A REPORT ON

Training Program for Ethiopian Food and Drug Authority (EFDA) Drug Inspectors on "Pharmaceutical and Vaccine Manufacturing"

Organised by

Centre of Excellence in Regulatory Sciences (CEReS),
Department of Pharmaceutics, JSS College of Pharmacy, Mysuru &
School of Life Sciences, Mysuru, JSS AHER

Date: 3rd to 11th June 2024

Venue: Board Room, JSS College of Pharmacy, Mysuru

Number of Participants: 03

1. Mr. Engida Samuel Marie
2. Mr. Mola Teferi Mantegaftot
3. Mr. Dibaba Dejena Daba

Duration: 09 Days

Agenda:

1. Vaccine manufacturing (Processes, Approaches, Safety, and Quality control).
2. Advancements in Bacterial and Viral vaccine manufacturing procedures.
3. Virus Inactivation, Removal and Product Safety.
4. Facility, Equipment, cGMP issues, and Technology Transfer.

Objectives of the training program

After completion of the training program, the trainee can

- Understand the fundamental differences between vaccines and conventional products.
- Explore the disadvantages of cell-based versus egg-based production methods.
- Discuss the requirements for early and late clinical trial phases.
- Examine the regulatory expectations for vaccine batches in phase 1/2/3 clinical trials.
- Explore modern vaccine technologies, including vector vaccines, Plasmid-DNA vaccines, and mRNA manufacturing.
- Understand the related regulations concerning cell lines and the risks of cross-contamination.
- Understand the cGMP development and manufacturing of recombinant viral vaccines
- Differentiate between the development and validation phases.
- Explore regulatory expectations for implementing analytical methods and contract manufacturing of IMPDs.
- Trace the journey from viral seeds to finished products.
- Discuss requirements for raw and starting materials, efficient process control, and viral safety aspects.
- Examine types of bacterial vaccines and challenges in manufacturing.
- Discuss concerns related to Master Cell Banking, cell culture, and upstream processing.
- Explore GMP considerations for raw materials, media preparation, and experiences from inspections.
- Understand containment measures and their impact on product and environmental safety.
- Explore the role of personnel in containment and experiences from inspections.
- Validate decontamination procedures and explore virus inactivation principles and methods.
- Discuss GMP issues related to virus inactivation and removal techniques.
- Address practical issues with material flow, personnel, and waste.
- Discuss clean room qualification, segregation of processes, and changeover procedures.
- Explore various manufacturing, analytical, and R&D equipment.
- Discuss the design, construction, and qualification challenges of isolator filling lines.
- Explore techniques such as ultrafiltration, ultracentrifugation, sterile filtration, and aseptic processing.
- Understand the principles of good laboratory practices and safety in vaccine production.
- Explore different quality control measures, including potency assay, in vitro testing, and sterility management.
- Define conditions and requirements for successful technology transfer.
- Address GMP concerns associated with technology transfer.

Learning Outcomes

- Upon completion of the training program, it is expected that the trainee will be able to
- Know the different types of vaccines, their production methods, modern approaches, production risks, and GMP requirements.
- cGMP development and manufacturing of recombinant viral vaccines for clinical trials.
- Know the regulatory expectations for vaccine manufacturing.
- The differences in viral and bacterial vaccines in terms of production, methods, stability, safety, product quality control, and new technologies.
- Know the issues with cell banking and cell culture, the importance of raw materials and media preparation steps.
- Understand the importance of product safety issues, contamination, and aseptic manufacturing.
- Know the importance of virus-removing techniques and their deployment.
- Understand the maintenance of the facility concerning human, material, and waste management.
- Know the equipments used for vaccine manufacturing and their operating techniques.
- Understand separation techniques like ultrafiltration, sterile filtration, and ultracentrifugation.
- Understand the principles of safety, quality control, potency, and sterility issues with vaccine manufacturing.
- Know the conditions, acceptance and GMP concerns regarding technology transfer related to the vaccine manufacturing.

Schedule of the Training Program

Sl. No.	Time (IST)	Training Topics	Resource Person / Trainer
Day 1: 03 June 2024 MONDAY Inauguration and introduction to the training program			
1	10.00 AM – 11.00 AM	Inauguration and Introduction to the Training Program	**JSS AHER Officials, Faculty**
2	11.15 AM – 1.00 PM	Fundamentals of Vaccines and modern vaccines	**Dr. Rashmi L,** Assistant Professor, Quality As, IAH-VB, Bengaluru.
3	2.00 PM – 3.00 PM	GMP requirements for vaccine manufacturing	**Dr. C Omprakash** Technical Director & Founding partner, Vyomus consulting
4	3.15 PM – 5.00 PM	cGMP Development and manufacturing of recombinant viral vaccines for clinical trials	**Dr. C Omprakash** Technical Director & Founding partner, Vyomus consulting

Day 2: 04 June 2024 **TUESDAY** **cGMP Development and Manufacturing of Vaccines for Clinical Trials**			
5	10.00 AM – 11.30 AM	cGMP issues for Upstream Processing	**Mrs. A Rajani,** Deputy General Manager-RA, Dossier Solutions.
6	11.45 AM – 1.00 PM	Regulatory Expectations of Vaccine Batches for Phase 1/2/3 Clinical Trials	**Dr. C Omprakash** Technical Director & Founding partner, Vyomus consulting
7	2.00 PM – 3.15 PM	cGMP issues for Downstream Processing	**Mrs. A Rajani,** Deputy General Manager-RA, Dossier Solutions.
8	3.30 PM – 5.00 PM	Contract Manufacturing of IMPDs	**Dr. C Omprakash** Technical Director & Founding partner, Vyomus consulting
Day 3: 05 June 2024 **WEDNESDAY** **Quality control of Vaccines**			
9	10.00 AM – 11.30 AM	Quality management Systems	**Ms. Lakshmi Achuta** Principal Strategic Advisor, AshRin Bio LLP
10	11.45 AM – 1.00 PM	cGMP requirements for vaccines	**Ms. Lakshmi Achuta** Principal Strategic Advisor, AshRin Bio LLP
11	2.00 PM – 3.15 PM	Quality control and Testing – Part I	**Dr. Shivakumar M C** Principal Scientific Advisor, Microbiology & Biotechnology
12	**3.30 PM – 5.00 PM**	Quality control and Testing – Part II	**Dr. Shivakumar M C** Principal Scientific Advisor, Microbiology & Biotechnology
Day 4: 06 June 2024 **THURSDAY** **Equipment's for vaccine Manufacturing**			
13	10.00 AM – 11.30 AM	Qualification and Validation	**Ms. Lakshmi Achuta** Principal Strategic Advisor, AshRin Bio LLP
14	11.45 AM – 1.00 PM	Quality Assurance	**Ms. Lakshmi Achuta** Principal Strategic Advisor, AshRin Bio LLP
15	2.00 PM – 3.15 PM	Analytical Equipment's for vaccine production	**Mr. Vireshkumar H Sheth** CEO & Director

			Shriyata Lifetech Private Limited
16	3.30 PM – 5.00 PM	Isolator Filling Line	**Mr. Vireshkumar H Sheth** CEO & Director Shriyata Lifetech Private Limited
Day 5: 07 June 2024 **FRIDAY** **Visit to the Institute of Animal Health & Veterinary Biologicals (IAH-VB), Bengaluru**			
Day 6: 08 June 2024 **SATURDAY** **Program management of vaccine manufacturing**			
17	10.00 AM – 11.30 AM	Project management of Vaccines – Part I	**Mrs. Lakshmi** Associate Director Client Services
18	11.45 AM – 1.00 PM	Project management of Vaccines – Part II	**Mrs. Lakshmi** Associate Director Client Services
Day 7: 09 June 2024 **SUNDAY**			
Day 8: 10 June 2024 **MONDAY** **Visit to the Pasteur Institute of India, Coonoor**			
Day 9: 11 June 2024 **TUESDAY** **Characteristics of Viral and Bacterial Vaccines**			
19	09.30 AM – 11.30 AM	Requirements, Efficient Process and Setting Specifications for Viral Vaccines	**Dr. Suchitra A D,** Professor and Head, Department of Pharmacology, ESIC Medical College, Bengaluru.
20	11.45 AM – 1.00 PM	Valedictory Function	

Daily: Tea Break: 11.30 – 11.45 AM; Lunch break: 1.00 – 2.00 PM; Tea break: 3.15 - 3.30 PM

Day 01 – 03/06/2024 Monday

Inauguration: On June 3rd, 2024, the JSS College of Pharmacy, Mysuru held an inauguration ceremony for the "Pharmaceutical and Vaccine Manufacturing" training program. The event highlighted the importance of collaborative efforts in advancing regulatory capabilities to maintain the quality and safety standards of pharmaceutical products and vaccines. This training program is expected to bring significant benefits to EFDA Drug Inspectors by equipping them with the necessary knowledge and skills to effectively oversee and regulate pharmaceutical and vaccine manufacturing in Ethiopia.

