**Document 1- Business case document**

* **Why is this project initiated?**

**Answer-**

This project is initiated to address the following key challenges and opportunities in the **retort sterilization process** at Tastybite India:

**Reasons for Initiation:**

1. **Automation and Efficiency:**
	* The existing manual process is time-consuming and prone to human error.
	* Automating the process will improve cycle consistency and reduce operational inefficiencies.
2. **Regulatory Compliance:**
	* Meeting stringent regulatory standards (e.g., FDA, HACCP) requires precise control and detailed documentation of sterilization processes.
	* A digital solution ensures adherence to compliance requirements and simplifies audits.
3. **Data Traceability and Record-Keeping:**
	* Current systems may lack comprehensive batch traceability and accessible data logs.
	* Digital logging and traceability improve record-keeping and product accountability.
4. **Real-Time Monitoring and Alerts:**
	* Manual monitoring may delay corrective actions during process deviations.
	* Real-time dashboards and alerts allow operators to respond quickly to abnormalities.
5. **Integration with Enterprise Systems:**
	* Limited or no integration with ERP or LIMS hinders smooth workflows and data sharing.
	* The project enables seamless integration to enhance productivity across departments.
6. **Cost Optimization:**
	* Reducing downtime, cycle deviations, and manual errors leads to cost savings.
	* Improved resource utilization enhances overall profitability.
7. **Scalability and Future-Readiness:**
	* As production scales, manual processes become less sustainable.
	* The system prepares Tastybite for future growth by supporting scalability and advanced features.

**Opportunity:**

By implementing this system, Tastybite can ensure product safety, maintain high-quality standards, and improve operational transparency, leading to better customer satisfaction and market competitiveness.

* **What are the current problems?**

**Answer-**

The following are the current problems

**1. Manual Process Challenges**

* **Human Errors:**
	+ Manual control of temperature, pressure, and sterilization duration increases the risk of errors, leading to inconsistent product quality.
* **Time-Consuming:**
	+ Setting up and monitoring cycles manually slows down operations.

**2. Lack of Real-Time Monitoring**

* **Delayed Response to Deviations:**
	+ Deviations in temperature or pressure during sterilization may not be identified immediately, leading to product rejections or wastage.
* **No Centralized Dashboard:**
	+ Operators lack a unified interface to monitor multiple retort machines in real time.

**3. Insufficient Data Logging and Traceability**

* **Manual Record-Keeping:**
	+ Current data logging practices are manual or fragmented, increasing the risk of missing or inaccurate records.
* **Limited Traceability:**
	+ Difficulty in linking sterilization data to specific product batches for audits or recalls.

**4. Compliance Risks**

* **Regulatory Non-Conformance:**
	+ Existing processes may not fully meet regulatory standards (e.g., FDA, HACCP), exposing the company to compliance risks.
* **Audit Challenges:**
	+ Lack of readily accessible and verifiable sterilization data complicates regulatory audits.

**5. Inefficient Resource Utilization**

* **Energy and Resource Wastage:**
	+ Suboptimal control over cycles leads to excessive use of energy and resources.

**6. Integration Limitations**

* **Workflow Inefficiencies:**
	+ Manual data entry and lack of automated data sharing slow down processes across departments.
* **With this project how many problems could be solved?**

**Answer-**

This project can address **all the major problems** identified in the current retort sterilization process. Here's how each issue is resolved:

**1. Manual Process Challenges**

**Solution:**

* Automating temperature, pressure, and cycle control eliminates human errors.
* Predefined sterilization programs reduce operator workload and save time.
**Problems Solved:**
* Human errors.
* Time inefficiencies.

**2. Lack of Real-Time Monitoring**

**Solution:**

* A centralized dashboard provides real-time monitoring of all critical parameters.
* Alerts notify operators of deviations immediately, enabling prompt corrective actions.
**Problems Solved:**
* Delayed response to deviations.
* Lack of unified monitoring.

