JSS Academy of Higher Education & Research

JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Mysuru-570015

Date: 3rd March 2023

REPORT ON WEBINAR

"Medical Device Rules 2017 and Software as a Medical Device"

Session 1

Speaker: Mr. Uday Kishore, Assistant Drug Controller, Karnataka
Title: Medical Device rules, 2017
Date: 3rd March, 2023
Venue: Online Webinar
Students for the program: 1st and 2nd M. Pharm students of Pharmaceutical Regulatory Affairs, Pharmaceutical Quality Assurance, Pharmaceutics and Industrial Pharmacy and PhD Scholars.

Dr. M.P Venkatesh, Associate Professor, Regulatory Affairs Group, Department of Pharmaceutics introduced about the speaker to the students and delivered opening remarks. The session comprised Dr. Balamuralidhara V, Head of Department, Regulatory Affairs Group, Department of Pharmaceutics, Dr. T M Pramod Kumar, Principal, Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics. The webinar featured prominent speaker Mr. Uday Kishore, who delivered an informative talk on the title "Medical Device Rules of 2017".

The session commenced with Mr. Uday Kishore providing a concise overview of the Drug and Cosmetics Act in India. He proceeded to discuss the regulations pertaining to Medical Devices, the general regulatory landscape for medical devices, classification of medical devices, the potential for the medical device industry, and the mandatory regulatory requirements that must be met by medical device manufacturers seeking market authorization approval in India. Additionally, he briefly highlighted educational institutions that offer courses related to medical devices.

He highlighted the importance of various classes of Medical Devices notified by the Central Government and classified by the Central Licensing Authority (CLA) based on the classification rules specified in the First Schedule of the drafted rules. Based on the severity of risk associated with the medical device which includes Class A, Class B, Class C and Class D. He shared the licensing requirements for the different classes of medical device and also gave information about State licensing authority and Central licensing authority. He briefly illustrated the procedure for obtaining various licenses under different bodies (SLA/CLA) based on the risk factors.

He discussed the Salient Features of MDR, 2017 that is Risk based classification, Provisions of Notified Bodies, Quality Management System in line with ISO.

He also explained Medical Device Rules, 2017 Chapters includes different chapters form Chapter-I to Chapter – XII. He gave information about the 12 chapters and also described about 8 Schedules which includes Classification of MD, Fee, Registration and functions of Notified Bodies, Documents required for grant of manufacture and Import licence, Quality Management System, Post Approval - Major and Minor Changes, Requirements to conduct Clinical Investigation and Exemptions.

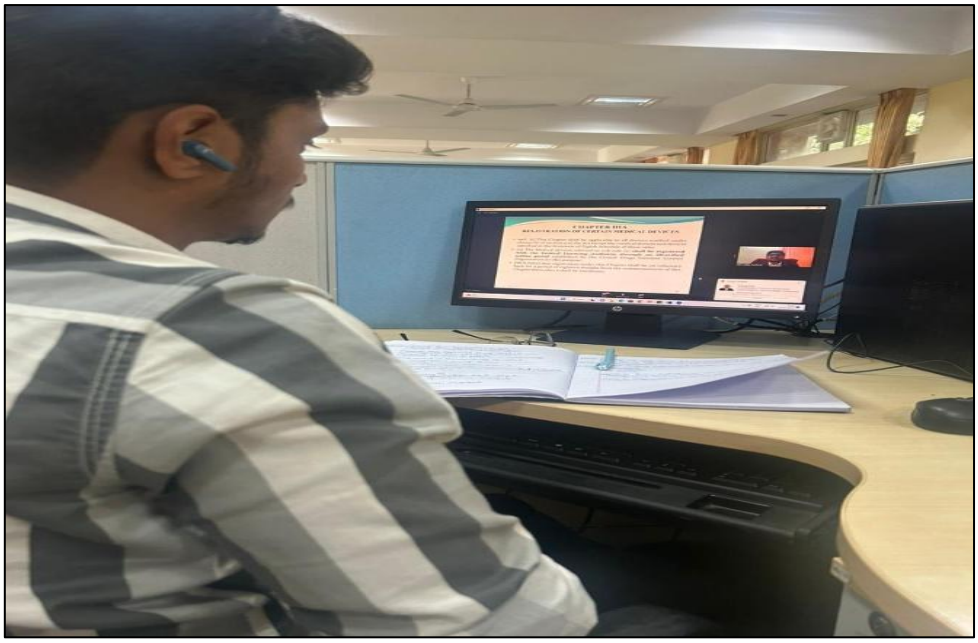
He discussed the medical device approval procedure and regulations in India. The approval process for medical devices in India typically involves the following steps:

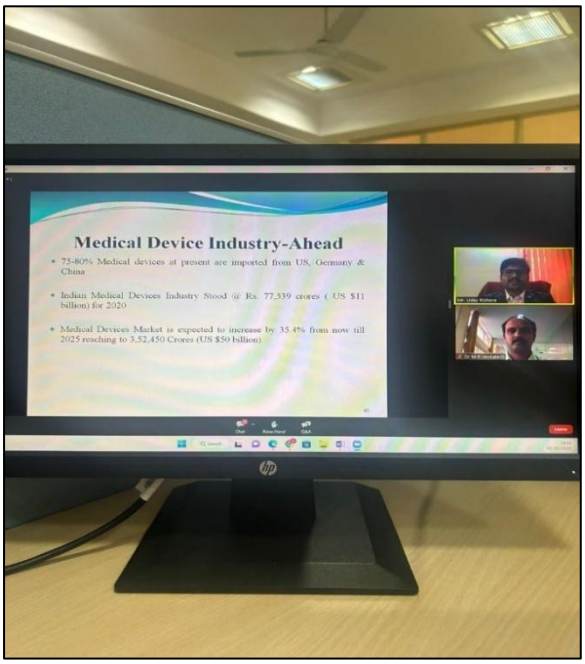
a. Device classification: Medical devices are classified into four classes based on their risk level, with Class A being low-risk devices and Class D being high-risk devices.
b. Registration: The device manufacturer must register the device with the CDSCO before it can be sold in India. The registration process involves submitting an application, along with the required documentation and fees.
c. Technical documentation: The device manufacturer must submit technical documentation, including a description of the device, its intended use, and its safety and performance data.
d. Testing: The CDSCO may require the device to undergo testing to verify its safety and performance.
e. Review of application: The CDSCO will review the application and make a decision on whether to approve the device.
f. Approval: If the device meets the regulatory requirements, it will be approved for use.

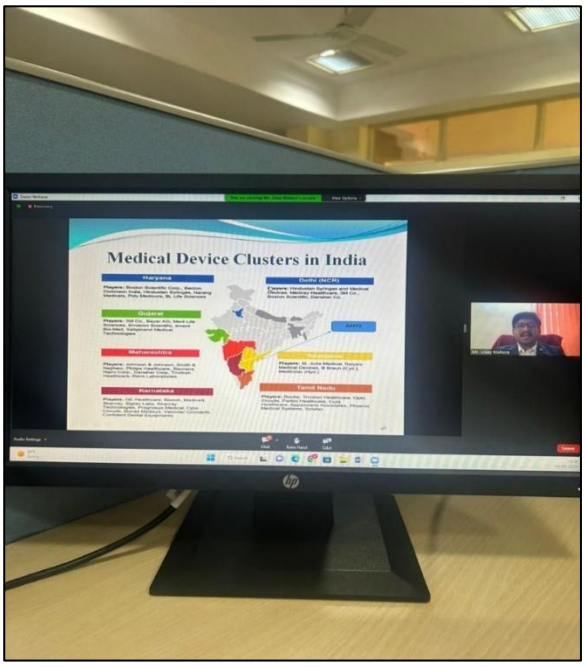
He briefly described about medical device clusters in India. These clusters are typically located in specific geographic regions and bring together a network of companies, research institutions, and government organizations to foster innovation and collaboration in the medical device industry.