The inauguration schedule was as follows:

10.00 AM	Welcome Address by **Dr Pramod Kumar T M**, Principal, JSSCPM and Dean, Faculty of Pharmacy, JSS AHER
10.05 AM	About the Training Program by **Dr. M.P. Venkatesh**, Coordinator CEReS, JSSCPM
10.15 AM	Remarks by **Dr. Raveesha**, Dean, School of Life Sciences and Life Science Departments, JSS AHER, Mysuru.
10.20 AM	Address by **Dr. Vishal K Gupta**, Dean-Academics, JSS AHER
10.25 AM	Interaction with Ethiopian FDA officers: 1. Mr Dibaba Dejene Daba 2. Mr. Mola Teferi Mantegaftot 3. Mr. Engida Samuel Marie
10.35 AM	Felicitation
10.40 AM	Vote of Thanks by **Dr Ramith Ramu**, Department of Biotechnology & Bioinformatics, JSSAHER, Mysuru.
10.45 AM	Photo session

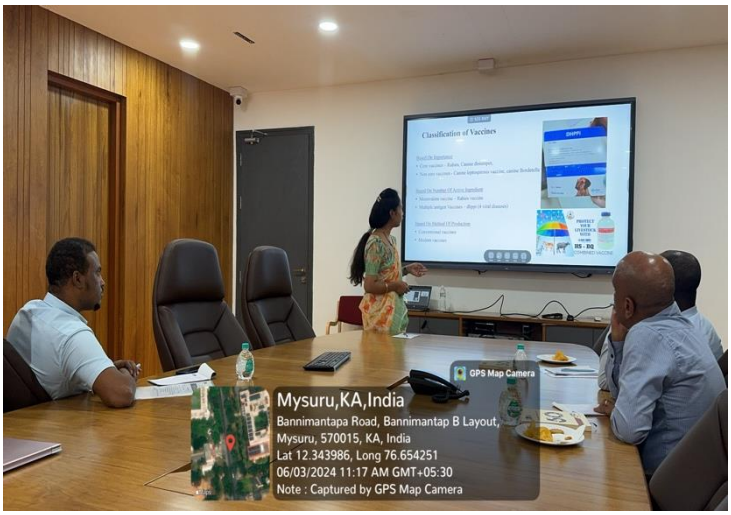
Inauguration of a nine-day training program on "Pharmaceutical and Vaccine Manufacturing" at JSS College of Pharmacy, JSSAHER, Mysuru.

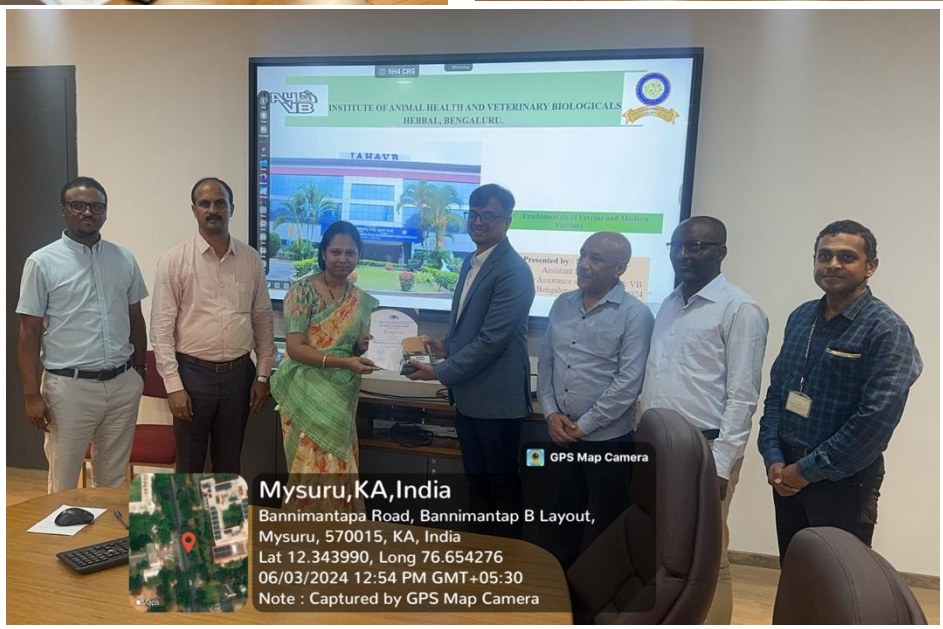
EFDA Drug Inspectors with the Dignitaries from the School of Life Sciences and JSS College of Pharmacy, JSSAHER, Mysuru, during the inauguration of the Pharmaceutical and Vaccine Manufacturing training program.

Day-1

Morning session

On June 3rd, 2024, Dr. Rashmi L, Assistant Professor in Quality Assurance at IAH-VB, Bengaluru, led a pivotal training session on "Fundamentals of Vaccines and Modern Vaccine Technologies" for the Ethiopian Food and Drug Authority (EFDA). The session provided comprehensive insights into vaccine development, mechanisms, and advancements, emphasizing their critical role in disease prevention and public health. Dr. Rashmi L's overview of vaccine principles, historical context, and interactive discussions equipped EFDA officials with essential skills for assessing and regulating modern vaccines effectively. This session significantly bolstered the capacity-building efforts of EFDA, empowering officials to enhance vaccine regulation and strengthen public health initiatives in Ethiopia.



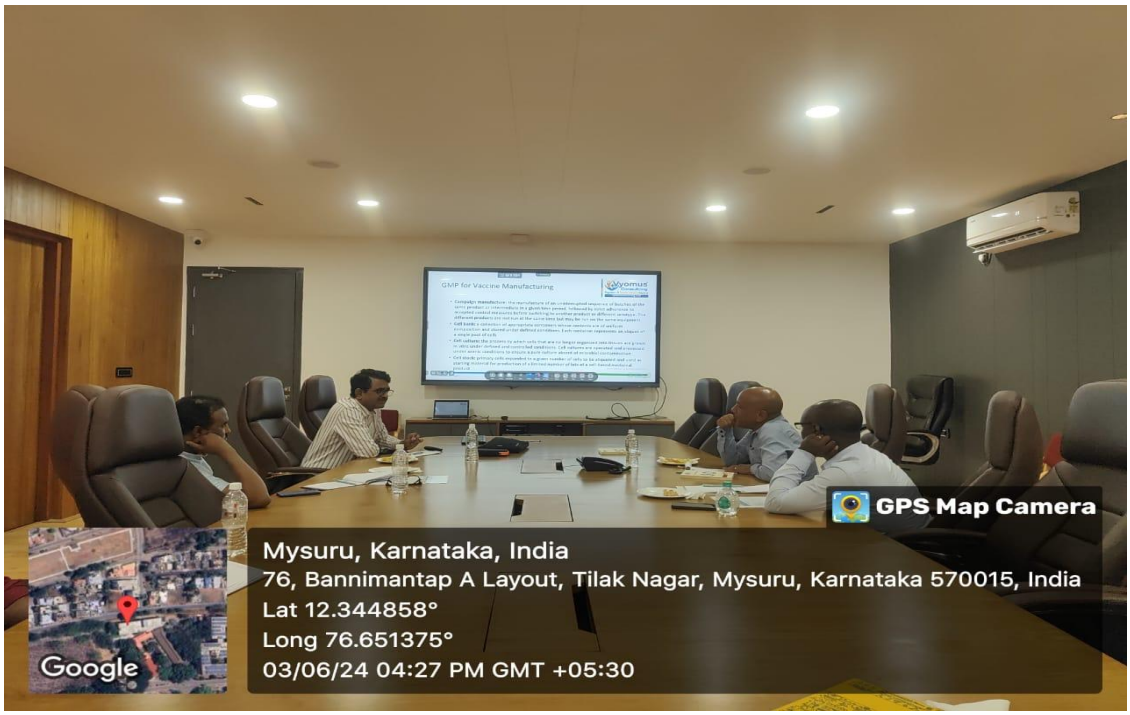


JSSAHER expresses sincere appreciation to Dr. Rashmi L for her invaluable training contributions to EFDA.

Day-1
Afternoon session

On June 3rd, 2024 the first half of the afternoon session Dr. C Omprakash, Technical Director, delved into the crucial topic of Good Manufacturing Practices (GMP) requirements for vaccine manufacturing. The session aimed to elucidate the intricate standards and protocols necessary for ensuring the safety, efficacy, and quality of vaccines. Participants gained a deeper understanding of the critical role played by GMP in safeguarding public health and facilitating global vaccine access.

During the second half of the session, Dr. C Omprakash, conducted a comprehensive session on cGMP (current Good Manufacturing Practices) development and manufacturing of recombinant viral vaccines for clinical trials. This segment aimed to provide attendees with an in-depth understanding of the processes involved in ensuring the quality and safety of viral vaccines intended for clinical use. Participants gained insights into cGMP regulations, manufacturing practices, quality control measures, and clinical trial considerations, equipping them with the knowledge necessary to navigate the complex landscape of vaccine development and regulatory compliance.



Dr. Omprakash has demonstrated the complexities of current Good Manufacturing Practice (cGMP) standards, thereby facilitating the development of safe and efficient viral vaccines.

Day-2
Morning session – 1

On June 4th, 2024, first half of the morning session led by Mrs. A Rajani focused on critical current Good Manufacturing Practice (cGMP) issues pertinent to upstream processing in biopharmaceutical manufacturing. The session covered various aspects including regulatory requirements, common challenges, and best practices to ensure compliance and product quality.Mrs. Rajani shared several real-world examples and case studies demonstrating the application of cGMP principles in upstream processing. These examples illustrated the consequences of non-compliance and the benefits of adhering to regulatory guidelines.

