**Document 1: Definition of Done**

* Business requirements and user stories are documented and approved.
* Functional and non-functional requirements are clearly defined.
* Compliance and regulatory requirements (FDA, GMP, etc.) are addressed.
* System architecture is reviewed and approved.
* Database schema is designed and optimized.
* UI/UX design is completed and reviewed.
* Integration points with lab instruments and other systems are defined.
* All planned features and functionalities are developed.
* Code follows best practices, coding standards, and security guidelines.
* API integrations with lab equipment, databases, and external systems are completed.
* User roles and access controls are implemented correctly.
* Unit testing is completed with 100% coverage for critical functions.
* Integration testing is performed to ensure seamless connectivity with instruments.
* Functional testing ensures that all workflows operate correctly.
* Performance testing verifies system stability under load.
* Security testing ensures data protection and access control.
* User acceptance testing (UAT) is completed, and feedback is addressed.
* System meets all regulatory requirements (GMP, FDA 21 CFR Part 11, etc.).
* Audit trail functionality is implemented and tested.
* Electronic signatures and data integrity features are validated.
* Documentation for validation and compliance is completed.
* Deployment plan is created and reviewed.
* Training materials and user guides are provided to end users.

**Document 2- Product Vision**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scrum Project Name:** | Lyophilizer |  |  |
| **Venue:** | Virtual |  |  |
| **Date:** | 25-12-2024 |  |  |
| **Client:** | Ventri Biologicals |  |  |
| **Stakeholder List:** | * Lab Technicians & Scientists * Quality Control (QC) & Quality Assurance (QA) Teams * Regulatory Compliance Officers * Production & Operations Managers * IT & System Administrators * Senior Management * Third-Party Vendors |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Scrum Team** | | | |
| **Scrum Master:** | Mr. Ahuja |  |  |
| **Product Owner:** | Mr. Tushar |  |  |
| **Scrum Developer 1:** | Mrs. Rani |  |  |
| **Scrum Developer 2:** | Mrs. Gauri |  |  |
| **Scrum Developer 3:** | Mr. Rana |  |  |
| **Scrum Developer 4:** | Mr. Gaurav |  |  |
| **Scrum Developer 5:** | Mrs. Shravani |  |  |

|  |  |
| --- | --- |
| **Vision:** | * The lyophilizer LIMS project is to streamline and automate the management of lyophilization (freeze-drying) processes in pharmaceutical and biotech laboratories. To enhance the user experience. * This system will enhance accuracy, compliance, and efficiency, ensuring high-quality product output while minimizing manual errors and regulatory risks. |

|  |  |
| --- | --- |
| **Target Group** | |
| Which market segment does the product address? | * Pharmaceutical and biotech companies * Vaccine manufacturers * Research laboratories |
| Who are the target users and customers? | * Lab technicians and scientists * Quality control (QC) and quality assurance (QA) teams * Regulatory compliance officers * Production managers * IT and system administrators |

|  |  |
| --- | --- |
| **Needs** | |
| What problem does the product solve? | * Currently, managing the lyophilization process involves manual documentation, leading to errors, inefficiencies, and compliance risks. Lab personnel struggle with tracking batches, recording process parameters, and ensuring regulatory adherence. * **Automation**: Reduces manual data entry and errors, Improves operational efficiency. And reduce the downtime. * **Compliance**: Ensures adherence to regulatory standards (FDA, GMP, etc.) * **Traceability**: Provides a digital record of all processes for audits * **Efficiency**: Saves time by integrating data from multiple sources. * **Quality Control**: Enhances product consistency and reliability and accuracy. Which helps in retention of customer trust. |

|  |  |
| --- | --- |
| **Product** | |
| What is the product? | A Lyophilizer with Lab Information Management System (LIMS) specifically designed for lyophilization, integrating process tracking , data logging, real-time monitoring, and regulatory compliance features. |
| What makes it desirable and special? | Real-time monitoring of lyophilization parametersVariety:  Automated data capture and reporting  Integration with existing lab instruments and software  User-friendly interface with customizable workflows  Compliance-ready with built-in audit trails |
| Is it feasible to develop the product? | Yes, the product is feasible with the right technology stack, integration capabilities, and domain expertise in LIMS and lyophilization processes.Technical Expertise  Resources |