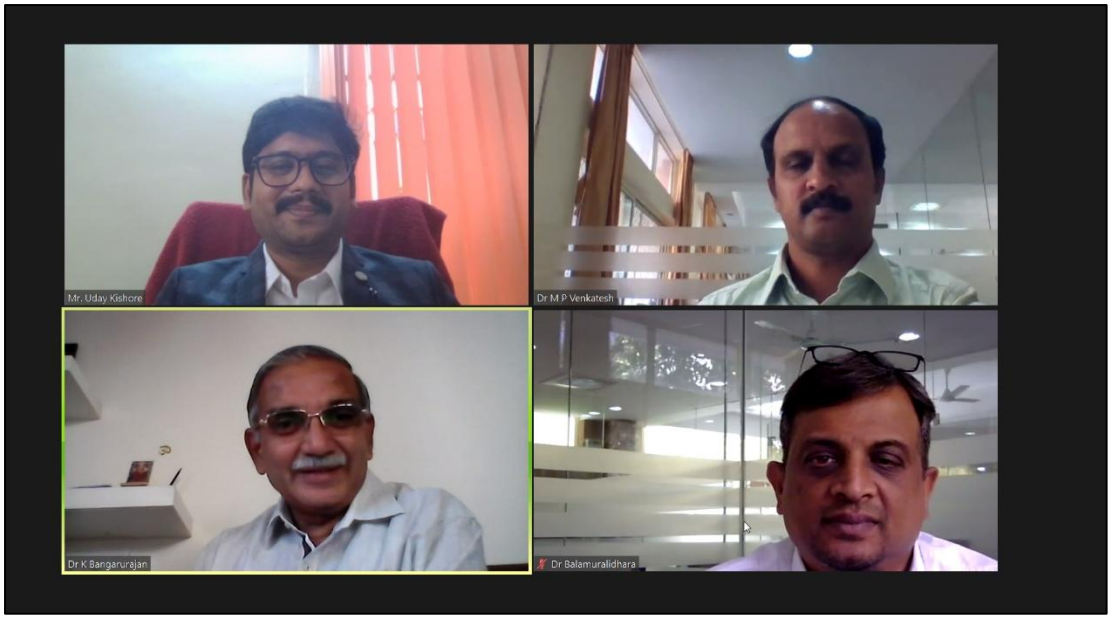
In addition to his lecture, Mr. Uday Kishore acknowledged the accomplishments of our institution's students in the field of Medical Devices. He proudly mentioned that our JSS students had secured awards in a Medical Device Hackathon, showcasing their talent and success in this area.

He concluded that the medical device regulation in India is an evolving field as the government continues to update and refine its regulatory framework to ensure patient safety and promote innovation in the medical device industry.




Medical Device Industry-Ahead
75-80% Medical devices at present are imported from US, Germany & China
Indian Medical Devices Industry Stood @ Rs. 77,539 crores (US $11 billion) for 2020
Medical Devices Market is expected to increase by 35.4% from now till 2025 reaching to 3,52,450 Crores (US $50 billion)


Medical Device Clusters in India
Haryana
Delhi (NCR)
Gujarat
Maharashtra
Karnataka
Tamil Nadu



Session 2

Speaker: Mr. Sandesh Prabhu, Skanray Technologies Ltd.

Title: Software development for a Medical Device

Date: 3rd March, 2023

Venue: Online Webinar

Students of program: 1st and 2nd M. Pharm students of Pharmaceutical Regulatory Affairs, Pharmaceutical Quality Assurance, Pharmaceutics and Industrial Pharmacy and PhD Scholars. Dr. M.P Venkatesh, Associate Professor, Department of Pharmaceutics introduced about the speaker to the students and delivered opening remarks. The session comprised Dr. Balamuralidhara V, Head of Department, Regulatory Affairs Group, Department of Pharmaceutics, Dr. T M Pramod Kumar, Principal, Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics. The webinar featured prominent speaker Mr. Sandesh Prabhu delivered a talk on the title "Software development for a Medical device". He discussed in brief about What is SW as a Medical Device and What is not, Software Development Lifecycle, the V model, Agile SW development and Cybersecurity.

He shared about the classification of software as a medical device includes SW as Part of Medical device, Software as a medical device, only software and no medical device and Accessory of a MD.

He explained about the uses of SaMD and gave few examples. He also mentioned Manufacturers of SaMD must follow established regulatory processes to ensure that their products meet these requirements and are cleared or approved for use in medical applications. He discussed SDLC helps software development teams to manage the complex process of building and maintaining software, and provides a framework for ensuring that software is high-quality, reliable, and meets user needs.

He discussed regarding the V model, which can be broken down into the following phases:

- Requirements gathering: In this phase, the requirements of the software are gathered and documented.
- System design: In this phase, the system architecture is designed and documented.
- Sub-system design: In this phase, the individual subsystems that make up the system are designed and documented.
- Implementation: In this phase, the code is written and the system is built.
- Unit testing: In this phase, individual units of code are tested to ensure that they function as expected.
- Integration testing: In this phase, the subsystems are integrated and tested to ensure that they work together as expected.
- System testing: In this phase, the entire system is tested to ensure that it meets the requirements.
- Acceptance testing: In this phase, the system is tested with real-world data to ensure that it meets the user's needs.
- Deployment: In this phase, the system is deployed and made available to the users.