**3. Insufficient Data Logging and Traceability**

**Solution:**

* Automatic data logging for every sterilization cycle ensures accurate and complete records.
* Batch traceability links data to specific products for audits and recalls.
**Problems Solved:**
* Inaccurate records.
* Limited traceability.
* Audit challenges.

**4. Compliance Risks**

**Solution:**

* Built-in compliance reporting tools ensure adherence to FDA, WHO, and local regulations.
* Digital logs and validation processes make regulatory audits straightforward.
**Problems Solved:**
* Regulatory non-conformance.
* Difficulty in meeting audit requirements.

Optimized cycle control reduces energy and resource wastage.

* **What are the resources required?**

**Answer-**

**1. Human Resources**

**Project Team**

* **Business Analyst:** Gather requirements, analyze processes and document specifications.
* **Project Manager:** Plan, coordinate, and oversee project execution.
* **Frontend Developers:** Build user interfaces and dashboards
* **Backend Developers**: Develop application coding
* **Database Administrator (DBA):** Design and manage databases
* **Hardware Integration Specialist:** Integrate the system with PLCs, IoT devices, and other hardware.
* **Quality Assurance (QA) Testers:** Test the application for functionality, performance, and compliance.
* **Regulatory Consultant**: Ensure the system meets FDA, WHO, and other regulatory standards**.**

**2. Hardware Resources**

* **Industrial Hardware:**
	+ Programmable Logic Controllers (PLCs).
	+ IoT sensors for temperature, pressure, and humidity monitoring**.**
* **Servers and Networking Equipment:**
	+ On-premises or cloud servers for application hosting and data storage.
	+ Secure network infrastructure for real-time communication**.**
* **Operator Terminals:**
	+ **Industrial-grade tablets for operator access.**

**3. Software Resources**

* **Frontend Frameworks:** React, Angular for building dashboards.
* **Backend Technologies:** Python, or .NET for application coding.
* **Database Management System:** SQL Server**.**
* **Integration Protocols:** Modbus for hardware communication**.**

**4. Time Resources**

* **Estimated project timeline: 6 months.**
	+ **Requirements Gathering: 1 month.**
	+ **Design and Vendor Selection: 1.5 months.**
	+ **Development: 2 months.**
	+ **Testing and Training: 1 month.**
	+ **Deployment and Go-Live: 0.5 months.**

**5. Financial Resources**

* **Software Development Budget:** Costs for development, testing, and integration.
* **Hardware Costs:** PLCs, IoT devices, and operator terminals.
* **Licensing Costs:** For third-party tools, frameworks, or database systems
* **How much organizational change is required to adopt this technology?**

**Answer-**

**Organizational Changes Required:**

1. **Process Adjustments**:
	* Transitioning from manual or semi-automated sterilization processes to a fully automated system.
	* Updating standard operating procedures (SOPs) to align with the new application.
2. **Training and Skill Development**:
	* Training operators, supervisors, and quality assurance teams to use the application.
	* Familiarizing IT and maintenance staff with system administration, troubleshooting, and integration requirements.
3. **Infrastructure Modifications**:
	* Installing or upgrading hardware such as IoT sensors, PLCs (Programmable Logic Controllers), and compatible network systems.
	* Ensuring proper integration with existing ERP
4. **Compliance Alignment**:
	* Aligning with industry standards and regulatory requirements for automated sterilization systems.
	* Documenting and validating the new system to ensure compliance with quality and safety standards.
5. **Change Management**:
	* Establishing a change management team to oversee the transition.
	* Communicating benefits and addressing resistance to change effectively.
* **Time frame to recover ROI?**

**Answer**

The time frame to recover the ROI for the Retort Sterilization Application depends on several factors, including the scale of operations, initial investment, operational efficiency improvements, and cost savings achieved.

**Expected Cost Savings and Benefits:**

* **Reduced Process Downtime**: 10% savings in production time.
* **Labor Cost Reduction**: Automation reduces dependency on manual labor by 20%.
* **Improved Energy Efficiency**: 8% reduction in energy costs per cycle.
* **Fewer Product Losses**: Improved process accuracy reduces defective batches.
* **Enhanced Market Competitiveness**: Better quality and faster production can attract more customers.
* Assuming the cumulative annual savings and additional revenue amount, the ROI recovery time is **2 years**.
* **How to identify Stakeholders?**

**Answer-**

Stakeholders are identified by considering various factors.