|  |  |
| --- | --- |
| **Value** | |
| How is the product going to benefit the company? | * **Improves Operational Efficiency and Reduces Manual Labor** * Automates data entry and batch tracking, eliminating manual logs. * Reduces human errors in documentation and process monitoring. * Integrates with lab instruments, enabling real-time data capture. * Reduces time spent on retrieving, verifying, and reporting data. * Standardizes workflows, ensuring seamless execution of processes.   Faster processing times, reduced workforce dependency, and increased productivity.   * **Enhances Regulatory Compliance, Reducing the Risk of Penalties** * Ensures adherence to regulatory requirements such as **FDA 21 CFR Part 11**, **GMP**, and **ISO standards**. * Maintains **audit trails** and **electronic signatures** for compliance verification. * Enables secure **data integrity**, preventing unauthorized modifications. * Generates **automated reports** for regulatory audits.   Minimizes the risk of non-compliance penalties, legal actions, and product recalls.   * **Ensures Better Product Quality and Batch Consistency**   - Tracks every stage of the lyophilization process, ensuring process repeatability.  - Monitors temperature, pressure, and drying cycles to maintain **optimal conditions**.  - Provides **real-time alerts** for process deviations, reducing batch failures.  - Standardizes procedures across different teams and locations.  Higher-quality products, fewer batch rejections, and better customer satisfaction.   * **Strengthens Competitive Advantage in the Pharmaceutical and Biotech Industry** * Positions the company as a **technology-driven** and **compliance-ready** solutions provider. * Enhances reputation by ensuring consistent **high-quality** manufacturing. * Differentiates from competitors by offering an **advanced, automated LIMS solution**. * Enables scalability for larger production facilities, expanding market reach.   Attracts more clients, builds trust in the industry, and increases revenue potential. |
| What are the business goals? | * Expands the company’s footprint in the **pharma & biotech** sector, increasing LIMS adoption. * **Lower operational expenses**, improved efficiency, and higher profitability. * Builds **trust** with regulatory bodies, improving market reputation and client confidence. * **Higher sales**, increased **market penetration**, and long-term growth in the **industry**. |
| What is the business model? | Custom Application development for specific client needs with strict adhere of regulatory compliances. |