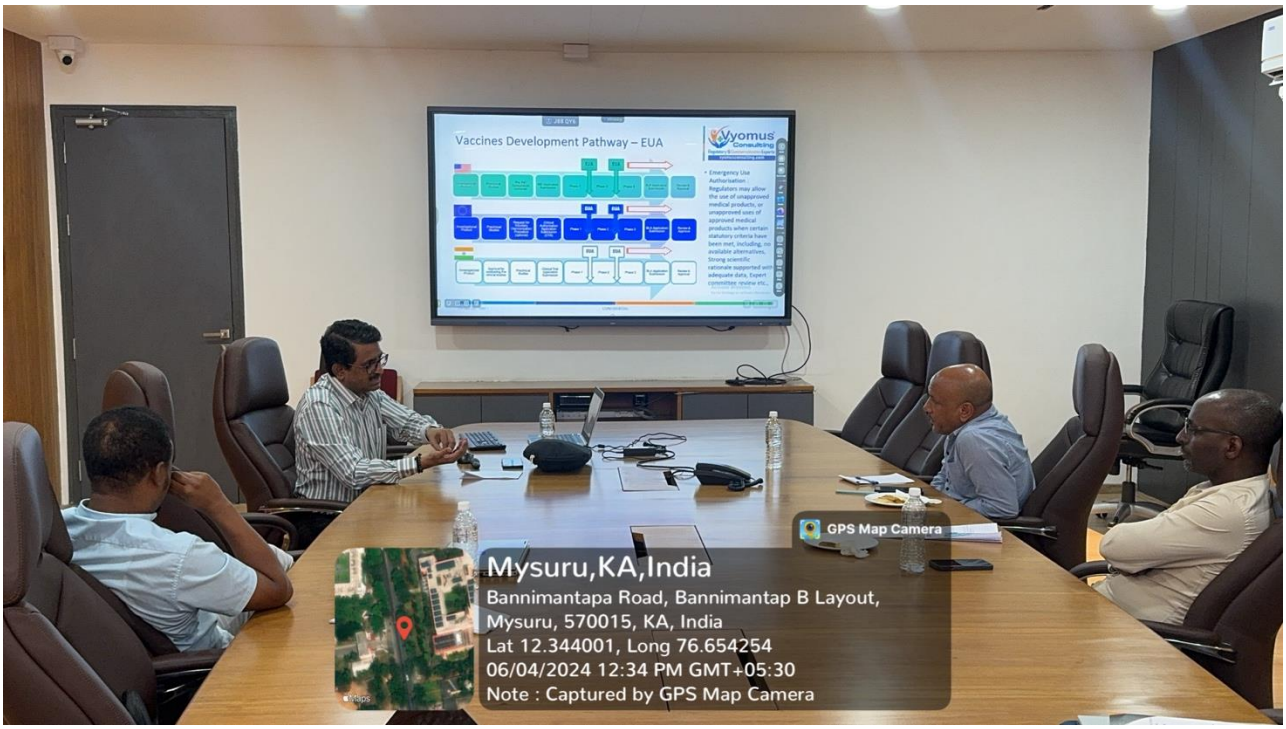
The session concluded with an interactive Q&A segment where participants had the opportunity to discuss specific challenges and scenarios related to their operations. Mrs. Rajani provided insights and practical solutions to address these issues.

Mrs. A. Rajani delivers an insightful talk on cGMP issues in Upstream Processing.

Day-2
Morning session – 2

On June 4th, 2024, the second half morning session, led by Dr. C Omprakash, focused on the regulatory expectations for vaccine batches during Phase 1, 2, and 3 clinical trials. Dr. Omprakash provided an in-depth analysis of the requirements and best practices to ensure compliance with regulatory standards throughout the clinical trial phases. Dr. Omprakash shared several case studies highlighting the successful navigation of regulatory requirements in different clinical phases.

Dr. Omprakash's session provided a comprehensive overview of the regulatory expectations for vaccine batches across different clinical trial phases. Attendees left with a clearer understanding of the critical aspects of regulatory compliance and practical strategies to meet these requirements effectively.



Day-2
Afternoon session – 1

On June 4th, 2024, the first half of the afternoon session led by Mrs. A Rajani, focused on critical current Good Manufacturing Practice (cGMP) issues in downstream processing. This session was a continuation of the morning session, delving into the complexities and regulatory requirements of the downstream phase of biopharmaceutical production. The session concluded with a Q&A segment, where participants engaged with Mrs. Rajani on specific issues and challenges they face in downstream processing.

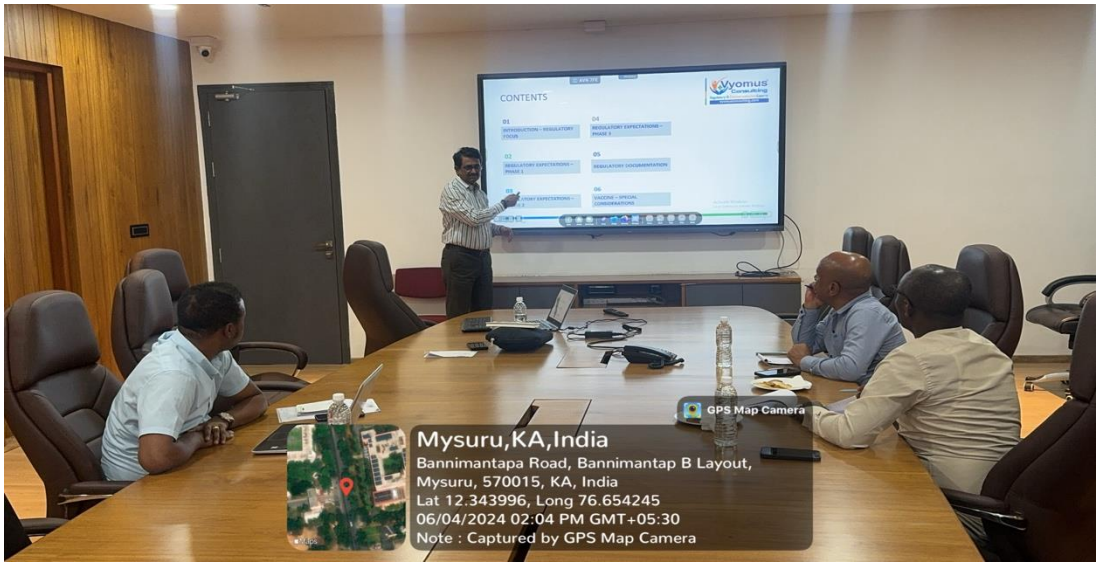
The insights provided by Mrs. Rajani equipped participants with practical knowledge to tackle common challenges in downstream processing effectively.

JSSAHER expresses profound gratitude to Mrs. A Rajani, for her invaluable training contributions to EFDA.

Day-2
Afternoon session – 2

The second half of the afternoon session on June 4th, 2024, led by Dr. C Omprakash, focused on the cGMP development and manufacturing of recombinant viral vaccines specifically for clinical trials. The session provided comprehensive insights into the regulatory, technical, and operational aspects of producing recombinant viral vaccines under cGMP conditions.

Dr. Omprakash's session on cGMP development and manufacturing of recombinant viral vaccines for clinical trials was highly informative. It offered attendees a deep understanding of the regulatory, technical, and practical aspects of vaccine production under cGMP conditions. Participants left with valuable knowledge and strategies to enhance their own manufacturing practices.

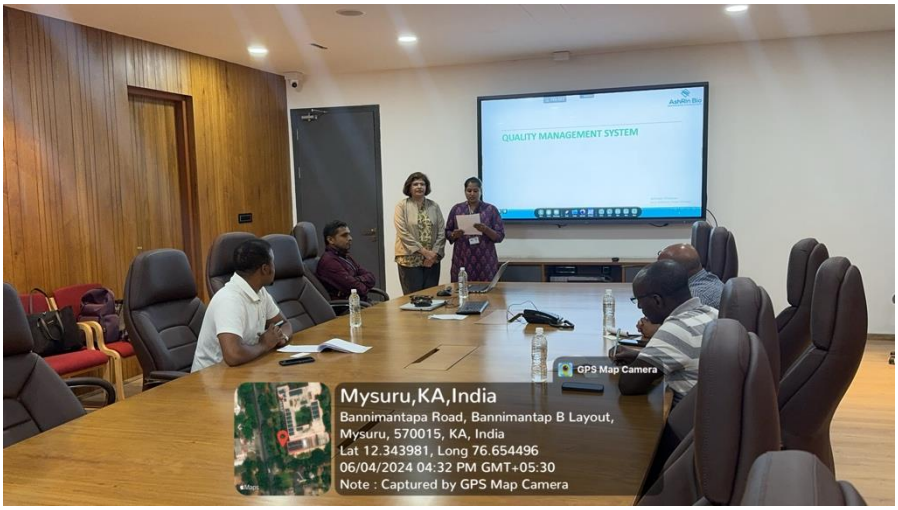


JSSAHER expresses profound gratitude to Dr. C. Omprakash for his invaluable training contributions to EFDA Drug Inspectors.

Day -3
Morning session – 1

The first half of the morning session on June 5th, 2024, was dedicated to an in-depth exploration of Quality Management Systems (QMS) in the biopharmaceutical industry. The session was led by Ms. Lakshmi Achuta, Principal Strategic Advisor at AshRin Bio LLP, who brought her extensive expertise and experience to the discussion. Ms. Achuta began the session by emphasizing the fundamental importance of Quality Management Systems in ensuring the safety, efficacy, and quality of biopharmaceutical products. She highlighted the core components of a robust QMS, which include:

1. Quality Planning
2. Quality Assurance
3. Quality Control
4. Quality Improvement.

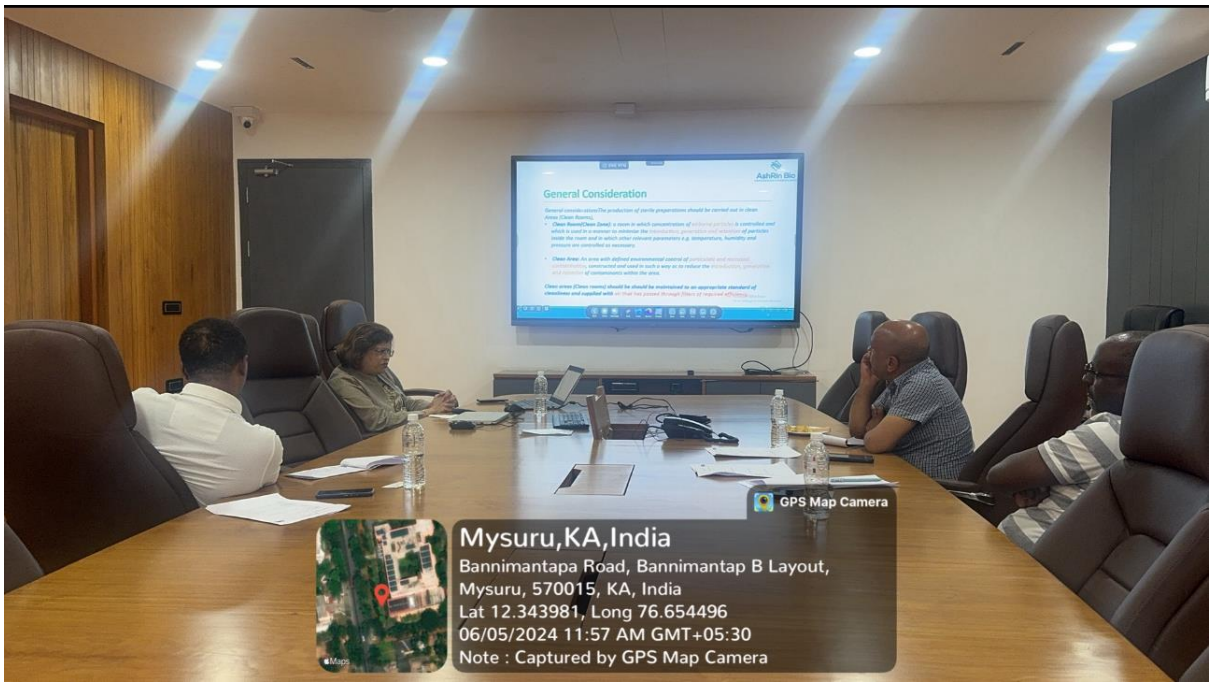


Ms. Lakshmi Achuta conducts a session on Quality Management Systems, highlighting essential elements for ensuring top-quality biopharmaceutical products.