 **Review the project goals**: Understand the purpose and scope of the project to identify who may be impacted.

 **Key questions**: Who will be directly or indirectly affected by the project? Who will benefit or be harmed?

 Accordingly, we categories Stakeholders as Primary stakeholders and secondary stakeholders.

Primary Stakeholders are the people or organizations who are directly impacted by the application.

e.g.- Operators, technician, Quality control Managers, Production Managers, Maintenance staff

Secondary stakeholders are indirectly involved but still have a level of interest in the project.

e.g.- Regulatory Bodies, End user/ Consumers

**Document 2: BA Strategy**



**Answer-**

As the project is small and requirements are enough clear we are going to use the Extended water fall i.e. V Model to complete the project. Following steps are considered to complete the project.

1- **Initiation Phase**:

* Understand the project goals and objectives.
* Identify stakeholders and establish a project charter.

2- **Requirement Gathering and Analysis**:

* Elicit functional and non-functional requirements using suitable techniques.
* Analyze requirements for feasibility and alignment with business objectives.

3- **System Design**:

* Create high-level and detailed design documents (HLD and LLD).
* Map requirements to design components using traceability matrices.

4- **Implementation/Development**:

* Translate designs into code and integrate modules.
* Conduct unit testing for each module.

5- **Validation and Testing**:

* Perform system integration testing and user acceptance testing (UAT).
* Verify requirements against test cases using the V-model.

6- **Deployment and Maintenance**:

* Deploy the system to production after approval.
* Provide ongoing support and address issues as they arise.

**Elicitation Techniques**

As client is using machine since long time he does not have document of its process so we need to go with

* **Observation**:Shadow operators to understand current workflows.
* **Prototyping**: Use mockups to clarify ambiguous requirements.
* **Document Analysis**: For compliance reports.
* **Interviews**: Conduct one-on-one interviews with operators, supervisors, and QA personnel.

**Stakeholder Analysis and RACI Matrix**

Stakeholders are Categorized as primary (users, operators), secondary (IT, QA teams), and tertiary (management, regulatory bodies).

**RACI Matrix**: Define roles and responsibilities:

* **Responsible**: Business Analyst, Developers, Testers.
* **Accountable**: Project Manager, Client Sponsor.
* **Consulted**: QA Team, Operators, Maintenance Staff.
* **Informed**: Regulatory Authorities, Senior Management

**Documents to Write**

 **To complete this project the different documents, need to write at different phases that are**

**1- Business Case Document:** Defines project goals, objectives, and justification**.**

**2- Functional Requirement Specification (FRS):** Details functional and non-functional requirements.

**3- Requirement Traceability Matrix (RTM):** Links requirements to design and testing.

**5- Test Plan and Test Cases:** Outlines testing strategy and test scenarios.

**6- User Manuals and Training Guides**: Provides instructions for system usage.

**7- Change Management Plan:** Details how change requests will be handled.

**8- UAT Sign-Off Form:** Documents client approval after UAT completion **.**

**Document Sign-Off Process**

* **Prepare the Document:** Finalize each document after reviews.
* **Internal Review:** Circulate the document among the internal team for feedback.
* **Client Review**: Share the document with stakeholders for their input.
* **Sign-Off:** Obtain written approval via email or a document sign-off form.

**Client Approval Process**

* Present requirements and designs to the client during scheduled meetings.
* Address any feedback or questions promptly.
* Use email for formal approvals

**Communication Channels**

* **Primary Channels:**
	+ Email for formal communication.
	+ Virtual meetings (Zoom/Teams) for discussions**.**
* **Project Updates:** Weekly status reports via email and review meetings.
* **Collaboration Tools:** Use Microsoft Teams for daily communication**.**

**Handling Change Requests**

* **Request Submission:** Clients submit a change request form detailing the proposed change**.**
* **Impact Analysis:** Assess the impact on scope, timeline, and budget.
* **Approval:** Present findings to stakeholders for approval.
* **Implementation:** Update the requirements and implement the change.