**Document 3: User stories**

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 1 | **Task:** 1 | | **Priority:** HIGH |
| As a system user,  I want to set batch parameters  so that they cannot be modified by unauthorized users. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should allow authorized users to define and save batch parameters. * Once saved, batch parameters should only be editable by users with the necessary permissions. * Unauthorized users attempting to change batch parameters should receive an access-denied message * The system should provide an option to lock batch parameters after finalization, preventing any further changes. * If changes are required after locking, only administrators or users with special permissions should be able to unlock and modify them. * The system should maintain version history, allowing users to view previous batch parameters and changes. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 2 | **Task:** 1 | | **Priority:** HIGH |
| As a System user,  I want to monitor the system in real-time, so that I can detect issues, track system performance, and respond quickly to ensure smooth operations and minimize downtime | | | |
| **BV: 500** | | **CP: 3** Unit | |
| **Acceptance Criteria:**   * The system should provide a real-time dashboard displaying key performance metrics (e.g., system status, batch progress, resource utilization). * Users should receive alerts and notifications for critical issues, such as system failures, performance degradation, or errors * The system should allow users to view logs and reports for troubleshooting. * The monitoring interface should be accessible based on user roles and permissions. * The system should allow users to filter and customize monitoring parameters based on their needs. | | | |
|  | | | |
| **User Story No:** 3 | **Task:** 1 | | **Priority:** MEDIUM |
| As a lab supervisor, I want to be alerted when calibration is due so that I can schedule it and prevent inaccuracies in future cycles. | | | |
| **BV:** 500 | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should track calibration due dates for all lab instruments. * The system should send automatic alerts to the lab supervisor before the calibration due date. * The alert should include details such as instrument ID, last calibration date, and next due date. * The lab supervisor should be able to acknowledge the alert and schedule calibration. * Only authorized users should be able to update calibration schedules. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 4 | **Task:** 1 | | **Priority:** MEDIUM |
| As a lab technician, I want to log calibration activities in the system so that I can track calibration history and ensure compliance. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should allow lab supervisors and auditors to review calibration history. * Logged calibration records should be timestamped and include the technician’s name for traceability. * The system should support uploading calibration certificates or reports as attachments. * The system should generate reports on calibration history for audit and compliance purposes. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 5 | **Task:** 1 | | **Priority:** HIGH |
| As a user, I want to receive automated reports after each lyophilization cycle so that I can track progress without manual intervention. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should automatically generate a report at the end of each lyophilization cycle. * The report should include key details such as cycle start and end times, temperature profiles, pressure readings, and any deviations. * The system should allow users to access historical lyophilization reports. * The report should be generated in a standardized format (e.g., PDF, CSV) for easy analysis and compliance documentation. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 6 | **Task:** 1 | | **Priority:** MIDIUM |
| As a quality manager, I want to see a dashboard of lyophilizer data so that I can quickly identify any process anomalies. | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The dashboard should highlight any deviations or anomalies in the process. * Users should be able to set threshold limits for critical parameters, triggering alerts when exceeded * Historical data should be available for trend analysis and investigation. * The system should allow users to export dashboard data for reporting and compliance. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 7 | **Task:** 1 | | **Priority:** LOW |
| As a user, I want to be able to reset my password in the LIMS if I forget it so that I can continue using the system without delay. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should provide a "Forgot Password" option on the login page. * Users should be able to request a password reset by entering their registered email or username. * The reset link should be valid for a limited time (e.g., 15–30 minutes). * If an incorrect email or username is entered, the system should display an appropriate error message without revealing whether the account exists. * Users should be required to create a new password that meets security criteria (e.g., minimum length, special characters, uppercase/lowercase). | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 8 | **Task:** 1 | | **Priority:** HIGH |
| As a lab supervisor, I want to receive alerts if there is an issue with data transfer between the LIMS and the lyophilizer system so that I can address it quickly. | | | |
| **BV: 500** | | **CP: 2** Unit | |
| **Acceptance Criteria:**   * The system should continuously monitor data transfer between the LIMS and the lyophilizer. * If a data transfer failure or delay occurs, the system should generate an alert. * Users should be able to acknowledge alerts and update the status (e.g., in progress, resolved). | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 9 | **Task:** 1 | | **Priority:** HIGH |
| As a user, I want the lyophilizer data to be automatically updated in the LIMS so that I don't need to enter it manually. | | | |
| **BV: 500** | | **CP: 2** Unit | |
| **Acceptance Criteria:**   * The system should automatically capture and transfer lyophilizer data to the LIMS in real time. * The system should support automatic synchronization between the lyophilizer and LIMS, ensuring data accuracy and consistency. * In case of any errors or issues with data transfer, the system should send an alert to the user for immediate resolution. * The system should allow users to configure data transfer intervals and settings, if necessary, based on user needs or system requirements. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 10 | **Task:** 1 | | **Priority:** HIGH |
| As a user, I want to receive a notification if a cycle fails so that I can address the issue promptly. | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should monitor the lyophilization cycle for failures * If a cycle fails (e.g., due to temperature or pressure deviations, system errors), the system should immediately trigger a notification. * The system should allow users to acknowledge the failure notification and update its status (e.g., "Resolved," "In Progress"). * The system should log all cycle failures and actions taken for audit and analysis purposes. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 11 | **Task:** 1 | | **Priority:** HIGH |
| As a regulatory officer, I want to generate audit-compliant reports for each lyophilization cycle so that I can ensure adherence to industry standards. | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The report should be formatted to meet industry-specific regulatory standards (e.g., GMP, ISO). * The report should include information on calibration, maintenance, and any deviations or anomalies during the cycle. * The system should log all changes to the report (e.g., edits, exports) for audit trails. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 12 | **Task:** 1 | | **Priority:** HIGH |
| As a lab supervisor, I want to automatically generate a report at the end of each batch so that I can save time on manual documentation. | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The report generation process should be triggered automatically without requiring manual input at the end of each batch. * The system should log the generation of each report for tracking purposes. * The report should include any deviations or issues during the batch and actions taken. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 13 | **Task:** 1 | | **Priority:** HIGH |