Day -3
Morning session – 2

The second half of the morning session on June 5th, 2024, was presented by Ms. Lakshmi Achuta, focusing on the current Good Manufacturing Practice (cGMP) requirements for vaccines. The session covered regulatory guidelines, best practices, and critical elements necessary to ensure the safe and effective production of vaccines.

Attendees gained valuable insights and practical knowledge to enhance their manufacturing practices and ensure regulatory compliance.



Ms. Lakshmi Achuta discussed cGMP requirements for vaccines.

Day -3
Afternoon session – 1

The first half of the afternoon session on June 5th, 2024, led by Dr. Shivakumar M C, focused on the critical aspects of quality control and testing in the biotechnology and microbiology sectors. This session, titled "Quality Control and Testing – Part I," provided foundational insights into the principles, methodologies, and regulatory requirements essential for ensuring the quality and safety of biotechnological products.
Dr. Shivakumar provided expert insights and practical solutions, drawing from his extensive experience in microbiology and biotechnology. Participants left with valuable knowledge to enhance their QC processes and ensure compliance with regulatory standards.

The second half of the afternoon session on June 5th, 2024, continued with Dr. Shivakumar M C's presentation on Quality Control and Testing, delving into more advanced and detailed aspects of the subject. This session, titled "Quality Control and Testing – Part II," built upon the foundational principles discussed in Part I, focusing on more complex methodologies and practical applications in the biotechnology and microbiology fields.
The comprehensive coverage of topics equipped participants with the knowledge and tools needed to enhance their quality control practices and ensure regulatory compliance.

Dr. Shivakumar M C explores advanced QC techniques in biotechnology during the afternoon session on June 5th, 2024.

Day 03

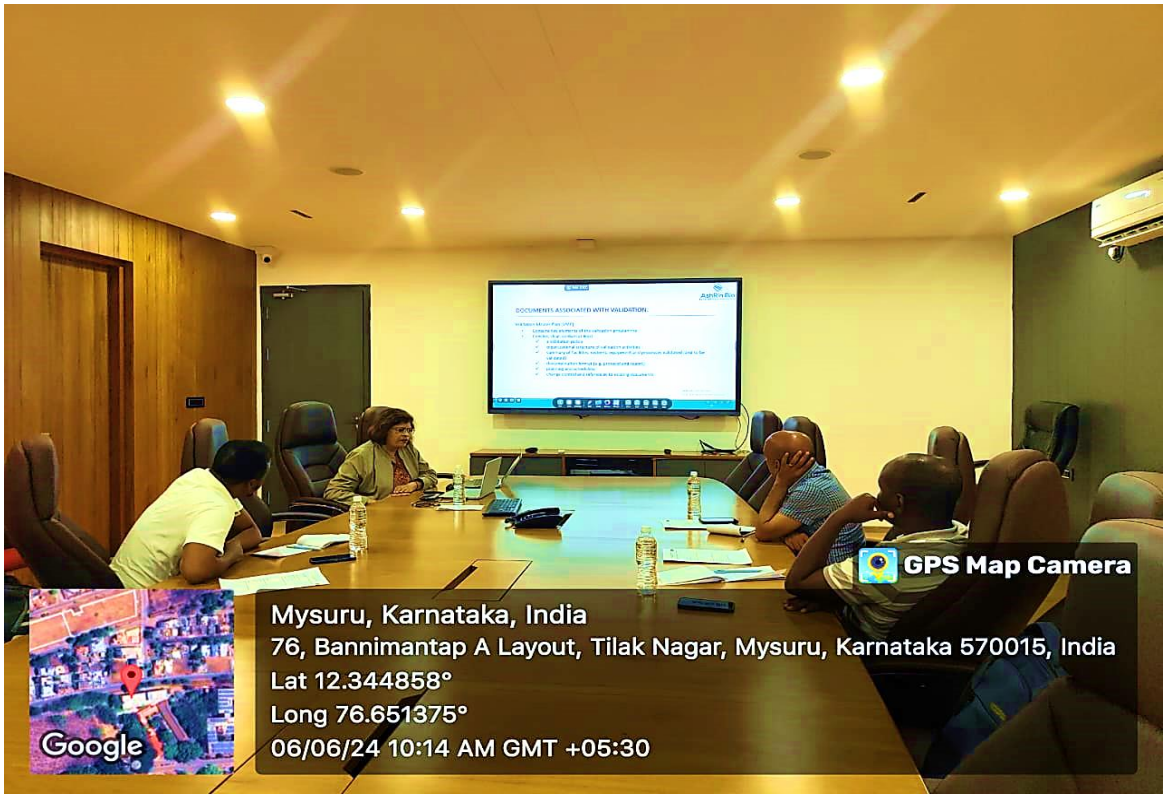
EFDA drug inspectors official meet with the Vice Chancellor of JSS AHER, Mysuru. From left Dr. Devanand, Assistant Dean (Academics), Dr. Vishal Kumar Gupta, Dean (Academics), Dr. Surinder Singh, Vice Chancellor, JSS AHER Mysuru, Mr. Dejene Dibaba Daba (EFDA drug inspector), Mr. Mola Teferi Mantegaftot (Drug inspector) and Mr. Engida Samuel Marie (EFDA Drug inspector).

Day-04

Morning session – 1

On June 6th, 2024, the First half of the morning session led by Ms. Lakshmi Achuta discussed Current trends in qualification and validation and, the importance of pharmaceutical manufacturing to ensure that equipment, systems, and processes consistently meet quality standards. Qualification involves design, installation, operational, and performance checks to ensure proper setup and functionality. Validation confirms that processes and methods produce reliable, compliant results, covering areas such as process, cleaning, and analytical methods. These practices ensure product quality, safety, and regulatory compliance, reducing risks and enhancing efficiency in manufacturing.

The session concluded by emphasizing the importance of qualification and validation processes to ensure reliable, compliant, and consistent pharmaceutical manufacturing, minimizing risks, enhancing efficiency, and maintaining regulatory standards.

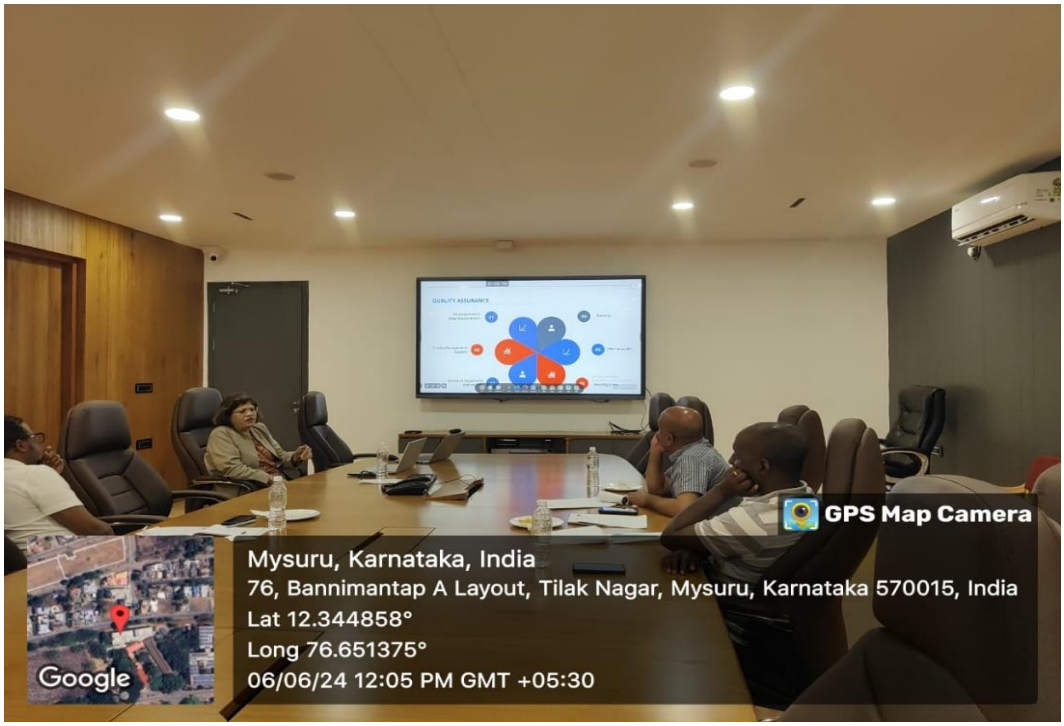


Ms. Lakshmi Achuta delves into advanced qualification, validation, and the significance of pharmaceutical manufacturing.