**Progress Updates to Stakeholders**

* **Weekly Status Reports:** Include completed tasks, ongoing work, risks, and mitigation plans.
* **Milestone Reviews:** Present progress at key milestones.
* **Dashboard Updates:** Share real-time updates images, screenshots via email or on Microsoft Team’s call

**UAT and Client Acceptance**

* **Preparation**: Develop UAT test cases and share them with the client.
* **Execution**: Conduct UAT with client involvement.
* **Sign-Off**: Use a UAT sign-off form, signed by the client, confirming project acceptance.

**Document 3- Functional Specifications**

|  |  |
| --- | --- |
| Project name | **Retort Sterilization Application** |
| Customer name | **Tastybite India** |
| Project Version  | 1.0 |
| Project Sponsor | Mr.Raj |
| Project Manager | Mr. Gopal |
| Project Initiation date | 15-01-2025 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Req ID** | **Req Name** | **Req Description** | **Priority** |
| FR0001 | Login | User should be able to log in to the application to perform inventory operations. | 10 |
| FR0002 | User Role Management | Allow administrators to manage user roles and permissions. | 10 |
| FR0003 | Dashboard | Provide a dashboard displaying real-time sterilization process data. | 10 |
| FR0004 | Cycle Control | Enable users to configure and start sterilization cycles with specific parameters. | 10 |
| FR0005 | Data Logging | Automatically log all cycle data, including temperature, pressure, and time. | 10 |
| FR0006 | Batch Traceability | Link cycle data to batch numbers for complete traceability. | 10 |
| FR0007 | Alerts and Notifications | Notify users of deviations, cycle completion, or system issues via email and SMS. | 10 |
| FR0008 | Reporting | Generate detailed compliance and performance reports. | 8 |
| FR0009 | Multi-language Support | Support multiple languages for user interfaces. | 6 |
| FR0010 | ERP Integration | Integrate with ERP systems for seamless inventory and production management. | 7 |
| FR0011 | LIMS Integration | Integrate with Laboratory Information Management Systems for data exchange. | 6 |
| FR0012 | IoT Sensor Connectivity | Connect and monitor IoT sensors for temperature and pressure in real-time. | 10 |
| FR0013 | Scalability | Support future addition of machines and expanded operations. | 6 |
| FR0014 | Audit Trail | Maintain an audit trail for all user activities and system changes. | 9 |
| FR0015 | System Backup and Recovery | Provide automated system backup and recovery mechanisms. | 8 |
| FR0016 | Role-Based Access Control | Restrict access to features based on user roles. | 8 |
| FR0017 | Process Automation | Automate routine tasks like cycle scheduling and maintenance alerts. | 9 |
| FR0018 | Compliance Validation | Validate all cycles against predefined regulatory compliance criteria. | 10 |
| FR0019 | Energy Usage Monitoring | Track and report energy consumption for each cycle. | 6 |
| FR0020 | Remote Access | Allow authorized users to access the system remotely for monitoring and control. | 5 |
| FR0021 | Mobile Application Support | Provide a mobile-friendly interface or application for operators. | 5 |
| FR0022 | Maintenance Scheduling | Schedule and track equipment maintenance tasks. | 7 |
| FR0023 | System Performance Metrics | Monitor and display system performance metrics such as uptime and response time. | 8 |
| FR0024 | Customizable Workflows | Allow users to customize workflows and settings for specific operations. | 8 |
| FR0025 | Multi-Site Management | Enable centralized control and monitoring for multiple facilities. | 5 |