| As a user, I want to create custom reports based on specific process parameters so that I can focus on relevant data. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * Users should be able to include or exclude specific data fields in the report based on relevance. * Users should be able to choose the date range, batch IDs, and other criteria to narrow down the data * The system should allow users to visualize the data with charts or graphs | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 14 | **Task:** 1 | | **Priority:** HIGH |
| As a quality manager, I want to view all batches processed by the lyophilizer so that I can ensure quality compliance. | | | |
| **BV: 100** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * The system should allow the quality manager to access a comprehensive list of all batches processed by the lyophilizer.. * The quality manager should be able to view batch history and status * The system should maintain an audit trail for each batch, including data changes, maintenance, and calibration activities. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 15 | **Task:** 1 | | **Priority:** HIGH |
| As a lab technician I want to log into the system so that I can access the system | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * The system should provide a secure login page for the lab technician to enter their credentials * The system should display an error message if incorrect credentials are entered, without revealing whether the username or password is incorrect. * Once logged in, the lab technician should have access to the necessary modules and features based on their role and permissions. * The system should have session management, automatically logging out the user after a certain period of inactivity. * The system should allow users to log out securely at any time. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 16 | **Task:** 1 | | **Priority:** HIGH |
| As a lab supervisor, I want to filter lyophilizer reports by date so that I can easily find reports for a specific time period. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * The system should provide options to filter by specific days, weeks, months, or custom date ranges. * The filtered reports should include all relevant batch data, including batch ID, process parameters, and any deviations or anomalies for the selected time period. * Only authorized users should be able to filter and access lyophilizer reports, ensuring that sensitive data is protected. * The system should provide an option to clear or reset the filters to view all reports again. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 17 | **Task:** 1 | | **Priority:** HIGH |
| As a quality manager, I want to review lyophilizer reports with a graphical representation of data (e.g., temperature and pressure over time) so that I can quickly identify patterns and anomalies. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * The system should include graphical representations (e.g., line charts, scatter plots) of key data from lyophilizer reports, such as temperature and pressure over time. * The graphs should display data for each batch processed by the lyophilizer, with the ability to zoom in on specific time periods or intervals. * graphs should highlight any deviations from acceptable ranges, such as sudden spikes or drops in temperature or pressure. * Data points on the graphs should be clickable, providing detailed information about specific events or parameters at that point in time. * The system should support real-time graphical monitoring for ongoing batches to identify issues as they arise. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 18 | **Task:** 1 | | **Priority:** HIGH |
| As a user, I want to set calibration reminders based on cycle count or date so that I don’t miss the calibration window. | | | |
| **BV: 200** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**  Basic Flow-   * The system should allow the user to set calibration reminders based on either the cycle count (e.g., after every 50 cycles) or a specific date (e.g., every 6 months). * The user should be able to set both options simultaneously for more flexible tracking. * The system should generate an alert or reminder when the set cycle count or date is reached. * If the user has missed a calibration reminder, the system should highlight the missed calibration with a priority alert. * Calibration reminders should be recorded in the system for audit and compliance purposes. * Only authorized users should be able to modify the calibration reminder settings. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 19 | **Task:** 1 | | **Priority:** HIGH |
| As a process engineer, I want to view the calibration status of the lyophilizer before starting a cycle so that I can ensure the equipment is operating accurately. | | | |
| **BV:** 500 | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should display the current calibration status of the lyophilizer before starting a cycle, including the last calibration date and the next due calibration. * The process engineer should be able to access calibration history for the lyophilizer to review previous calibration results and ensure consistency. * If the calibration is overdue or out of tolerance, the system should prevent the cycle from starting and prompt the process engineer to perform or schedule a calibration. * The system should allow the process engineer to acknowledge and confirm that they have reviewed the calibration status before proceeding with the cycle. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 20 | **Task:** 1 | | **Priority:** HIGH |
| As a lab technician, I want to be able to print lyophilizer reports for physical documentation so that I can keep a hard copy of critical data. | | | |
| **BV: 500** | | **CP:** 1 Unit | |
| **Acceptance Criteria:**   * The system should allow the lab technician to print lyophilizer reports directly from the user interface. * Reports should be formatted for easy printing, including essential data such as batch ID, cycle parameters, and any deviations or issues. * The printed reports should include a timestamp and system-generated ID for auditing and tracking purposes. * The print option should only be available to authorized users to prevent unauthorized access to critical data. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 21 | **Task:** 1 | | **Priority:** HIGH |
| As a System user I want to create lab technician account so that authorized personnel will operate the system | | | |
| **BV: 500** | | **CP: 2** Unit | |
| **Acceptance Criteria:**   * The system should allow the user to set a secure password for the lab technician account, with password strength validation. * The account creation process should include role-based permissions to ensure that the lab technician has the appropriate access to system features and data. * The system should provide an option for the user to assign a lab technician to specific locations or equipment within the system for better tracking and accountability. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 22 | **Task:** 1 | | **Priority:** HIGH |
| **As** a maintenance manager, **I want** the system to trigger an alarm to remind me of upcoming or overdue scheduled maintenance for the lyophilizer, **so that** I can ensure the equipment remains in optimal condition and compliant with regulatory standards. | | | |
| **BV:** 500 | | **CP: 2** Unit | |
| **Acceptance Criteria:**   * The system should trigger an alarm based on a predefined maintenance schedule * The alarm should notify the maintenance team via the user interface and send email/SMS reminders. * The alarm should be reset once the maintenance task is completed and recorded in the system | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **User Story No:** 23 | **Task:** 1 | | **Priority:** HIGH |
| As an IT Administrator I want to monitor and manage the disk size of the LIMS database So that I can ensure sufficient storage is available and prevent potential system slowdowns or crashes due to disk space limitations. | | | |
| **BV:** 500 | | **CP: 3** Unit | |
| **Acceptance Criteria:**   * The system should automatically monitor database disk usage and alert the IT team when the disk space exceeds a predefined threshold. * The system should generate regular reports showing the growth of the database over time, including the amount of space used by tables, indexes, logs, and backups * The system should support database compression options to reduce the overall disk usage for large datasets, such as test results and sample logs. | | | |

