Training Program on "Medical Device Regulations and Quality Control of IVDs and Analysis of PCR and ELISA systems"
JSS College of Pharmacy, Mysuru
9th to 20th December, 2023

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Report on Training Program on Medical Device Regulations and Quality Control of IVDs

JSS College of Pharmacy, Mysuru organised a Training Program for officers of the Ethiopia Food and Drug Administration to provide them with knowledge and skills on the regulatory and quality aspects of medical devices, especially in vitro diagnostics (IVDs). The training was scheduled from 9th to 20th December 2023.

The program's launch took place on 9th December 2023, Saturday at JSS College of Pharmacy, Mysuru. The event aimed to welcome the new participants, introduce the program and felicitate the FDA officers. A detailed schedule of the sessions organised as part of the program is mentioned in Table 1.

Day 1: Inauguration Session

The event commenced with a welcome address from Dr T M Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru, where he welcomed all participants and dignitaries. He emphasized collaborative learning and encouraged everyone to utilize the training program as a learning and upskilling opportunity.

Dr M.P. Venkatesh, Associate Professor at JSS College of Pharmacy, provided insights about the training program and took participants through the program schedule, rules, and regulations.

This was followed by valuable remarks from Dr Surinder Singh, Vice Chancellor, JSS AHER, Dr Vishal K Gupta, Dean-Academics, JSS AHER, Dr Akhila Prashant. Head, Department of Biochemistry, JSS Medical College, Mysuru, and Dr Arshiya, Assistant Professor, Department of Medical Genetics, JSS

Medical College, Mysuru, who emphasized the importance of these kinds of programs, encouraged active participation, proactive interaction, and felicitated the FDA officers.

The program included an interaction with Ethiopian FDA Officers, Mr. Habteyes Chubaro Chucho, Ms. Semira Dino Seman, and Ms. Belyou Kinfe Wendaferaw. The event concluded with felicitation and a vote of thanks by Dr K Bangarurajan, Professor at JSS College of Pharmacy, Mysuru.

Session 1 Day 1: “Introduction and essential principles of medical devices” - Dr. K Bangarurajan

The session on "Introduction and essential principles of medical devices" by Dr K Bangarurajan, Professor, JSS College of Pharmacy, Mysuru was conducted on 9th December 2023. He delivered an insightful lecture on Indian medical device regulations, delving into the industry landscape, CDSCO's role, key legislation like the Drugs and Cosmetics Act 1940 and Medical Device Rules 2017, and crucial aspects like safety principles, risk control, clinical investigations, and environmental considerations for non-IVD devices. This comprehensive overview proves valuable for manufacturers, healthcare professionals, researchers, and anyone navigating the Indian medical device regulatory domain.

Session 1 Day 2: “Risk-Based Classification of Medical Devices and Medical Device Audits” - Dr. K Bangarurajan

The session on " Risk-Based Classification of Medical Devices and Medical Device Audits" by Dr. K Bangarurajan was conducted on 11th December 2023. The discussion was focused on the risk-based classification of medical devices and medical device audits. The necessity of classification, general principles and global classification standards were covered. Further, key aspects of medical device audits were also covered.

Dr. Bangarurajan’s expertise, which was gained through vast experience as a regulatory and pharmaceutical professional as a former Joint Drug Controller of India, was extremely valuable to all

participants. Through his discussions, participants gained key insights about the necessity of medical device classification, general principles of classification, and classification systems followed in India and globally. They were able to navigate into the intricate details about associated parameters that contribute to different standards followed across geographies and nuances behind regulations and regulatory responsibilities of various authorities as per Medical Device Rules 2017. The emphasis on a risk-based approach underscored the need for strategic planning to identify and mitigate potential risks during device classification.

The session on medical devices audit was crucial for understanding how audits are important to ensure that the manufacturing, operations and quality of a medical device conform to regulatory standards. Participants understood the various types of audits, documentation, steps, roles and responsibilities of audit personnel, timeline, and key activities that are required for audit preparation and execution. The emphasis on audits for upholding the highest standards in medical device manufacturing, the importance of documentation and personnel qualification further reinforced the need for audit as a function to adhere to strict quality standards.