**Document 4- Requirement Traceability Matrix**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Req ID** | **Req Name** | **Req Description** | **Design** | **D1** | **T1** | **D2** | **T2** | **UAT** |
| FR0001 | Login | User must be able to login to access the application | Yes | Yes | Yes | Yes | Yes | YES |
| FR0002 | User Registration | Allow users to register for access to the application | Yes | Yes | Yes | Yes | Yes | YES |
| FR0003 | Password Reset | Provide secure password reset functionality | Yes | Yes | Yes | Yes | Yes | YES |
| FR0004 | Dashboard | Display key metrics and system status on a dashboard | Yes | Yes | Yes | Yes | Yes | YES |
| FR0005 | Cycle Scheduling | Enable scheduling of sterilization cycles | Yes | Yes | Yes | Yes | Yes | YES |
| FR0006 | Real-Time Alerts | Notify users about deviations in real-time | Yes | Yes | Yes | Yes | Yes | YES |
| FR0007 | Batch Management | Manage sterilization batches effectively | Yes | Yes | Yes | Yes | Yes | YES |
| FR0008 | Data Logging | Log process data automatically | Yes | Yes | Yes | Yes | Yes | YES |
| FR0009 | Compliance Reporting | Generate compliance reports | Yes | Yes | Yes | Yes | Yes | YES |
| FR0010 | User Role Management | Manage access levels for users | Yes | Yes | Yes | Yes | Yes | YES |
| FR0011 | System Audit Logs | Maintain logs for accountability | Yes | Yes | Yes | Yes | Yes | YES |
| FR0012 | Integration with ERP | Integrate data with enterprise systems | Yes | Yes | Yes | Yes | Yes | YES |
| FR0013 | IoT Sensor Integration | Monitor critical parameters with sensors | Yes | Yes | Yes | Yes | Yes | YES |
| FR0014 | Energy Usage Optimization | Reduce energy usage during operations | Yes | Yes | Yes | Yes | Yes | YES |
| FR0015 | Multi-Language Support | Provide multi-language support for a diverse user base | Yes | No | No | No | No | No |
| FR0016 | Mobile App Support | Access functionalities through a mobile app | Yes | No | No | No | No | No |
| FR0017 | Scalability | Support the addition of new machines and features | Yes | Yes | Yes | Yes | Yes | YES |
| FR0018 | Historical Data Analysis | Analyze past data trends for improvements | Yes | Yes | Yes | Yes | Yes | YES |
| FR0019 | Operator Training Module | Provide an integrated training module | Yes | Yes | Yes | Yes | Yes | YES |
| FR0020 | Backup and Recovery | Ensure secure data backup and quick recovery | Yes | Yes | Yes | Yes | Yes | YES |
| FR0021 | System Health Monitoring | Monitor the health of connected devices | Yes | No | No | No | No | No |
| FR0022 | Custom Reporting | Generate custom reports based on parameters | Yes | Yes | Yes | Yes | Yes | YES |
| FR0023 | Access from Remote Locations | Enable remote monitoring and control | Yes | No | No | No | No | No |
| FR0024 | Maintenance Scheduling | Schedule and track system maintenance activities | Yes | Yes | Yes | Yes | Yes | YES |
| FR0025 | Security Features | Implement robust security protocols | Yes | Yes | Yes | Yes | Yes | YES |

1.**Document Revisions**

|  |  |  |
| --- | --- | --- |
| **Date**  | **Version Number**  | **Document Changes**  |
| 05/02/20xx  | 0.1  | Initial Draft  |

**2.Approval**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Role | Name | Title | Signature | Date |
| Project Sponsor | Mr. Raj | Director , Operations |  | 15-01-2025 |
| Business Owner | Mr. Jeevan | Business Development |  | 15-01-2025 |
| Project Manager | Mr. Gopal | Senior Manager |  | 15-01-2025 |
| Quality Lead | Ms. Sejal | Quality Assurance Manager |  | 15-01-2025 |
| Architect | Mr. Ashish | System Architect |  | 15-01-2025 |
| Development | Mr. Mahesh | Tech Lead |  | 15-01-2025 |
|  |  |  |  |  |

**3.RACI Chart**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name**  | **Position** | **R** | **A** | **S** | **C** | **I** |
| Mr. Raj | Director |  | x |  |  | x |
| Mr. Gopal | Manager |  |  | x |  | x |
| Mr. Tushar | BA | x | x |  |  |  |
| Ms. Sejal | QA |  |  |  | x |  |
| Mr. Mahesh | Tech Lead |  |  | x | x |  |
| Mr. Govind | Operator |  |  | x |  |  |
| Mr. krishna | Regulatory body |  |  | x | x |  |
| Mr.Abhijit | PLC Engineer |  |  | x | x |  |

**4. Introduction**

**4.1. Business Goals**

**Need:**

* To enhance the efficiency and precision of the sterilization process.
* To reduce manual errors and improve traceability.
* To comply with regulatory requirements for sterilization in manufacturing.