**Document 4: Agile PO Experience**

* In our LIMS Lyophilizer Project, as a Product Owner (PO), my role was to ensure that the product met the needs of the vaccine manufacturing process
* I studied the market to see why an Advanced Lyophilizer need and that has to integrate with the LIMS
* I worked with stakeholders (lab managers, production heads, quality teams, and regulatory teams) to understand their challenges in lyophilization data management.
* I ensured that our LIMS solution aligned with compliance needs (like FDA & GMP regulations) and business objectives.
* The vision is - tracking lyophilization cycles, recording batch details, and improving compliance.
* Roadmap- real-time monitoring, automated report generation, and integration with LIMS
* I prioritized features based on business value (BV) and complexity points (CP), ensuring the most critical functionalities were built first.
* I worked with the **development team** to break features into **user stories** with clear acceptance criteria.
* Regularly **refined the backlog** based on stakeholder feedback and sprint progress.

Prioritization Framework-

* Develop a prioritization framework based on factors such as business value, technical complexity, customer impact, and strategic alignment.
* Use techniques like MoSCoW (Must have, Should have, Could have, Won't have) prioritization.

Prioritization Process-

* Start by identifying epics, which are high-level features or initiatives that deliver significant value to the product.
* Break down epics into smaller user stories that represent specific functionalities or tasks from the user's perspective.
* Prioritize epics and stories.

ROI Analysis-

* Estimate the potential return on investment for each feature by considering the expected revenue increase, cost savings, and other measurable benefits.

From this project I have learned how to handle sprint meetings such as:

Sprint planning meeting-

* It is the main aspect of Agile framework.
* Sprint planning takes place at the beginning of the sprint.
* It determines the sprint plan and goal.
* Here the team understands the work to be done in that specific sprint.
* The team discuss here what is to be done in the sprint.

Daily scrum meeting –

* It is a time box meeting for about 15-20 min.
* The daily scrum meetings should be as small as possible.
* The daily scrum meetings discuss what that particular team member has accomplished, what is the team members plan to complete, and what are the issues that team member is facing in the work.

Sprint review & Sprint retrospective meeting-

* At the end of the development, the development team conducts a sprint review meeting.
* In this meeting, the completed work is shown to the stakeholder and the product owner.
* The team gathers feedback from the stakeholder, which in turn helps the development team to understand what could be improved.
* In sprint retrospective meeting the team will address the issues that occurred in each sprint, how that issues can be resolved and also what was good about the sprint.