Session 2 Day 2: “Reliance and Recognition Approach (Abbreviated Review) Of Medical Devices in Other Countries” – Mr Chandan MS

The session on " Reliance and Recognition Approach (Abbreviated Review) Of Medical Devices in Other Countries" by Mr Chandan MS, Clinical Evaluation and Regulatory Officer, Skanray Technologies, Mysuru was conducted on 13th December 2023. The objectives of the session were to provide an overview of medical device regulations and approval processes by addressing the following points. Through this session, the participants were provided with the basic concept of regulatory review, a comparison of key aspects of regulatory systems, a review of the concept and key requirements of Abbreviated Pathways and global recognition of approvals.

The discussion focused intently on the evolution of the regulatory landscape in medical devices and pharmaceuticals. Participants were provided key insights into how different countries and regions address regulatory issues and challenges and provided an all-encompassing overview of key concepts of regulations across different countries. Additionally, participants were detailed on how regulatory approvals are undertaken and how regulatory harmonization addresses geographical differences in regulations to create a uniform landscape of device accessibility and approvals.



The discussion emphasized the need for regulatory harmonization and the importance of mutual recognition of regulated medical devices. Mr Chandan’s expertise in this domain helped participants understand the need for mutual recognition. This offers accelerated global availability, streamlining regulatory processes, reducing manufacturer efforts, and establishing a standardized review system. This efficiency benefits patients, healthcare systems, manufacturers, and regulatory agencies, contributing to a more effective and harmonized global regulatory landscape.

Session 3 Day 2: “Risk-based medical device inspection techniques at port of entry” - Mr Rajashekar

The session on "Risk-based medical device inspection techniques at port of entry" by Mr Rajashekar, Deputy Drugs Controller(I), CDSCO, Bengaluru, was conducted on 11th December 2023. He delivered an extensive presentation on risk-based medical device inspection at Indian ports of entry. The discussion encompassed key topics such as drug regulations, India's regulatory framework, and the roles of State and Central Licensing Authorities.

Emphasis was placed on the Medical Device Rules 2017, including risk criteria for classifying medical devices and in vitro diagnostics based on their intended use in India. Additionally, the speaker detailed the requisite forms and licenses for importing, manufacturing, and selling medical devices, outlined general criteria for drawing testing samples, and highlighted import exemptions.

The session concluded with an interactive segment where Mr. Rajashekhar addressed queries from EFDA delegates, enhancing clarity on the discussed matters.

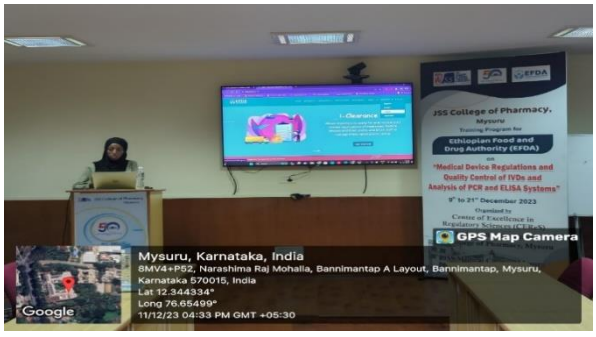

Session 4 Day 2: “Medical Device Labelling, Packaging, storage, and transportation of medical devices- instructions for use” - Dr Sella Senthil

The session on "Medical Device Labelling, Packaging, storage, and Transportation of medical devices-instructions for Use" by Dr Sella Senthil, Assistant Drugs Controller(I), CDSCO, New Delhi, was conducted on 12th December 2023. The speaker initiated his presentation by focusing on medical device labelling, packaging, storage, and transportation. The discussion delved into critical aspects such as instructions for use, encompassing components of both medical devices and in vitro diagnostics (IVD) labelling. Dr Senthil also covered instructions for use, labelling, and packaging, shedding light on the software utilized for labelling medical devices. The presentation concluded with an exploration of the symbols employed in medical device labels.