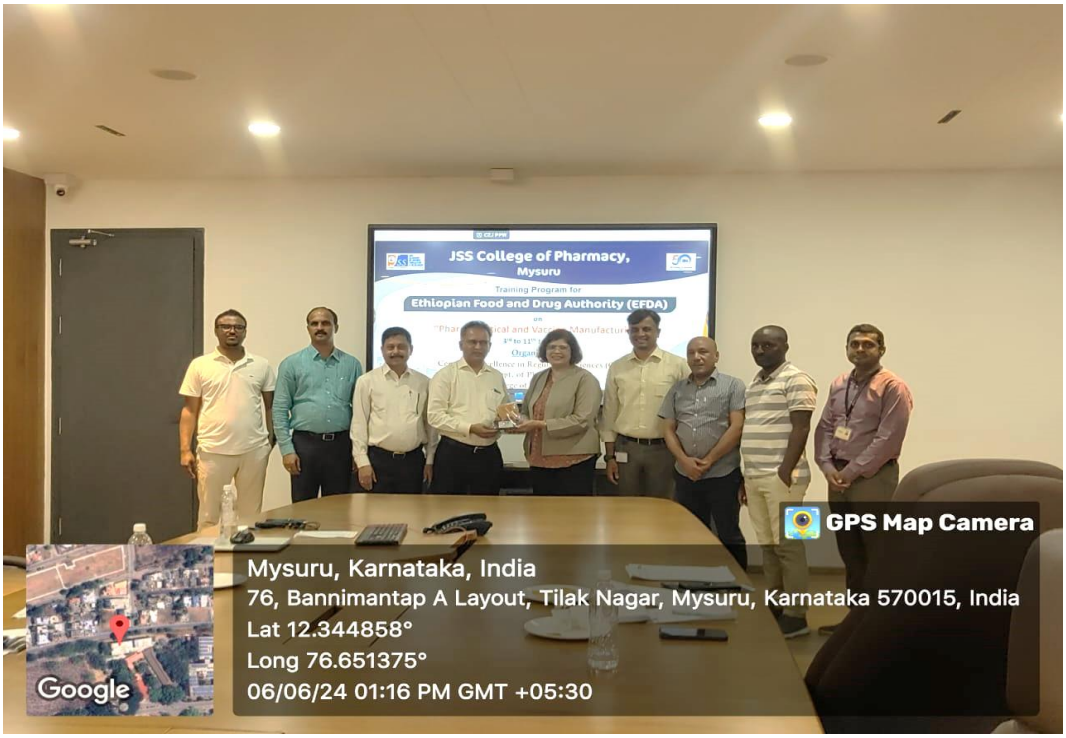
Day -04
Morning session – 2

The second half of the morning session on June 6th, 2024, was presented by Ms. Lakshmi Achuta. She focused on the critical role of Quality Assurance (QA) in pharmaceutical manufacturing, emphasizing its importance in ensuring product safety, efficacy, and regulatory compliance. Key components discussed included the establishment of a Quality Management System (QMS), adherence to Good Manufacturing Practices (GMP), meticulous documentation, ongoing staff training, and a commitment to continuous improvement. Effective QA practices are essential for maintaining high-quality standards, preventing production errors and costly recalls, and building consumer trust.

The session concluded by highlighting its pivotal role in the pharmaceutical industry. Effective QA practices ensure that products are safe, effective, and of high quality, which is essential for regulatory compliance and consumer trust. Regular training and continuous improvement are key to maintaining robust QA systems.



Ms. Lakshmi Achuta delves into the pivotal role of Quality Assurance in pharmaceutical manufacturing.



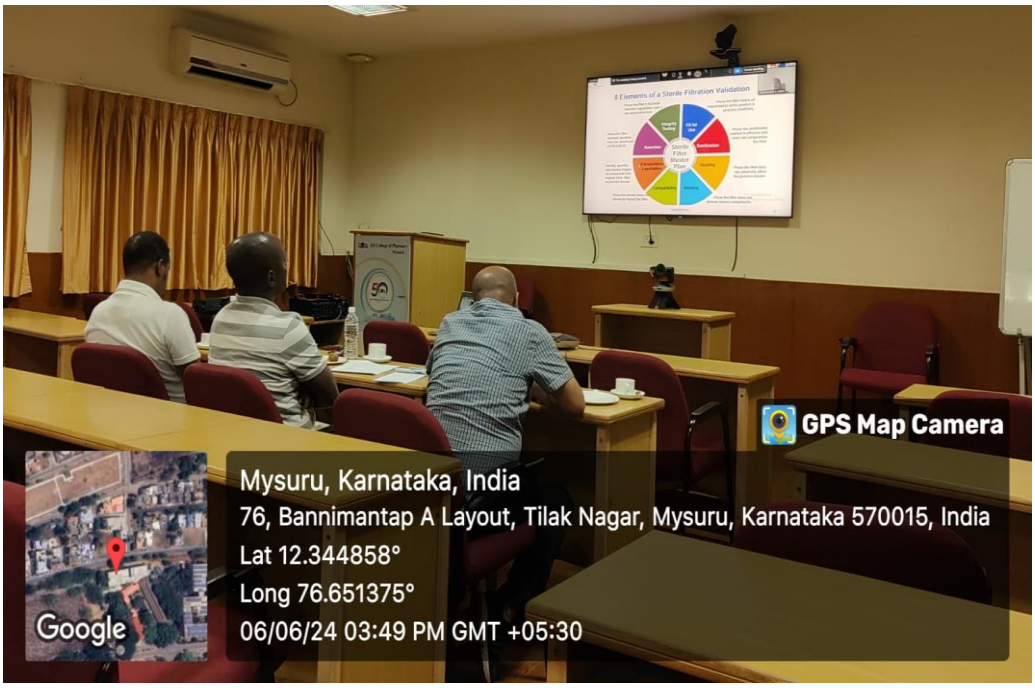
JSSAHER expresses deep appreciation to Ms. Lakshmi Achuta for her invaluable training support to EFDA Drug Inspectors.

Day 4
Afternoon session

The first half of the afternoon session on June 5th, 2024, continued with Mr. Viresh Kumar H Sheth, presenting on Analytical Equipment for vaccine production into the important role of analytical equipment in vaccine production. He emphasized the importance of these tools in ensuring vaccine quality and safety, highlighting various analytical tools and advancements in real-time monitoring technologies that have improved vaccine production efficiency and reliability.

In the second half of the afternoon section, Mr. Viresh focused on the isolator filling line, which is important for the aseptic filling process of vaccines. He explained how isolators create a sterile environment, preventing contamination during filling and packaging. This technology is vital for maintaining the integrity of sensitive biological products. The workflow of an isolator filling line and the integration of automation, emphasize the importance of analytical equipment and isolator technology in vaccine production.

This section concluded the crucial roles of advanced analytical equipment and isolator filling lines in ensuring the quality and sterility of vaccine production and the importance of technological innovation in meeting regulatory standards and safeguarding public health.



Mr. Viresh Kumar H Sheth discussed Analytical Equipment and Isolator Filling Line for Vaccine Production.

Day 05

Visit to the Institute of Animal Health & Veterinary Biologicals (IAH-VB), Bengaluru (June 2024, Friday)

On June 7th, 2024, the EFDA Drug Inspectors visited the Institute of Animal Health & Veterinary Biologicals in Bengaluru. The visit provided them with an insightful overview of the institute's cutting-edge research in animal health and vaccine development. They toured advanced laboratories, witnessed live demonstrations of diagnostic techniques, and engaged in discussions with leading researchers about current challenges and innovations in veterinary science. The experience highlighted the institute's important role in improving animal health and disease management.

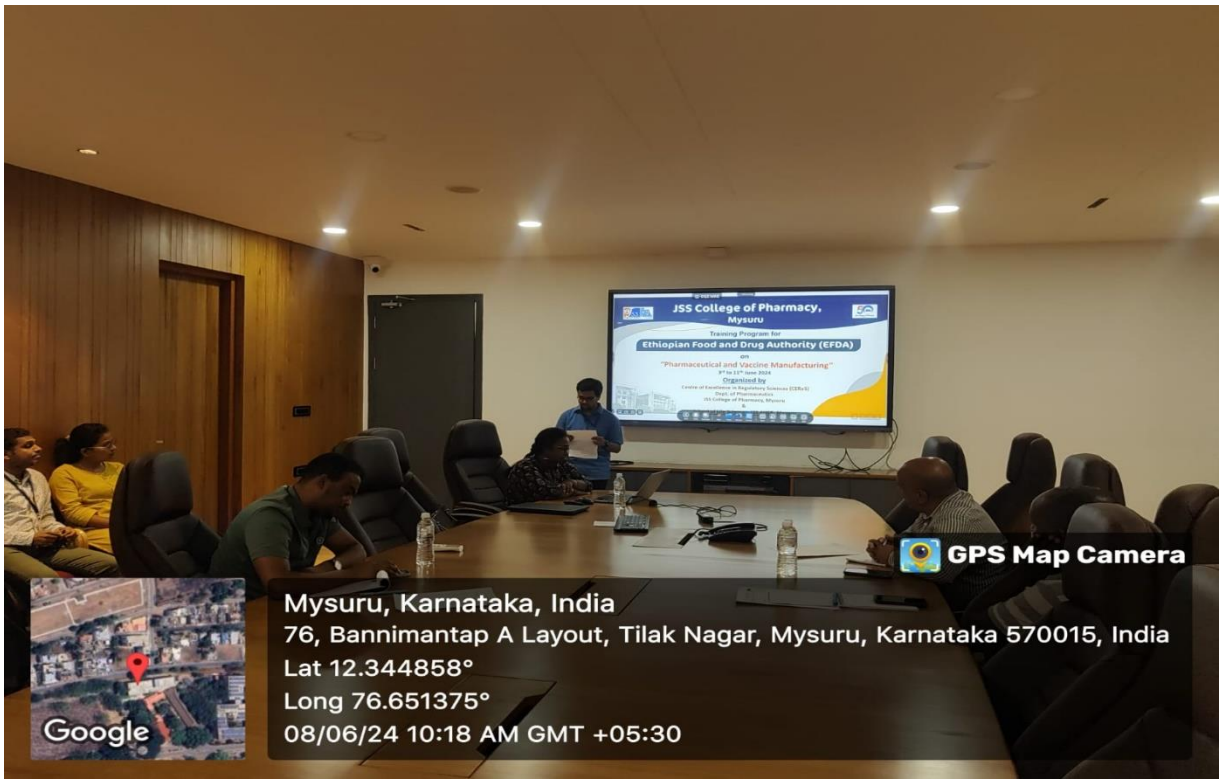
The EFDA Drug Inspectors visited the Institute of Animal Health & Veterinary Biologicals, Bengaluru on June 7th, 2024.