**Document 5: Product and sprint backlog and product and sprint burndown charts**

**Product Backlog**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **User Story ID** | **User story** | **Task** | **Priority** | **BV** | **CP** | **Sprint** |
| 1 | As a system administrator, I want to assign user roles and permissions in the LIMS so that access to data is restricted appropriately. | Develop Authorization and assign role | High | 100 | 2 | Sprint 1 |
| 2 | As a user, I want to be able to reset my password in the LIMS if I forget it so that I can continue using the system without delay. | User Registration | High | 500 | 2 | Sprint 1 |
| 3 | As a lab technician I want to enter batch details so that I can enter batch details | Design and implement product detail page layout | High | 200 | 2 | Sprint 1 |
| 4 | As a lab technician, I want to be able to print lyophilizer reports for physical documentation so that I can keep a hard copy of critical data | Report print functionality for technician | High | 100 | 3 | Sprint 2 |
| 5 | As a quality manager, I want to review lyophilizer reports with a graphical representation of data (e.g., temperature and pressure over time) so that I can quickly identify patterns and anomalies. | Report Feature for Quality Assurance | High | 100 | 5 | Sprint 2 |
| 6 | As a lab supervisor, I want to be alerted when a calibration is due so that I can schedule it and prevent inaccuracies in future cycles. | Calibration notification | High | 100 | 3 | Sprint 3 |
| 7 | As a System user,  I want to monitor the system in real-time, so that I can detect issues, track system performance, and respond quickly to ensure smooth operations and minimize downtime. | Design and develop process monitoring functionality | High | 200 | 4 | Sprint 4 |
| 8 | As a lab supervisor, I want to automatically generate a report at the end of each batch so that I can save time on manual documentation.  . | Auto report generation | Medium | 200 | 4 | Sprint 4 |
| 9 | As a system user I want alarm indication so that I can attain the faults | Design and implement alarm system | Medium | 200 | 3 | Sprint 5 |
| 10 | As a regulatory officer, I want to generate audit-compliant reports for each lyophilization cycle so that I can ensure adherence to industry standards. | Develop audit trail functionality | Medium | 200 | 5 | Sprint 5 |

**Sprint Backlog-**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **User Story ID** | **User Story** | **Tasks** | **Owner** | **Status** | **Estimated Effort** |
| 1 | As a system administrator, I want to assign user roles and permissions in the LIMS so that access to data is restricted appropriately. | Develop category navigation feature | Developer 1 | In Progress | 3 hours |
| **2** | As a user, I want to be able to reset my password in the LIMS if I forget it so that I can continue using the system without delay. | Implement search functionality with filters | Developer 2 | To Do | 5 hrs |
|  |  | Test search functionality on different browsers | Tester 1 | To Do | 2 hours |
| **3** | As a lab technician I want to enter batch details so that I can enter batch details | Design and implement batch detail page layout | Developer 3 | To Do | 5 hours |
| **4** | As a lab technician, I want to be able to print lyophilizer reports for physical documentation so that I can keep a hard copy of critical data | Develop Print functionality | Developer 4 | To Do | 6 hours |
|  |  | Test print process | Tester 1 | To Do | 2 hours |
| **5** | As a quality manager, I want to review lyophilizer reports with a graphical representation of data (e.g., temperature and pressure over time) so that I can quickly identify patterns and anomalies. | Implement graph function | Developer 5 | To Do | 8 hours |
|  |  | Review and test graph function | Designer 2 | To Do | 4 hours |
| **6** | As a lab supervisor, I want to be alerted when a calibration is due so that I can schedule it and prevent inaccuracies in future cycles. | Set Alert system | Developer 1 | To Do | 5 hours |
| **7** | As a System user,  I want to monitor the system in real-time, so that I can detect issues, track system performance, and respond quickly to ensure smooth operations and minimize downtime. | Develop system process overview screens | Developer 2 | To Do | 5 hours |
|  |  | Test screens | Tester 1 | To Do | 2 hours |
| **8** | As a lab supervisor, I want to automatically generate a report at the end of each batch so that I can save time on manual documentation. | Implement auto report generation |  |  |  |
|  |  | Test auto report generation | Tester 2 | To Do | 2 hours |
| **9** | As a system user I want alarm indication so that I can attain the faults | Create alarm indicator for faults | Developer 4 | To Do | 5 hours |
|  |  | Design alarm indicatior | Designer 1 | To Do | 4 hours |
| **10** | As a regulatory officer, I want to generate audit-compliant reports for each lyophilization cycle so that I can ensure adherence to industry standards. | Develop Report generation | Developer 5 | To Do | 5 hours |
|  |  | Test report generation | Tester 1 | To Do | 2 hours |

**Document-6- Sprint Meetings**

**Sprint Planning Meeting-**

|  |  |
| --- | --- |
| **Date** | **29-01-2025** |
| **Time** | 12 PM |
| **Location** | Virtual |
| **Prepared By** | Mr. Rahul |
| **Attendees** | |  |  | | --- | --- | | Product Owner | Mr. Tushar | | Scrum Master | Mr. Ahuja | | Developers | Mrs. Rani, Mrs. Gauri, Mr. Rana, Mr. Gaurav, Mrs. Shravani | | Designers | Mrs. Komal | | Quality Assurance Engineers | Mrs. Saniya | | Project Managers |  | | Stakeholders | POC from Business Stakeholder | |