Session 1 Day 3: “Analytical performance study evaluation for IVDs, Stability study evaluation for IVDs” - Dr Sella Senthil

The session on "Analytical performance study evaluation for IVDs, Stability study evaluation for IVDs" by Dr Sella Senthil, was conducted on 12th December 2023. The speaker discussed the evaluation of analytical performance and stability studies for In Vitro Diagnostics (IVDs), distinguishing them from Medical Devices (MDs), and the role of the Central Medical Device Testing Laboratory.

He also covered the submission process for IVD reports on the official website and the review process by government officials. The speaker also discussed the special considerations for fast-track approvals during the COVID period, and flow charts illustrating approval processes for different IVD types in India. The lecture also covered Medical Device Labelling, Instructions for Use, Packaging, Storage, and Transportation, and the responsibilities of stakeholders in post-market surveillance and reporting processes.



Session 2 Day 3: Industrial visit to Skanray Technologies Pvt. Ltd. & Lahari - advanced electronics test facility; Mysore ESDM cluster

The industrial visit to the manufacturing site of SkanRay and the Testing facilities of Lahari was organised on 12th December 2023. It was coordinated by Mr Chandan MS. Through this industrial visit, participants aimed to gain valuable insights into the intricate world of medical device manufacturing, R&D, and testing.

The visit to Skanray was undertaken considering critical objectives, such as gaining knowledge about their technologies and products, understanding manufacturing processes, observing research activities, and engaging with professionals to exchange industry insights. The visit aimed to interpret how Skanray incorporates regulatory requirements into its device development process.

The visit to Lahari was primarily aimed at understanding the testing methodologies to which medical devices are subjected to ensure stable performance, effective output, and quality. The insights gained will help medical device professionals design their product testing and quality assurance programs more effectively.

The guided visits to SkanRay divisions covering manufacturing, raw material handling, marketing, and regulatory control, highlighted the firm's manufacturing practice ensuring compliance, quality control, and successful market positioning of their diverse range of medical products. Their product portfolio consists of Imaging & Diagnostic Devices (High-Frequency Digital Radiotherapy Machines, Dental X-ray Systems), Critical Care Devices (Patient Monitoring Systems, Defibrillators), Surgical Imaging Systems, Image Acquisition Software etc.

The next phase of the visit was at Lahari's testing facilities which was an enriching experience for participants. They observed various testing services and methods of medical devices, to ensure adherence to global and Indian quality standards. They gained an understanding of testing devices and types of equipment such as Dust Test Chamber, Salt Spray Corrosion Test Chamber, Dry Hot Air, Cath Test, Thermal Shock Chamber, Walk-In Climatic Test Chamber, EMI/EMC Test Chamber, Electrostatic Discharge (ESD) Immunity lab and a Shock and Vibration Test lab.

The visits to these facilities provided enriching experiences for all participants. Key learnings encompassed understanding manufacturing complexities and cutting-edge medical device technologies, emphasizing design, resources, and regulatory compliance. This included recognizing the importance of stringent quality control measures, various testing procedures, diverse testing capabilities, awareness of industry standards, observation of advanced equipment, and existing expertise in medical device testing.

Session 1 Day 4: "Overview of Materiovigilance Programme of India Step Towards Promoting Safety of Medical Devices" - Dr M Ramesh

The session on " Overview of Materiovigilance Programme of India Step Towards Promoting Safety of Medical Devices" by Dr M Ramesh, Professor, JSS College of Pharmacy, Mysuru was conducted on 13th December 2023. The presentation aimed to provide valuable insights into the Materiovigilance Programme of India (MvPI), which is a crucial initiative launched by the Ministry of Health & Family Welfare, Government of India.

The session provided important insights into the background of MvPI, its purpose, objectives and goals, and its functioning, which is to monitor the safety of medical devices in the Indian market. It also covered information on the partner organizations, data collation and evaluation process, communication flow, and learning about the importance of reporting adverse events, the process of reporting these events, and the role of various stakeholders in the program.

The session underscored the need for the program and its impact on improving the safety and efficacy of medical devices in India. Through this session, participants gained a fair understanding of the key aspects of the program and how the effective conduct of the same ensures the well-being of patients by monitoring and addressing issues related to medical devices.

