and why they are required. Third party consultation services specialised in regulatory aspects, GMP, GLP etc. What are calibration labs. What are mould manufacturers and why IVD's require specific moulds.

He further ended the discussion with the different job roles and their importance like sale and marketing and their importance increasing the growth and revenues of the company. Duties of bio medical engineers for maintaining the instruments and their role in extracting the maximum life of the instruments. What are the roles of R&D in the development of new devices or improving the present devices. What is the role of supply chain management and how proper supply chain management can boost company operations. What are the roles of HR in finding the best talents for the organisation. What is the role of Finance and why finance specialists are needed, how they plan to make maximum profits from a project or planning of future projects.

In conclusion, the webinar on recent updates on IVD Regulations, Business and employment Opportunities in IVD's. The session was interactive, the speakers answered all the questions and clarified the doubts of the students and faculty. The session was concluded by addressing a vote of thanks by Dr. M P Venkatesh.

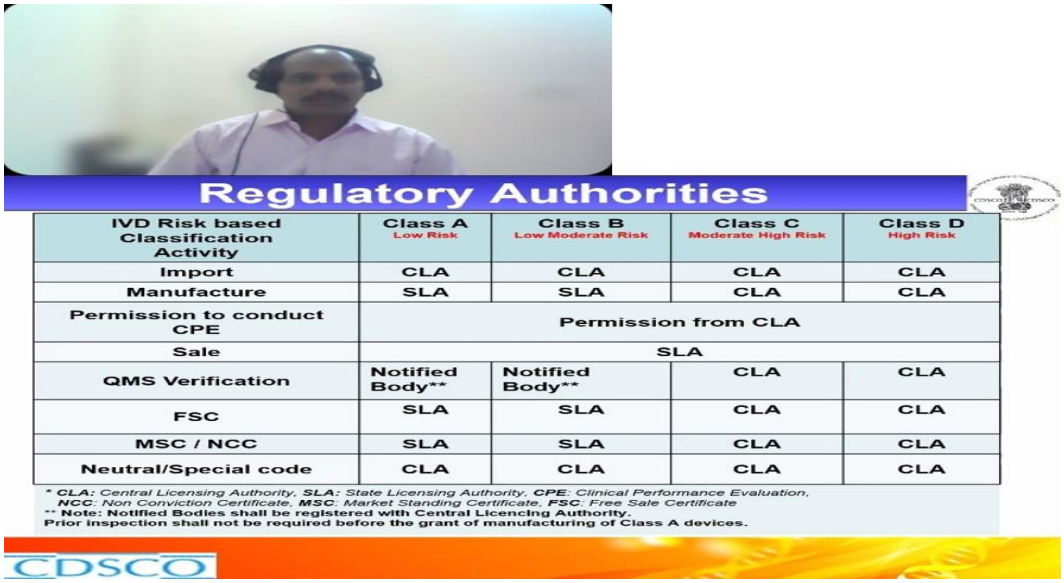

Figure 1: Dr. Sella Senthil. Topic: Indian IVD Regulatory Landscape.

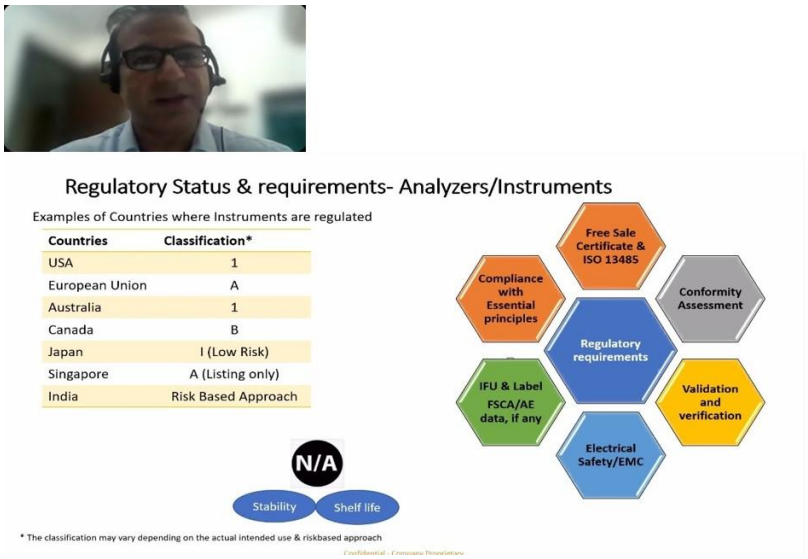

Figure 2: Mr. Manish Ragtah. Topic: Regulation Requirments of IVD Instrumets and Softwares

Figure 3: Mr. Hasmuk Rawal. Topic: Business and Employment Opportunities in IVD's