**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?**

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?**

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?**

**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-premise or cloud servers for application hosting and data storage.**
  + **Secure network infrastructure for real-time communication.**
* **Operator Terminals:**
  + **HMI (Human-Machine Interface) devices or industrial-grade tablets for operator access.**

**3. Software Resources**

* **Frontend Frameworks: React, Angular, or Vue.js 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 (if applicable).**
* **Training and Support: Costs for training sessions and ongoing support.**
* **Contingency Budget: Additional funds to handle unexpected issues.**