Session 2 Day 4: “Causality Assessment of Medical Devices Adverse Events” – Dr Sriharsha Chalasani

The session on "Causality Assessment of Medical Devices Adverse Events" by Dr Sriharsha Chalasani, Assistant Professor, JSS College of Pharmacy, Mysuru was conducted on 13th December 2023. He delivered a comprehensive presentation on the Detection, Reporting, and Causality Assessment of adverse events associated with Medical Devices. Beginning with an introduction to materiovigilance, and provided insights into the identification of adverse events related to medical devices.

The presentation delved into the crucial reporting aspects, elucidating the significance of reporting on medical devices, addressing the who, what, why, and to whom reporting is vital, and detailing the reporting process itself. The speaker also covered instances where events or incidents are not required to be reported and expounded on the classification of severity associated with medical devices based on the health hazard. Real-life case studies from the speaker's experience were presented, highlighting the importance of reporting even minor incidents to the relevant authorities.

The session concluded with a thorough explanation of causality assessment, including categories such as not related, probable, unlikely, possible, and un-assessable, and the establishment of a causal relationship in the reporting of medical devices.

Session 3 Day 4: Industrial visit: L & T Technological Services, Mysuru

The visit was coordinated by Dr M.P. Venkatesh and Dr Hemant Kumar S, JSS College of Pharmacy, Mysuru.

The company operates as a service provider for major medical device companies such as Phillips, GE, Toshiba, Beckman, and Coulter. With a meticulous approach, it categorizes medical devices based on risk and upholds industry standards by adhering to ISO 13485 and ISO 9001. The presentation elucidates various sections within the industry, including the receiving area and component storage and release processes, along with a comprehensive overview of the flow process from product reception to dispatch.

In the realm of ultrasound scanners, the company provides detailed insights into their classification, operational mechanisms, applications, quality control measures, and maintenance procedures. Additionally, the company offers a range of medical imaging services, encompassing AI, high-performance computing, computer vision, and PDT software.

The presentation extends to the company's wet lab operations, shedding light on biochemical analysers, haematology analysers (CBC, CPC), and agar plate analysers. This holistic overview showcases the company's commitment to quality, industry standards, and diverse service offerings within the medical device sector.

Session 4 Day 4: “Documentation of Medical Devices Adverse Events” - Dr Ascharya Chintalapati

The session on "Documentation of Medical Devices Adverse Events" by Dr Ascharya Chintalapati, Pharmacovigilance Associate, JSS Medical College, Mysuru was conducted on 13th December 2023. The presentation aimed to provide an overview of the Medical Device Adverse Event Reporting Form which is an important tool provided by the Materiovigilance Programme of India (MvPI). This is a standardized form for reporting AEs, ensuring consistency and completeness of data.

Through this session, participants were introduced to the purpose, intended users, partnering agencies, and various sections of the form. The speaker emphasized the importance of the form and the timely usage of the same to ensure adverse events are reported accurately and within the stipulated timeframe to regulators. This is indeed crucial to ensure patient safety is not compromised and all adverse events are reported and users are adequately compensated. This also helps regulators assess the cause of the event and take appropriate action regarding the reported device.

The session equipped participants to appreciate the vital role played by MvPI and the form as one of its crucial tools in improving patient outcomes and healthcare delivery.

Session 5 Day 4: “General classification and overview IVD regulations in USA” - Dr Balamuralidhara V

The session on " General classification and overview IVD regulations in USA" by Dr Balamuralidhara V, Associate Professor, JSS College of Pharmacy, was conducted on 13th December 2023. The presentation focused on Invitro Diagnostic Devices (IVDs), highlighting their definition under section 210(h) and labelling requirements in 21 CFR 809. The speaker discussed the U.S. Food and Drug Administration's divisions, classification principles, and Class I, Class II, and Class III classifications. He covered FDA regulations, including general purpose, analyte-specific

reagents, and controls. Sir has also covered procedural aspects like pre-submission processes, Investigational Device Exemption, Pre-market Notification, Pre-Market Application, and De Novo processes. She also discussed IVD labelling requirements, recall considerations, and Medical Device Reporting procedures. The speaker provided a comprehensive understanding of the US regulatory landscape for IVDs.