EFDA Drug Inspectors Insightful Visit to the Institute of Animal Health & Veterinary Biologicals, Bengaluru- A Glimpse into the Future of Animal Health Research and Vaccine Development.

Day 06
Morning session – 1

In the first half of the morning session on June 5th, 2024, Mrs. Lakshmi delivered an insightful presentation titled "Project Management of Vaccines – Part I." She emphasized the important aspects of managing vaccine development and distribution projects, highlighting the complexities involved. These included coordinating multidisciplinary teams, ensuring regulatory compliance, managing timelines, and overseeing the supply chain logistics. Mrs. Lakshmi stressed the importance of meticulous planning and risk management strategies to address potential challenges such as supply shortages, manufacturing bottlenecks, and distribution hurdles. Her presentation also covered the role of stakeholder engagement and effective communication in maintaining transparency and fostering collaboration among various entities involved in the vaccine lifecycle.

Mrs. Lakshmi concluded the session by emphasizing the critical need for meticulous planning and risk management in vaccine projects. She highlighted the importance of effective stakeholder engagement and communication in overcoming challenges throughout the vaccine development and distribution process.



Mrs. Lakshmi presents her insightful talk on the Project Management of Vaccines.

Day 06
Morning session – 2

The second half of the morning session also continued with Mrs. Lakshmi. In her session on "Project Management of Vaccines – Part II," Mrs. Lakshmi delved deeper into the post-development phase, focusing on the challenges and strategies for large-scale vaccine distribution and administration. She discussed the importance of maintaining cold chain logistics to ensure vaccine efficacy, the role of data management in tracking distribution and immunization coverage, and the necessity of adapting to real-time challenges such as public resistance and logistical disruptions. Mrs. Lakshmi also emphasized the significance of continuous monitoring and feedback mechanisms to improve future vaccination campaigns, highlighting case studies where adaptive management led to successful outcomes. Her insights reinforced the need for flexibility and proactive problem-solving in the dynamic field of vaccine project management.

Mrs. Lakshmi concluded by emphasizing the critical role of continuous monitoring and adaptive management in overcoming real-time challenges in vaccine distribution. Her insights emphasize the importance of flexibility and proactive problem-solving for successful vaccination campaigns.

JSSAHER expresses appreciation to Mrs. Lakshmi, for her invaluable training contributions to EFDA Drug Inspectors.

Day 07: Sunday

Day 08
Visit to the Pasteur Institute of India, Coonoor

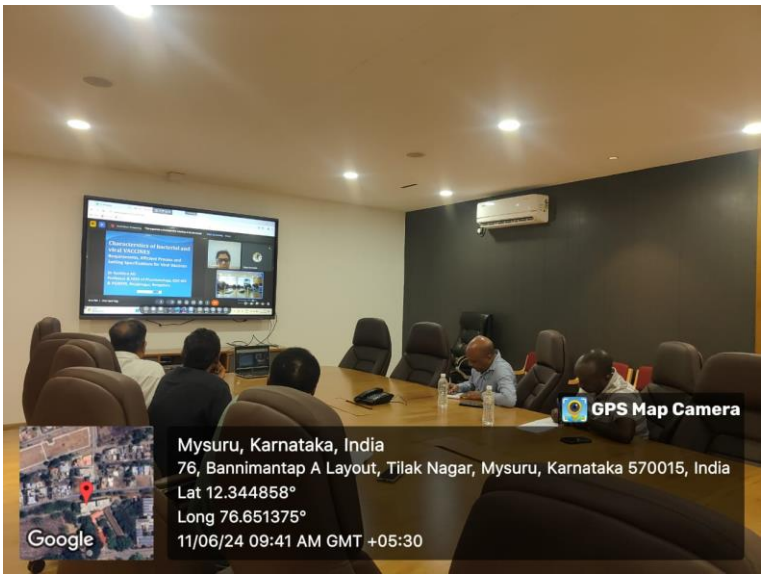
On June 10th, 2024, the EFDA team, visited the Pasteur Institute of India in Coonoor, marking a significant step in their mission to learn and collaborate with Indian pharmaceutical institutions. The EFDA team was warmly welcomed and given an insightful tour of the institute's state-of-the-art research labs, advanced production units, and meticulous quality control departments, with a particular emphasis on the impressive vaccine production process. Engaging in discussions with senior scientists and management provided the trainees with valuable knowledge about ongoing projects and potential future collaborations. The EFDA Drug Inspectors conducted a compliance review, focusing on Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), and were impressed by the institute's adherence to international standards. The visit was highly educational and inspiring, highlighting the institute's commitment to public health and cutting-edge research. The trainees left with a deeper understanding of vaccine production and regulatory compliance, and excited about future collaborative opportunities.

EFDA Drug Inspectors Engaged in Enlightening Discussions at the Pasteur Institute of India, Coonoor – A Day of Learning and Collaboration in Vaccine Research and Production.

Day 09

Morning session

On June 11th, 2024 the morning session was led by Dr. Suchitra AD, she delivered a comprehensive presentation on "Requirements, Efficient Processes, and Setting Specifications for Viral Vaccines," stressing the paramount importance of adhering to stringent regulatory standards to guarantee vaccine safety and efficacy. She emphasized optimizing manufacturing processes through advanced technologies like single-use systems and continuous manufacturing to enhance efficiency and reduce costs, alongside the critical need for process validation and quality control measures. Moreover, Dr. Suchitra emphasized the significance of setting precise specifications for viral vaccines, including defining critical quality attributes (CQAs) and continually monitoring and adjusting these specifications based on real-world data and evolving scientific understanding, ultimately providing a holistic perspective on the essential elements of vaccine development and manufacturing.



Dr. Suchitra AD delivers a comprehensive presentation on Requirements, Efficient Processes, and Setting Specifications for Viral Vaccines.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University-Accredited "A+" Grade by NAAC)

JSS College of Pharmacy, Mysuru

(ISO 9001: 2015 Certified)

Certificate

This is to Certify that

Mr. Dibaba Dejene Daba

had undergone a Training program on

"Pharmaceutical and Vaccine Manufacturing"

from 3rd to 11th June 2024

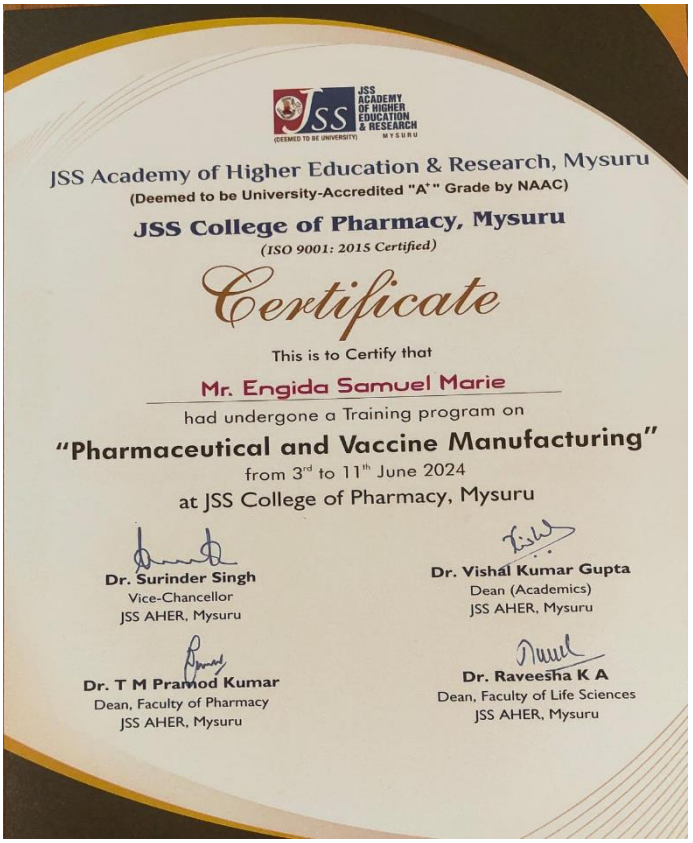
at JSS College of Pharmacy, Mysuru

Dr. Surinder Singh
Vice-Chancellor
JSS AHER, Mysuru

Dr. Vishal Kumar Gupta
Dean (Academics)
JSS AHER, Mysuru

Dr. T M Pramod Kumar
Dean, Faculty of Pharmacy
JSS AHER, Mysuru

Dr. Raveesha K A
Dean, Faculty of Life Sciences
JSS AHER, Mysuru



JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University-Accredited "A+" Grade by NAAC)

JSS College of Pharmacy, Mysuru

(ISO 9001: 2015 Certified)