Later he explained Agile software development relies heavily on collaboration and communication. The development team works closely with the product owner and other stakeholders to ensure that the software being developed meets the needs of the users.

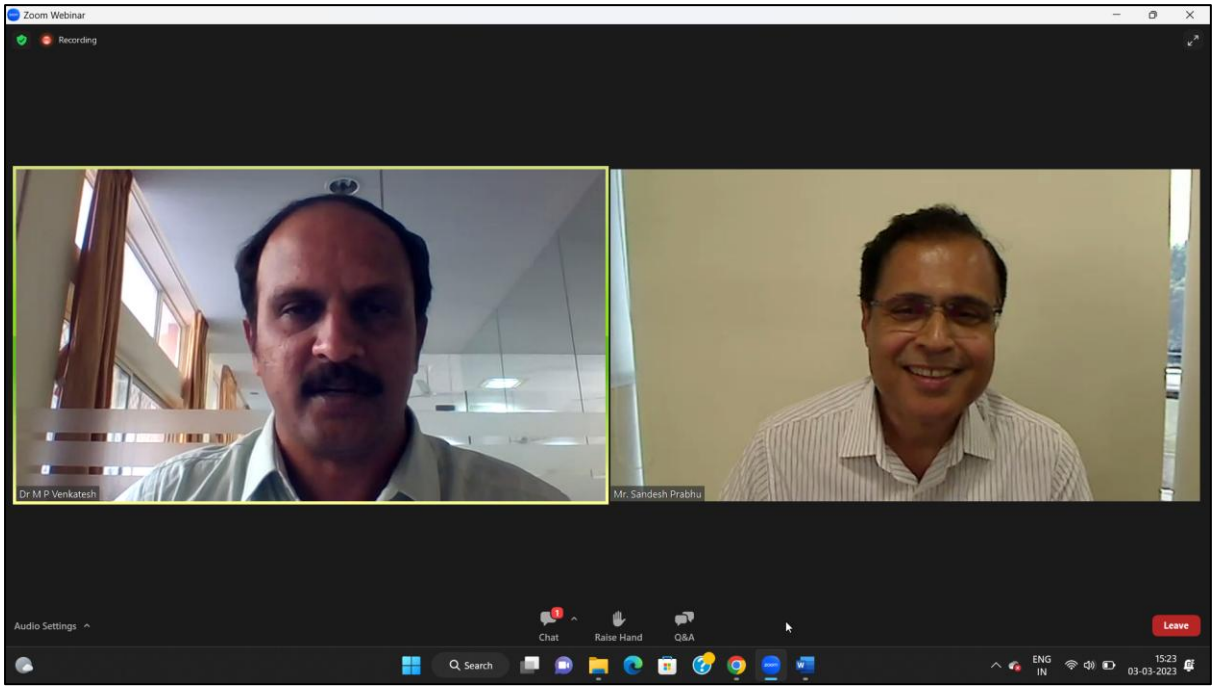
He explained the 12 principles of Agile software development are:

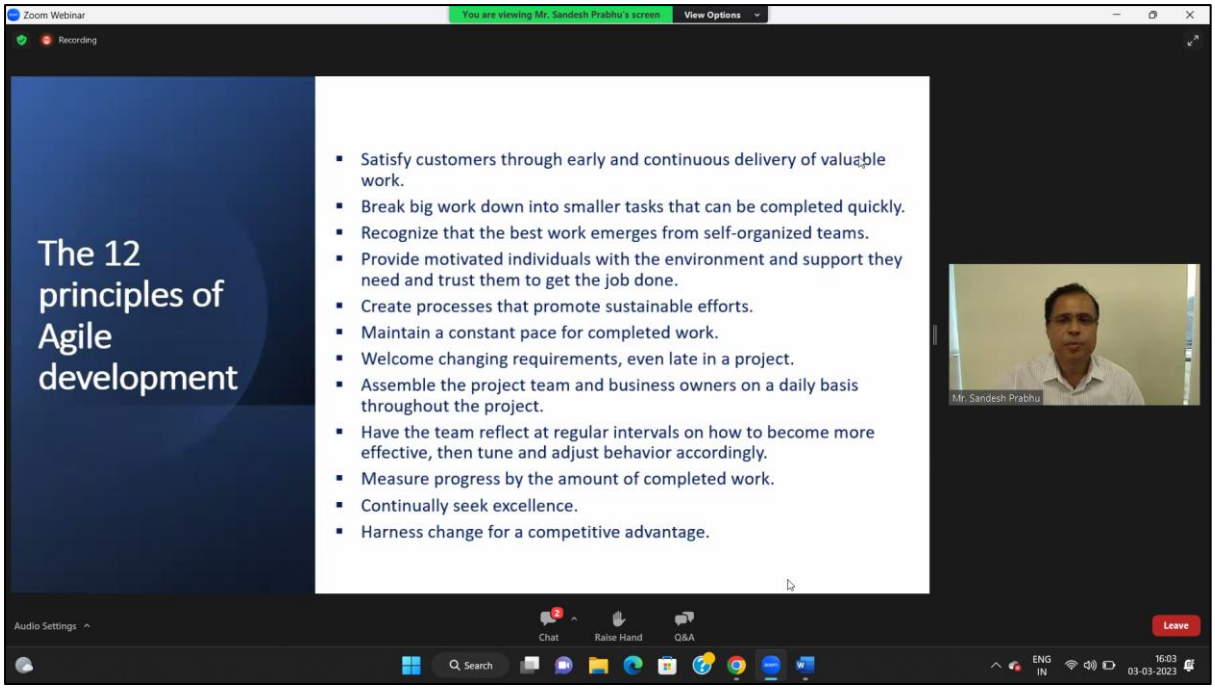
1. Customer satisfaction through early and continuous delivery of valuable software.
2. Embrace changing requirements, even in late development stages.
3. Deliver working software frequently, with a preference for shorter timescales.
4. Collaboration between developers and business people throughout the project.
5. Build projects around motivated individuals and give them the support and trust they need.
6. Use face-to-face communication as much as possible.
7. Working software is the primary measure of progress.
8. Maintain a sustainable pace of work for the development team.
9. Continuous attention to technical excellence and good design enhances agility.
10. Simplicity - the art of maximizing the amount of work not done - is essential.
11. Self-organizing teams encourage great architectures, requirements, and designs.
12. Reflect regularly on the team's effectiveness and adjust behaviour accordingly.

Also mentioned that the cybersecurity is a critical aspect of the design, development, and use of software-enabled medical devices. Manufacturers must take a comprehensive approach to cybersecurity, including implementing technical measures to secure the device and network, and implementing policies and procedures to ensure that the device is used securely by

healthcare professionals and patients. By doing so, manufacturers can help to ensure that their medical devices are safe and secure for use in healthcare settings.

Finally, he concluded software development for a medical device requires a careful and thorough approach that integrates the principles of software engineering with the regulatory requirements of the healthcare industry.