Session 1 Day 5: Industrial Visit to TUV India Pvt. Ltd., Bengaluru

The industrial visit to TUV was organised on 14th December 2023. It was coordinated by Mr Mr Moloy Dhar, TUV India. Through this industrial visit, participants aimed to gain valuable insights into the intricate world of medical device testing, inspection services, and certification.

Mr Dhar's guided tour of the testing intended to provide participants with an understanding of the testing methodologies to which medical devices are subjected to ensure stable performance, effective output, and quality. The insights gained will help medical device professionals design their product testing and quality assurance programs more effectively.

Participants were introduced to various cutting-edge testing labs, equipment, testing methods, and chambers which are internationally certified and recognized as state-of-the-art. Overviews were provided on the functions and intended results of the Reliability Chamber, Thermal Shock Chamber, Medical Lab, Electrosurgery Analyser, Vital Sign Simulator & Gas Flow Analyser, Incubator Analyser, Electrical Safety Analyser, Transthoracic Pacing Analyser & Defibrillator Selector Loads, Ingress protection chamber, Dust Test Chamber, Non-metallic salt test, Immersion Water test, Needle flame test, Flexibility cord test, Electrostatic Discharge (ESD) test, Electrical fast transients (EFT) test, PCB tester voltage breakdown test, Glow wire test apparatus, Laboratory oven, Drop test machine, Stability test apparatus, Bump tester, Abrasion tester, Vibration and Shock lab, Cord anchorage and strain relief test setup, EMI/EMC Test Chamber, and Battery testing area.

This visit proved fruitful to participants as they were able to form a basic practical idea of advanced electronic testing and validation methods and processes for medical devices. These are crucial to ensure compliance with national and international regulatory standards, guarantee end-user safety, and ensure the intended outcome. This also introduced participants to diverse testing capabilities, created awareness of industry standards, and familiarised them with advanced testing equipment, and existing expertise in medical device testing.

Session 2 Day 5: “Regulatory Approval Process for Medical Devices (510k) Premarket Notification, PMA” – Dr M P Venkatesh

The session on " Regulatory Approval Process for Medical Devices (510k) Premarket Notification, PMA" by Dr M P Venkatesh, Associate Professor, JSS College of Pharmacy, Mysuru was conducted on 14th December 2023. The discussion was focused on the risk-based classification of medical devices and medical device audits. The necessity of classification, general principles and global classification standards were covered. Further, key aspects of medical device audits were also covered.

The session provided a comprehensive overview of medical device regulations and approval processes, covering key aspects of the Premarket Notification 510(k) process, Premarket Approval (PMA), and the overall flow of PMA and 510(k) processes, and databases. The session provided participants with a thorough understanding of medical device classification, the need for FDA registration, and the compliance protocols applicable to Class I, II, and III devices.

A clear outline of the process flow from device classification to FDA approval and post-approval compliance was provided. The importance of maintaining full compliance with Quality System Regulations (QSR) Considerations for device classification by the FDA and the potential for De Novo Classification submissions were also highlighted.

Through this session, participants were able to navigate through the intricacies of medical device regulations in the USA intended to uphold quality standards and were equipped with a deeper understanding of the crucial steps, documentation, and processes involved in obtaining regulatory approval for devices.

Session 1 Day 6: “Quality Control/QC testing of IVDs: HIV” - Dr M Dhanasekaran and team

The session commenced with an introduction by Dr. M. Dhanasekaran, Director and Admin of Genuine Biosystems Pvt Ltd, Chennai, where he familiarized the delegates and students with both himself and the company. Dr. Dhanasekaran then elaborated on the history and present goals of Genuine Biosystems, emphasizing their commitment to delivering improved In Vitro Diagnostic (IVD) products globally at a minimal cost.

The speaker delved into the crucial role of Research and Development (R&D), underscoring its significance in the continuous enhancement of their product offerings. Following a noon break, Dr Dhanasekaran shifted the focus to the importance of Instruction for Use (IFU) in every IVD device, providing insights into its relevance and detailing the contents integral to effective product usage.