**Organization Goals:**

* Implement a robust IT solution to streamline the retort sterilization process.
* Ensure consistent product quality and regulatory compliance.
* Minimize operational downtime and optimize resource utilization.

**4.2. Business Objectives**

The IT solution aims to:

* Automate the retort sterilization process.
* Provide real-time monitoring and control of sterilization parameters.
* Maintain detailed logs for compliance and audit purposes.
* Offer integration with existing systems for seamless data exchange.

**4.3. Business Rules**

* Adherence to industry standards and regulatory frameworks (e.g., FDA, ISO).
* Strict control over process parameters such as temperature, pressure, and time.
* Role-based access control for system users.
* Data retention policies as per compliance requirements.

**4.4. Background**

The project was initiated to address inefficiencies in the manual sterilization process, which posed risks of inconsistency, regulatory non-compliance, and increased operational costs. By automating and digitizing the process, the organization expects to achieve greater reliability, compliance, and operational efficiency.

**4.5. Project Objective**

* Develop a user-friendly software solution for managing retort sterilization processes.
* Align with business objectives by improving process accuracy and compliance.
* Ensure interoperability with existing systems for a holistic approach to process management.

**4.6. Project Scope**

**4.6.1. In-Scope Functionality**

* Automation of retort sterilization workflows.
* Real-time monitoring and control of sterilization parameters.
* Audit trail and reporting features.
* Alerts and notifications for deviations or errors.
* Integration with ERP/LIMS systems.

**4.6.2. Out-of-Scope Functionality**

* Hardware development for retort machines.
* Integration with unrelated manufacturing systems.

**Assumptions:**

* Retort machines are compatible with the proposed software.
* Necessary resources and expertise will be available during the project.

**6. Constraints**

* Dependency on third-party systems for integration.
* Regulatory changes during the project lifecycle.

**7. Risks**

**Technological Risks**

* Integration challenges with legacy systems.
* Software bugs affecting sterilization accuracy.

**Skills Risks**

* Lack of availability of domain experts for testing and validation.

**Political Risks**

* Organizational resistance to adopting new technology.

**Business Risks**

* Delays in deployment impacting production timelines.

**Requirements Risks**

* Misinterpretation of sterilization compliance requirements.

**Other Risks**

* Unexpected downtime during the transition phase.

**8. Business Process Overview**

**8.1. Legacy System (AS-IS)**

The current process relies on manual data entry and physical monitoring of sterilization cycles, leading to inconsistencies and limited traceability.

**Process Flow Diagram:**
(Include a diagram showing the manual process steps.)



**8.2. Proposed Recommendations (TO-BE)**

The proposed system automates data capture and process monitoring, ensuring consistent compliance and efficiency.

**Process Flow Diagram:**
(Include a diagram showing the automated process steps.)



**9. Business Requirements**

List functional and non-functional requirements with priority levels:

**Functional Requirements**

* Ability to configure and monitor sterilization parameters.
* Generate detailed compliance reports.
* Provide role-based access control.

**Non-Functional Requirements**

* High system availability and reliability.
* Secure storage of sensitive data.

**10. Appendices**

**10.1. List of Acronyms**

* LIMS: Laboratory Information Management System
* ERP: Enterprise Resource Planning

**10.2. Glossary of Terms**

* Retort Sterilization: A process to sterilize products using heat and pressure.

**10.3. Related Documents**

* Regulatory guidelines for sterilization.
* User manuals for retort machines.