Certificate

This is to Certify that

Mr. Engida Samuel Marie

had undergone a Training program on

"Pharmaceutical and Vaccine Manufacturing"

from 3rd to 11th June 2024

at JSS College of Pharmacy, Mysuru

Dr. Surinder Singh
Vice-Chancellor
JSS AHER, Mysuru

Dr. Vishal Kumar Gupta
Dean (Academics)
JSS AHER, Mysuru

Dr. T M Pramod Kumar
Dean, Faculty of Pharmacy
JSS AHER, Mysuru

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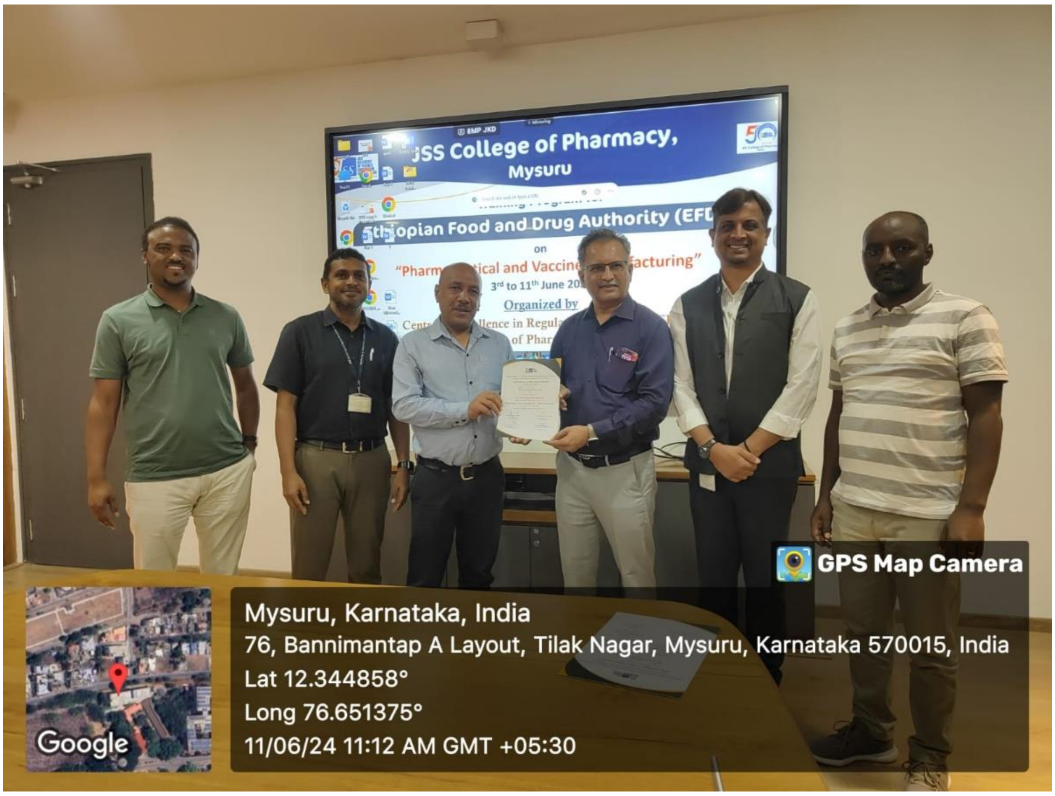
Certificates issued to the EFDA drug inspectors by JSSAHER, Mysuru for the completion of the training program on "Pharmaceutical and Vaccine Manufacturing".



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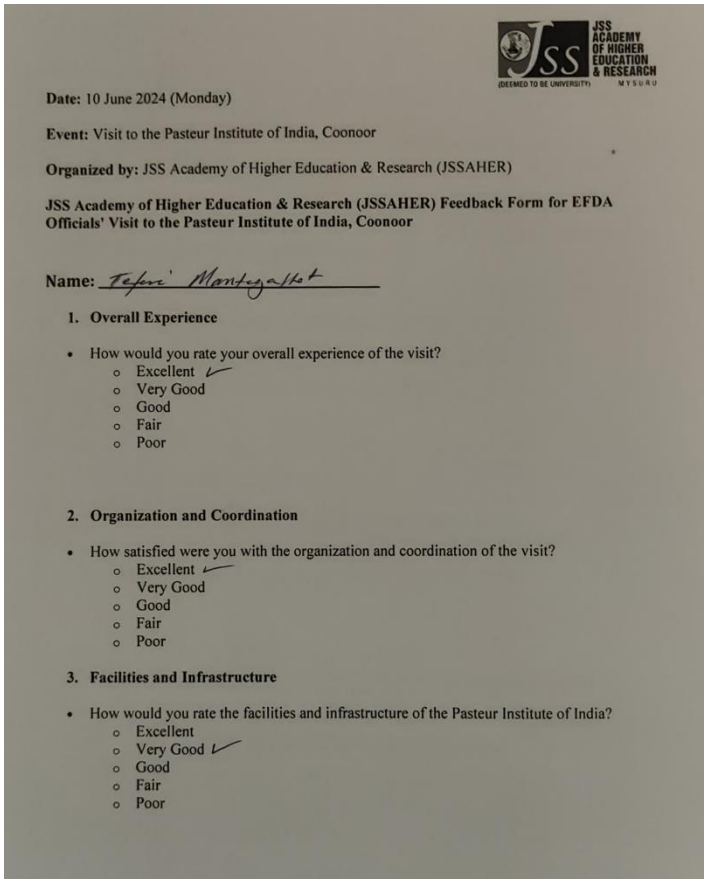


Date: 10 June 2024 (Monday)

Event: Visit to the Pasteur Institute of India, Coonoor

Organized by: JSS Academy of Higher Education & Research (JSSAHER)

JSS Academy of Higher Education & Research (JSSAHER) Feedback Form for EFDA Officials' Visit to the Pasteur Institute of India, Coonoor

Name: Tefere Montegalbot

1. **Overall Experience**

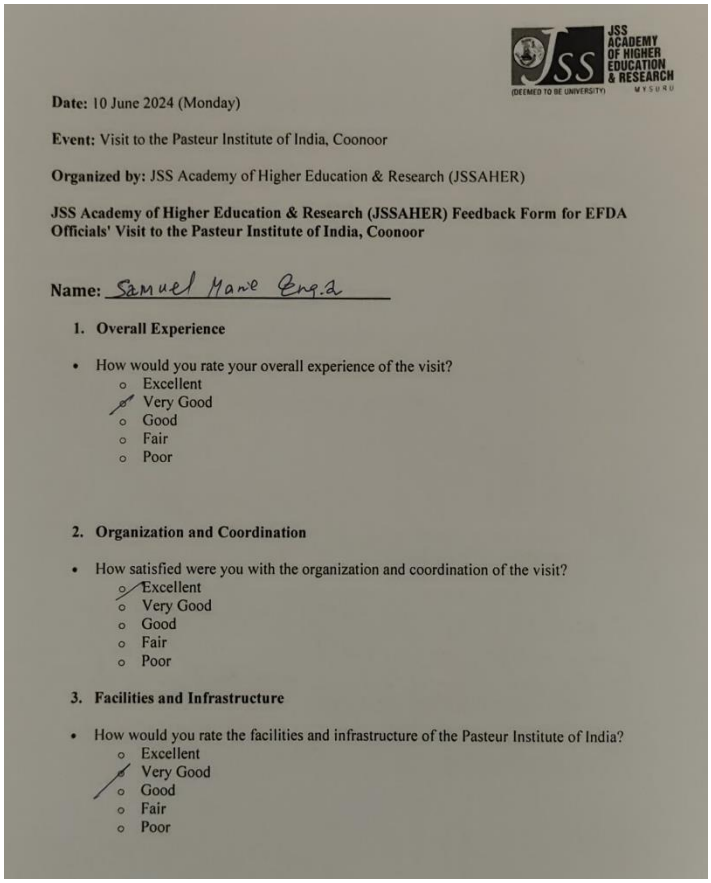
- How would you rate your overall experience of the visit?
  - Excellent ✓
  - Very Good
  - Good
  - Fair
  - Poor

2. **Organization and Coordination**

- How satisfied were you with the organization and coordination of the visit?
  - Excellent ✓
  - Very Good
  - Good
  - Fair
  - Poor

3. **Facilities and Infrastructure**

- How would you rate the facilities and infrastructure of the Pasteur Institute of India?
  - Excellent
  - Very Good ✓
  - Good
  - Fair
  - Poor



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Organized by: JSS Academy of Higher Education & Research (JSSAHER)

JSS Academy of Higher Education & Research (JSSAHER) Feedback Form for EFDA Officials' Visit to the Pasteur Institute of India, Coonoor

Name: Samuel Mare Eng.a

1. **Overall Experience**

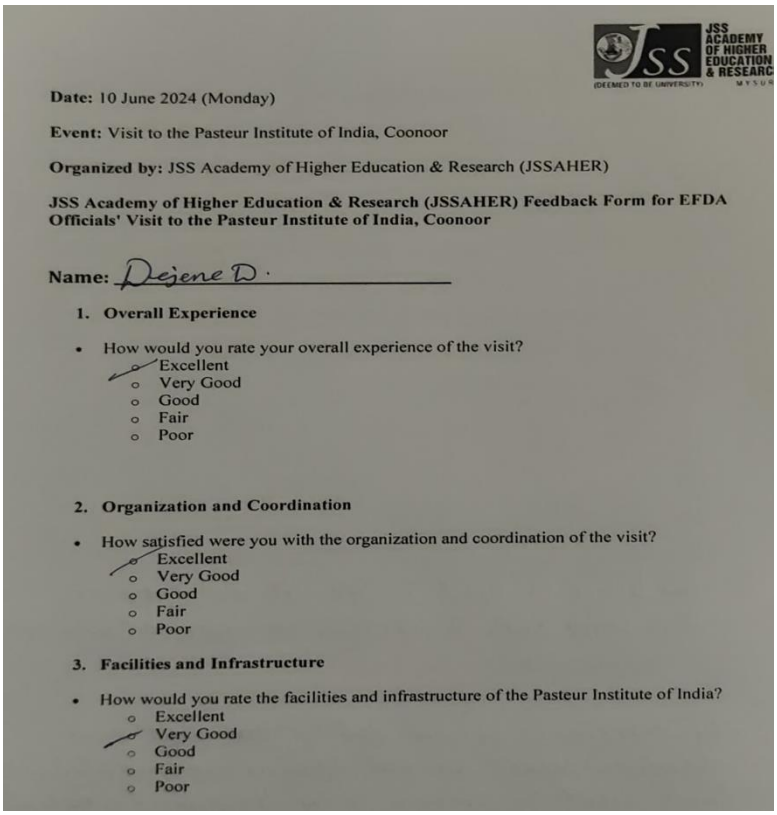
- How would you rate your overall experience of the visit?
  - Excellent
  - Very Good ✓
  - Good
  - Fair
  - Poor

2. **Organization and Coordination**

- How satisfied were you with the organization and coordination of the visit?
  - Excellent ✓
  - Very Good
  - Good
  - Fair
  - Poor

3. **Facilities and Infrastructure**

- How would you rate the facilities and infrastructure of the Pasteur Institute of India?
  - Excellent
  - Very Good ✓
  - Good
  - Fair
  - Poor



Date: 10 June 2024 (Monday)

Event: Visit to the Pasteur Institute of India, Coonoor

Organized by: JSS Academy of Higher Education & Research (JSSAHER)

JSS Academy of Higher Education & Research (JSSAHER) Feedback Form for EFDA Officials' Visit to the Pasteur Institute of India, Coonoor

Name: Dejene D.