Zoom Webinar
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The 12 principles of Agile development
Satisfy customers through early and continuous delivery of valuable work.
Break big work down into smaller tasks that can be completed quickly.
Recognize that the best work emerges from self-organized teams.
Provide motivated individuals with the environment and support they need and trust them to get the job done.
Create processes that promote sustainable efforts.
Maintain a constant pace for completed work.
Welcome changing requirements, even late in a project.
Assemble the project team and business owners on a daily basis throughout the project.
Have the team reflect at regular intervals on how to become more effective, then tune and adjust behavior accordingly.
Measure progress by the amount of completed work.
Continually seek excellence.
Harness change for a competitive advantage.
Mr. Sandesh Prabhu
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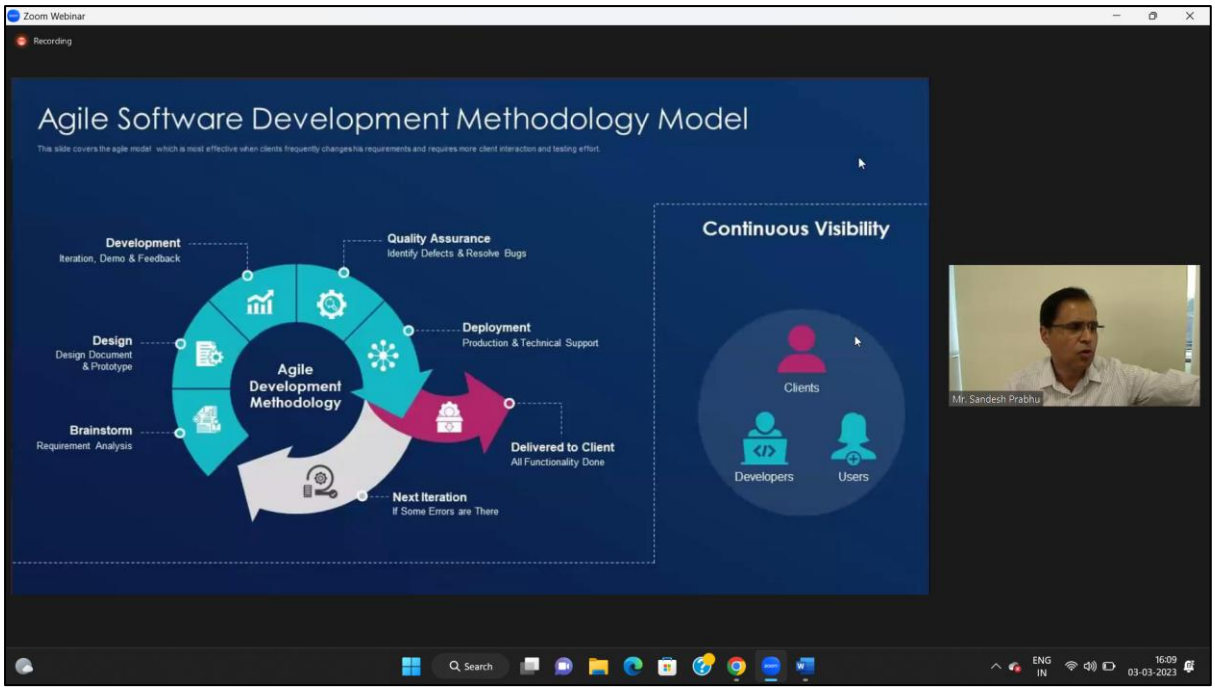
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Agile Software Development Methodology Model
This slide covers the agile model which is most effective when clients frequently changes his requirements and requires more client interaction and testing effort.
Development
Iteration, Demo & Feedback
Quality Assurance
Identify Defects & Resolve Bugs
Design
Design Document & Prototype
Deployment
Production & Technical Support
Agile Development Methodology
Brainstorm
Requirement Analysis
Delivered to Client
All Functionality Done
Next Iteration
If Some Errors are There
Continuous Visibility
Clients
Developers