Session 2 Day 6: “Quality Control/QC testing of IVDs: Hepatitis, Malaria” – Dr Shivakumar Banakar and Mr K Kiran Kumar

Dr. Shivakumar Banakar, Senior Scientist in R&D at Genuine Biosystems, initiated his speech by underscoring the pivotal role of innovation in the In Vitro Diagnostic (IVD) sector. He highlighted how innovation serves as a catalyst for company growth and proceeded to share information on recently patented products, such as the C3 pad for cervical screening and the BARC project. Dr Banakar further elaborated on the company's involvement in the development and production of diverse products, including WIDAL antigens, blood group clones, haematology reagents, eCLIA buffers, raw materials/biosimilars, and various other concentrated projects. Additionally, he shed light on the technical consultancy services offered by Genuine Biosystems Pvt Ltd.

Mr. K. Kiran Kumar, General Manager, Technical at Genuine Biosystems, discussed the production system within an In Vitro Diagnostic (IVD) company, detailing manufacturing processes for serology, biochemistry, and ELISA products. He also discussed the intricacies of quality control, presenting a workflow chart and performance studies per ISO 23640 standards. Kumar highlighted the diverse roles of the Quality Assurance department across various production facets, including QC, logistics, purchase, warehouse, and human resources. He also discussed IVD regulations in Ethiopia, including risk classes, registration processes, and registration exemptions for medical devices approved by the SRA. He also discussed the technical and administrative documents required for submission and the time frame for registration.

Session 3 Day 6: Hands on training

After the end of the session, the delegates and students are introduced to practical experience on how to handle IVDs and how different types of IVDs work based on the type of test, reagent, and specimen to be used.

The whole session ended after felicitation of the guests by Dr K Bangarurajan.

Day 7: Industrial Visit – Bhat Bio Products, Bengaluru

Bhat Bio-tech India (P) Limited, specializing in diagnostic and biotechnology products, hosted delegates and PhD scholars. Mr. Sham Bhat, Head of Bhat Biotech, and Mr. Vinay, Head of Quality Assurance and Regulatory Analysis, welcomed the attendees, providing an overview of the company and its products. The session covered essential topics such as In Vitro Diagnostics (IVDs), ISO 9001, and ISO 13485, emphasizing their significance.

Delegates were introduced to the Manufacturing and R&D team, who explained the use of recombinant proteins in sample determination and their incorporation into medical devices. The presentation then shifted to design analysis, exploring factors considered when launching new IVD products. The process of validating manufactured lots based on WHO guidelines and the documentation required for CDSCO approval were detailed, along with the roles of the State Licensing Authority and Central Licensing Authority.

Different labs, including monoclonal and polyclonal labs, were described, along with the manufacturing processes for various sizes of nanoparticles. The flow-through method in manufacturing was presented with clear flow charts, highlighting sampling and in-house quality tests according to ISO 13485.

The Quality Control department showcased methods for determining the sensitivity and specificity of IVDs and quality tests for reagents. The tour concluded with visits to areas like raw material quarantine, approved raw material, rejected material, stability, and control sample storage, ELISA kit production, and a cold temperature room.

Valedictory Session

As the training reached its culmination, Dr T M Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru and, on behalf of the entire team, extended his deepest gratitude to all the individuals who contributed to making this program a resounding success. The collective efforts, dedication, and passion exhibited by each person involved have left an indelible mark on the participants' learning experience and the overall success of the program. His closing remarks underscored the importance of continual learning in this ever-evolving field, and the session concluded on a note of shared accomplishment and future promise. At the end of the session, certificates were handed over to FDA officers.