1. **Overall Experience**

- How would you rate your overall experience of the visit?
  - Excellent ✓
  - Very Good
  - Good
  - Fair
  - Poor

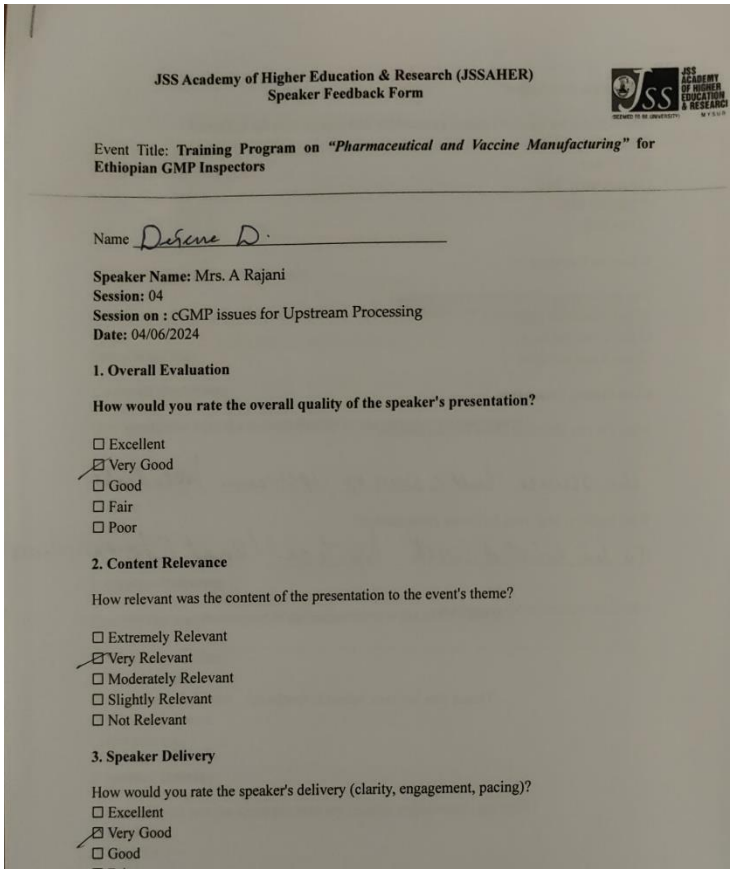
2. **Organization and Coordination**

- How satisfied were you with the organization and coordination of the visit?
  - Excellent ✓
  - Very Good
  - Good
  - Fair
  - Poor

3. **Facilities and Infrastructure**

- How would you rate the facilities and infrastructure of the Pasteur Institute of India?
  - Excellent
  - Very Good ✓
  - Good
  - Fair
  - Poor

Feedback given by the EFDA Drug Inspectors about their visit to the Pasteur Institute of India, Coonoor.



JSS Academy of Higher Education & Research (JSSAHER)
Speaker Feedback Form

Event Title: **Training Program on *"Pharmaceutical and Vaccine Manufacturing"* for Ethiopian GMP Inspectors**

Name Dereme D.

Speaker Name: Mrs. A Rajani
Session: 04
Session on : cGMP issues for Upstream Processing
Date: 04/06/2024

1. Overall Evaluation

How would you rate the overall quality of the speaker's presentation?

☐ Excellent
☑ Very Good
☐ Good
☐ Fair
☐ Poor

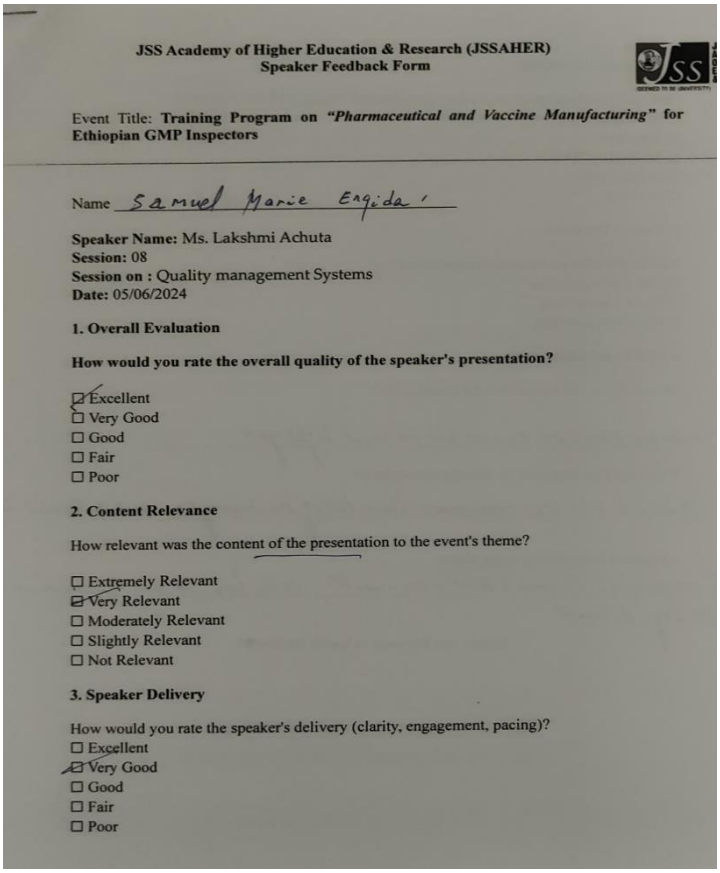
2. Content Relevance

How relevant was the content of the presentation to the event's theme?

☐ Extremely Relevant
☑ Very Relevant
☐ Moderately Relevant
☐ Slightly Relevant
☐ Not Relevant

3. Speaker Delivery

How would you rate the speaker's delivery (clarity, engagement, pacing)?
☐ Excellent
☑ Very Good
☐ Good



JSS Academy of Higher Education & Research (JSSAHER)
Speaker Feedback Form

Event Title: **Training Program on *"Pharmaceutical and Vaccine Manufacturing"* for Ethiopian GMP Inspectors**

Name Samuel Marie Engida

Speaker Name: Ms. Lakshmi Achuta
Session: 08
Session on : Quality management Systems
Date: 05/06/2024

1. Overall Evaluation

How would you rate the overall quality of the speaker's presentation?

☑ Excellent
☐ Very Good
☐ Good
☐ Fair
☐ Poor

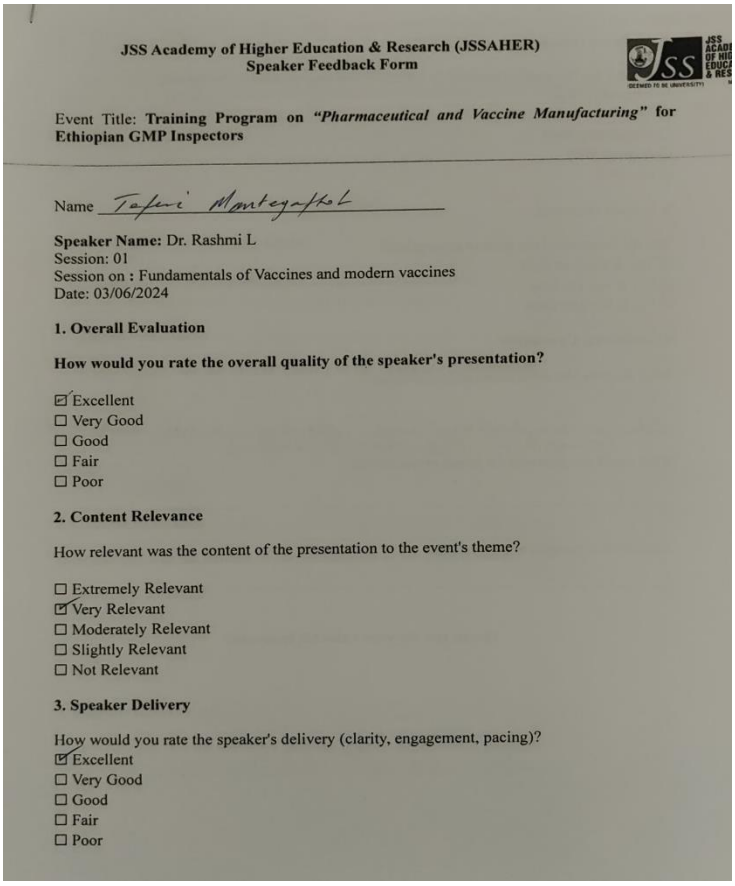
2. Content Relevance

How relevant was the content of the presentation to the event's theme?

☐ Extremely Relevant
☑ Very Relevant
☐ Moderately Relevant
☐ Slightly Relevant
☐ Not Relevant

3. Speaker Delivery

How would you rate the speaker's delivery (clarity, engagement, pacing)?
☐ Excellent
☑ Very Good
☐ Good
☐ Fair
☐ Poor



JSS Academy of Higher Education & Research (JSSAHER)
Speaker Feedback Form

Event Title: **Training Program on *"Pharmaceutical and Vaccine Manufacturing"* for Ethiopian GMP Inspectors**

Name Tafere Mantegaftot

Speaker Name: Dr. Rashmi L
Session: 01
Session on **:** Fundamentals of Vaccines and modern vaccines
Date: 03/06/2024

1. Overall Evaluation

How would you rate the overall quality of the speaker's presentation?

☑ Excellent
☐ Very Good
☐ Good
☐ Fair
☐ Poor

2. Content Relevance

How relevant was the content of the presentation to the event's theme?

☐ Extremely Relevant
☑ Very Relevant
☐ Moderately Relevant
☐ Slightly Relevant
☐ Not Relevant

3. Speaker Delivery

How would you rate the speaker's delivery (clarity, engagement, pacing)?
☑ Excellent
☐ Very Good
☐ Good
☐ Fair
☐ Poor

Feedback given by the EFDA Drug Inspectors about the training program on "Pharmaceutical and Vaccine Manufacturing".