Users
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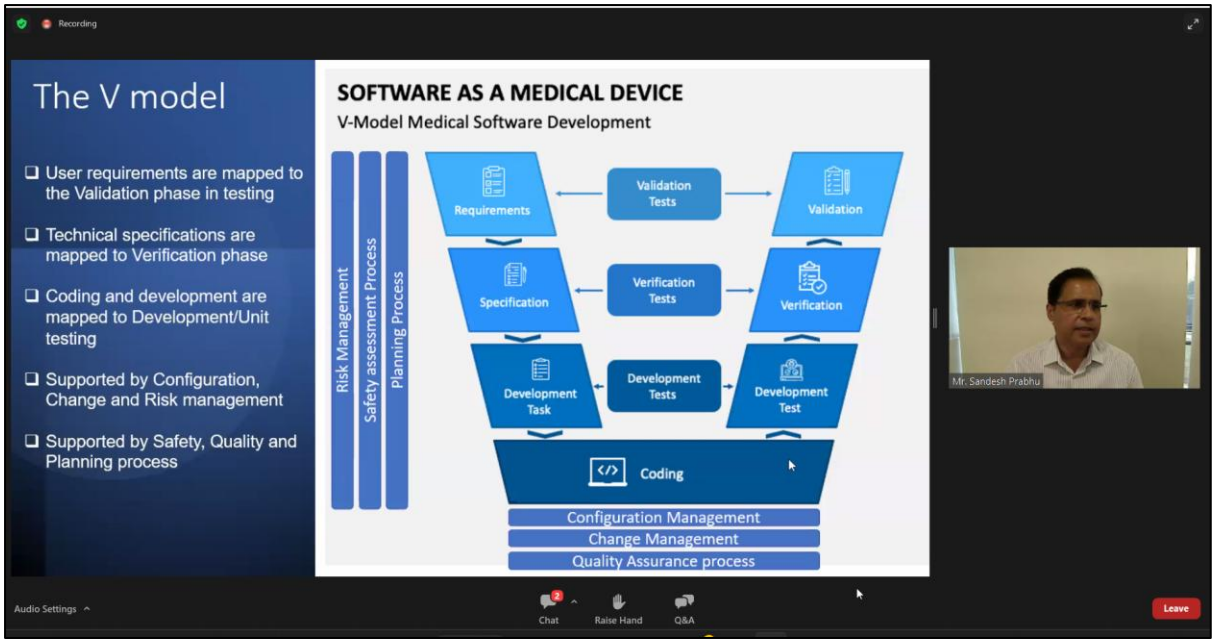
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The V model
User requirements are mapped to the Validation phase in testing
Technical specifications are mapped to Verification phase
Coding and development are mapped to Development/Unit testing
Supported by Configuration, Change and Risk management
Supported by Safety, Quality and Planning process
SOFTWARE AS A MEDICAL DEVICE
V-Model Medical Software Development
Risk Management
Safety assessment Process
Planning Process
Requirements
Validation Tests
Validation
Specification
Verification Tests
Verification
Development Task
Development Tests
Development Test
Coding
Configuration Management
Change Management
Quality Assurance process
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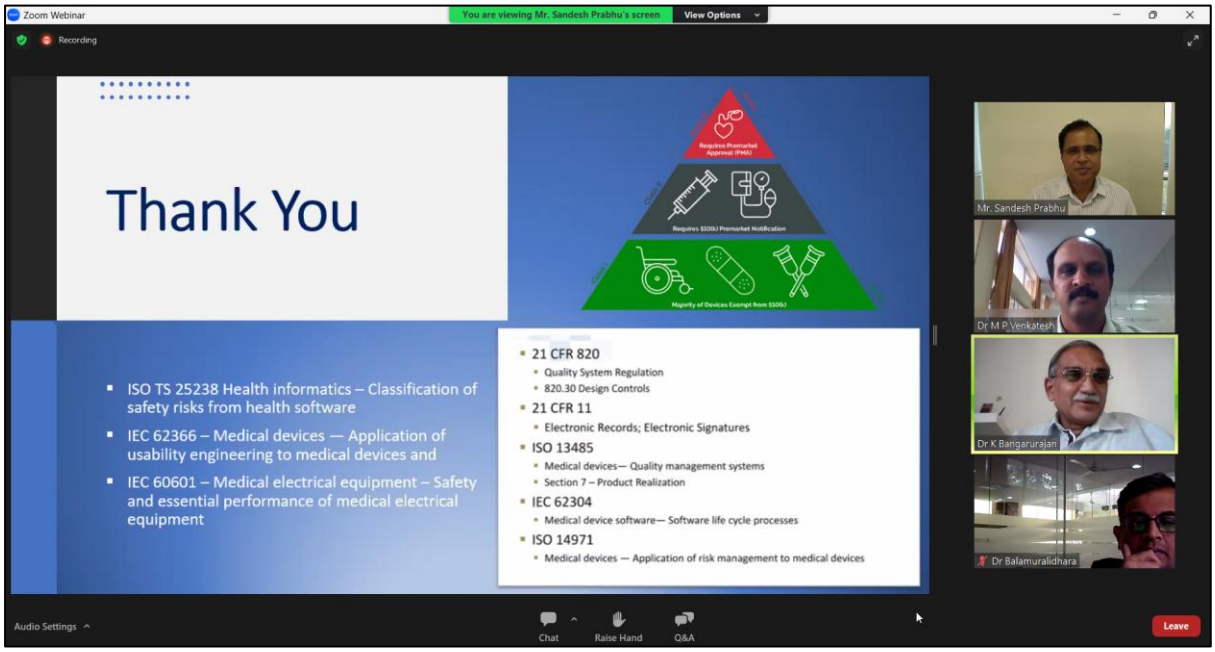
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Thank You
ISO TS 25238 Health informatics – Classification of safety risks from health software
IEC 62366 – Medical devices — Application of usability engineering to medical devices and
IEC 60601 – Medical electrical equipment – Safety and essential performance of medical electrical equipment
21 CFR 820
Quality System Regulation
820.30 Design Controls
21 CFR 11
Electronic Records; Electronic Signatures
ISO 13485
Medical devices— Quality management systems
Section 7 – Product Realization
IEC 62304
Medical device software— Software life cycle processes
ISO 14971
Medical devices — Application of risk management to medical devices
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