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Table 1: Schedule of Training Program

Sl. No.	Time (IST)	Training Topics	Resource Person / Trainer
Day 1 – 9th Dec 2023 Inauguration and introduction to the Training program			
1	9.00 AM – 9.30 AM	Welcome Address	Dr. T M Pramod Kumar Principal JSS College of Pharmacy, Mysuru
2	9.30 AM – 11.00 AM	Introduction and essential principles of medical devices	Dr. K Bangarurajan, Professor JSS College of Pharmacy, Mysuru
3	11.00 AM – 11.15 AM	About the Training Program	Dr. M.P. Venkatesh Associate Professor JSS College of Pharmacy, Mysuru
4	11.15 AM – 11.30 AM	Tea Break	
5	11.30 AM – 11.40 AM	Remarks	Dr. Surinder Singh – Vice Chancellor, JSS AHER
6	11.40 AM – 11.50 AM	Remarks	Dr. Vishal K Gupta – Dean-Academics, JSS AHER
7	11.30 AM – 11.40 AM	Interaction with Ethiopian FDA Officers	1. Mr. Habteyes Chubaro Chucho – Medical Device Quality Testing Analyst 2. Ms. Semira Dino Seman – Medical Device Dossier Assessor 3. Ms. Belyou Kinfe Wendaferaw – Medical Device Quality Testing Analyst
8	11.40 AM – 11.50 AM	Felicitation	
9	11.50 AM – 11.55 AM	Vote of Thanks	Dr K Bangarurajan, Professor JSS College of Pharmacy, Mysuru
10	11.55 AM – 12.15 PM	Photo Session	
Day 1 – 9th Dec 2023 Introduction to Medical devices, GHTF, IMDRF, registration and inspection			
11	12.15 PM - 1.00 PM	***Registration:*** Risk management evaluation of class C/ D and class 1/2 devices	Mr. Lokesh Glova Pharma Solutions Bengaluru
12	2.00 PM – 3.30 PM	***Inspection:*** Risk based inspection and Good manufacturing inspection for high risk medical devices	Mr. Badari Narayan MD, S3V Vascular Technologies, Mysuru
13	4.00 PM- 5.00 PM	***Inspection:*** Quality Management Systems and issuance of manufacturing licence	Mr. Lokesh Glova Pharma Solutions Bengaluru
Day 2 – 11th Dec 2023 Auditing, review, import and labelling of Medical Devices			
14	9.00 AM - 11.00 AM	***Audits:*** • Regulations for audit of medical device facility • Auditing process of medical devices facility	Dr. K. Bangarurajan Professor JSS College of Pharmacy, Mysuru
15	11.15 AM- 1.00 PM	***Review:*** Reliance and recognition approach (abbreviated review) in other countries	Mr. Chandan MS SkanRay Technologies Mysuru
16	2.00 PM- 3.45 PM	***Port of entry:*** Risk based medical device inspection techniques at port of entry.	Mr. Rajashekar Deputy Drugs Controller(I) CDSCO, Bengaluru
17	4.00 PM - 5.00 PM	Medical device labelling, packaging, storage, and transportation Medical devices – Instructions for use	Dr. Sella Senthil Assistant Drugs Controller(I) CDSCO, New Delhi
Day 3 – 12th Dec 2023 IVDs: Overview, performance, and evaluation & SkanRay visit			