**Agenda Topics**

|  |  |  |
| --- | --- | --- |
| **Topic** | **Presenter** | **Time Allotted** |
| Review of previous sprint and retrospective | Scrum Master | 15 minutes |
| Sprint goals and objectives | Product Owner | 10 minutes |
| Backlog grooming and prioritization | Product Owner / Scrum Team | 20 minutes |
| Sprint planning and task assignment | Scrum Master / Development Team | 30 minutes |
| Q&A and Next Steps | All | 10 minutes |

**Other Information**

|  |  |
| --- | --- |
| **Observer** |  |
| **Resources** |  |
| **Special Notes** |  |

**Spring Review Meeting**

|  |  |
| --- | --- |
| **Date** | **13-2-2025** |
| **Time** | 12 PM |
| **Location** | Virtual |
| **Prepared By** | Mr. Rahul |
| **Attendees** | |  |  | | --- | --- | | Product Owner | Mr. Tushar | | Scrum Master | Mr. Ahuja | | Developers | Mrs. Rani, Mrs. Gauri, Mr. Rana, Mr. Gaurav, Mrs. Shravani | | Designers | Mrs. Komal | | Quality Assurance Engineers | Mrs. Saniya | | Project Managers |  | | Stakeholders | POC from business Stakeholders, and particular stakeholder from department according to feature | |

|  |  |
| --- | --- |
| **Sprint Status** | Provide an overview of the progress made during the sprint. |
| **Things To demo** | Show case the features, functionalities, or improvements completed during the sprint. |
| **Quick Update** | Provide brief updates on any important developments or announcements related to the project or team. |
| **What’s Next** | Discuss the goals and objectives for the upcoming sprint. |
|  |  |
| **Sprint Status** | Highlight any completed user stories or tasks. |
| **Things To demo** | Present any new user stories, enhancements, or bug fixes that were worked on. |
| **Quick Update** | Share any relevant information about upcoming sprints, deadlines, or milestones. |
| **What’s Next** | Review the prioritized backlog items for the next sprint. |
|  |  |
| **Sprint Status** | Discuss any issues or obstacles encountered and how they were addressed. |
| **Things To demo** | Demonstrate how the implemented features meet the user requirements or acceptance criteria. |
| **Quick Update** | Address any outstanding action items or decisions from previous meetings. |
| **What’s Next** | Assign tasks or user stories to team members based on their expertise and availability. |
|  |  |
| **Sprint Status** | Review the sprint backlog and compare it to what was actually accomplished.  Summarize any changes made to the sprint scope or goals. |
| **Things To demo** | Encourage feedback from the stakeholders and team members regarding the demonstrated items. |
| **Quick Update** | Allow stakeholders and team members to ask questions or provide updates on their respective areas. |
| **What’s Next** | Outline any dependencies, risks, or challenges that need to be addressed in the next sprint.  Confirm the timeline and expectations for the next sprint review and planning meetings. |

**Sprint Retrospective Meeting-**

|  |  |
| --- | --- |
| **Date** | **14**/02/2025 |
| **Time** | 12 PM |
| **Location** | Virtual |
| **Prepared By** | Mr. Rahul |
| **Attendees** | |  |  | | --- | --- | | Product Owner | Mr. Tushar | | Scrum Master | Mr. Ahuja | | Developers | Mrs. Rani, Mrs. Gauri, Mr. Rana, Mr. Gaurav, Mrs. Shravani | | Project Managers |  | | Stakeholders | POC from business Stakeholder. | | SME(Subject Matter Expert) | Mr. Nikhil | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Agenda** | **What went well** | **What didn’t go well** | **Questions** | **Reference** |
|  |  |  |  |  |
| Review of the previous sprint | Successfully launched new functionality. | Experienced delays in implementing integration with lab instruments. | What factors contributed to the successful launch of new functionality? | Sprint backlog, User feedback |
|  | Improved UI/UX based on user feedback. | Bug discovered in functionality affecting user experience. | How can we address the delays in integrating the instruments for future sprints? | Development logs |
|  |  |  |  |  |
| What went well | Achieved 90% customer satisfaction rate based on feedback. |  | What strategies contributed to the high customer satisfaction rate? | Customer feedback surveys, Analytics data |
|  | Completed all planned tasks within the sprint timeframe. |  | How can we sustain and improve the high level of customer satisfaction in future sprints? | ask completion reports, Sprint burndown charts |
|  |  |  |  |  |
| What didn’t go well |  | Server downtime resulted in temporary loss of service. | What measures can we take to prevent server downtime and ensure continuous service availability? | Incident reports, Server logs |
|  |  | Miscommunication led to misunderstandings in feature requirements. | How can we improve communication and clarity of feature requirements to avoid misunderstandings? | Meeting minutes, Communication logs |