18	9.00 AM– 11.00 AM	• Analytical performance study evaluation for IVDs Stability study evaluation for IVDs	Dr. Sella Senthil Assistant Drugs Controller(I) CDSCO, New Delhi Mr. M. Bhaskaran Ex-Director of Drugs Control Tamilnadu
19	11.15 AM - 5.00 PM	• ***Industrial visit:*** ***1. SkanRay Technologies, Mysuru*** ***2. LAHARI ESDM Cluster, Mysuru***	Dr. Hemanth Kumar S Assistant Professor JSS College of Pharmacy, Mysuru
Day 4 – 13th Dec 2023 Materiovigilance Program and LTTS visit			
20	9.00 AM – 9.30 AM	Overview of materiovigilance program of India	Dr. M. Ramesh Professor JSS College of Pharmacy, Mysuru
21	9.30 AM -11.15 AM	Causality assessment of Medical Devices Adverse Events	Dr. Sriharsha Chalasani Assistant Professor JSS College of Pharmacy, Mysuru
22	11.15 AM – 1.00 PM	***Industrial visit: L & T Technological Services, Mysuru***	Dr. Hemanth Kumar S Assistant Professor JSS College of Pharmacy, Mysuru
23	2.00 PM – 3.30 PM	Documentation of Medical Devices Adverse Events	Dr. Ascharya PVPI associate, AMC, JSS Medical College and Hospital, Mysuru
24	4.00 PM – 5.00 PM	General classification and overview IVD regulations in USA	Dr. Balamuralidhara V Associate Professor JSS College of Pharmacy, Mysuru
Day 5 – 14th Dec 2023 Industrial Visit – TUV Rheinland, Bengaluru			
25	8.00 AM – 3.00 PM	***Industrial Visit – TUV Rheinland, Medical Device Testing facility, Bengaluru***	Dr. M.P. Venkatesh and Dr. Hemant Kumar S JSS College of Pharmacy, Mysuru
26	4.00 PM- 5.00 PM	Regulatory approval process for Medical Devices (510k) Premarket Notification, PMA	Dr. M.P. Venkatesh Associate Professor JSS College of Pharmacy, Mysuru
Day 6 – 15th Dec 2023 Quality Control of IVDs and Hands on training - QC testing of IVDs			
27	9.00 AM – 11.00 AM	Quality control/ testing of IVDs: HIV	Dr. M. Dhanasekaran and team Genuine Biosystems, Chennai
28	11.15 AM - 1.00 PM	Quality control/ testing of IVDs: Hepatitis, Malaria	Dr. M. Dhanasekaran and team Genuine Biosystems, Chennai
29	2.00 PM– 5.00 PM	***Hands-on-training: Genuine Biosystems, Chennai***	Dr. M. Dhanasekaran and team Genuine Biosystems, Chennai
Day 7 – 16th Dec 2023 Industrial Visit – Bhat BioProducts and Drug Testing Laboratory, Bengaluru			
30	8.00 AM – 6.00 PM	***Industrial Visit –*** ***1. Bhat Bio Products, Bengaluru and*** ***2. Drug Testing Laboratory, Govt. of Karnataka, Bengaluru***	Dr. Balamuralidhara and Dr. Hemanth Kumar S JSS College of Pharmacy, Mysuru
Day 8 – 18th Dec 2023 DNA Isolation & Quality check			
31	9:30 AM - 9:40 AM	Welcome address	Dr Akhila Prashant

32	9:40 AM -10:10 AM	Talk – Different methods of DNA isolation from blood samples & Quality check	Head, Dept. of Biochemistry, JSS Medical College, Mysore Dr Arshiya, Asst. Professor, Dept of Medical Genetics, JSS Medical College, Mysore
33	10:10 AM -10:30 AM	Talk – Brief introduction to databases and primer designing	
34	10:30 AM -10:45 AM	Tea break	
35	10:45 AM -11:30 AM	Tour around the laboratory facility	
36	11:30 AM - 1:00 PM	Hands-on session – DNA Isolation & Quality check	
37	2:00 PM - 5:00 PM	Hands-on session – DNA Isolation & Quality check	
Day 9 - 19th Dec 2023 Real-time PCR assay			
38	9:30 AM - 10:00 AM	Talk – Basics of PCR with introduction to qPCR data analysis	Dr Vinay Dr Praveen Asst. Professor, Dept of Medical genetics. JSS Medical College, Mysore
39	10:00 AM - 11:00 AM	Hands-on session – Instrumentation, Setting up real time PCR assay	
40	11:15 AM - 11:45 PM	Talk – Application of Immunoassays in diagnostics	
41	11:15 AM - 11:45 PM	Talk – Application of Immunoassays in diagnostics	
42	11:45 AM - 1:00 PM	Hands-on session – Instrumentation & assay set-up	
43	2:00 PM - 5:30 PM	Hands-on session – ELISA run and data analysis	
Day 10 - 20th Dec 2023 – Microscopic Laboratory Quality Control			
44	9:30 AM - 01.00 PM	Characterization of control samples for RTD testing	Dr Tejashree Professor & Head, Dept of Microbiology, JSS Medical College, Mysore
45	2:00 PM - 5:30 PM	Valedictory function	Dr M P Venkatesh Associate Professor JSS College of Pharmacy, Mysuru