**Daily Stand-up Meetings-**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Question | Role | Week X (dd-mm-yyyy to dd-mm-yyyy) | | | | |
|  |  | **Mon** | **Tue** | **Wed** | **Thu** | **Fri** | **Sat** | **Sun** |
|  |  |  |  |  |  |  |  |  |
| What did you do yesterday? |  |  |  |  |  |  |  |  |
|  | Dev1 | Implemented login functionality, fixed bugs in user profile page. | Designed UI wireframes for the dashboard, started frontend implementation. | Implemented responsive design for dashboard, fixed UI bugs. | Reviewed PRs, provided feedback, fixed minor UI issues. | Assisted teammates with UI improvements, prepared for sprint demo. |  |  |
|  | Dev2 | Worked on database schema design, started implementing backend APIs. | Completed backend API implementation, started writing unit tests | Wrote unit tests for authentication and data retrieval, started integration testing. | Completed integration testing, started documentation for API endpoints. | Finalized API documentation, prepared demo script for stakeholders. |  |  |
|  | Dev3 | Researched third-party libraries for data visualization, started integration. | Integrated data visualization library, experimented with different chart types. | Optimized data fetching methods, fixed compatibility issues. | Implemented caching mechanism, documented integration process. | Investigated caching bugs, provided fixes. |  |  |
|  |  |  |  |  |  |  |  |  |
| What will you do today? |  |  |  |  |  |  |  |  |
|  | Dev1 | Continue working on user authentication, start UI design for dashboard. | Continue frontend implementation, work on responsive design. | Refactor code for better code structure, review PRs from teammates. | Address feedback from PRs, assist teammates with any issues. | Participate in sprint demo, address any feedback received. |  |  |
|  | Dev2 | Complete backend API implementation, begin testing and debugging. | Write unit tests for authentication and data retrieval APIs. | Continue integration testing, coordinate with frontend team for API endpoints. | Finalize API documentation, start preparing for demo to stakeholders. | Conduct sprint demo, gather feedback from stakeholders. |  |  |
|  | Dev3 | Integrate chosen library into the project, start working on data fetching. | Customize chart styles to match project's theme, start data integration. | Implement caching mechanism for improved performance, document integration process. | Investigate reported bugs related to caching, provide fixes. | Test caching fixes, document troubleshooting steps. |  |  |
|  |  |  |  |  |  |  |  |  |
| What is blocking your progress? |  |  |  |  |  |  |  |  |
|  | Dev1 | Waiting for approval on UI wireframes from the design team. | No blockers currently. | No blockers currently. | No blockers currently. | No blockers currently. |  |  |
|  | Dev2 | Need clarification on certain business logic requirements from the product owner. | Waiting for sample data from the testing team to complete testing. | Need to coordinate with frontend team for API changes. | No blockers currently. | No blockers currently. |  |  |
|  | Dev3 | Facing difficulties in understanding the documentation of the chosen library. | Facing performance issues with large datasets, exploring optimizations. | None at the moment. | Debugging caching issues is taking longer than expected. | No blockers currently. |  |  |

**Product Burndown chart-**

It is the visual representation of the progress of the project that is done.

It shows the amount of work that is completed and the amount of work that is remaining.

It shows the progress of entire project.

**Sprint Burndown chart-**

It shows the progress of specific sprint.

A graph with a red line

Description automatically generated

**Elicitation techniques used for this project-**

1. Interview: -

Purpose- to gather information from the stakeholders by interviewing them and asking them questions.

How- conducted A structured interview.

1. Document Analysis:-

Purpose- Reviewed the existing document to understand the current process, policies.

How- Analyzed business process document, user manuals or any Regulatory compliance document

1. Prototyping: -

Purpose: - Provided with a working model to the stakeholder so that it will become easy for them to understand the actual working.

How: - Created wireframes for this application to show the design and page

1. Observation: -

Purpose: - Observe the existing LIMS process. And inventory material handling procedure