**Project Title: Development and Implementation of Retort Sterilization Application for**

 **Tastybite India**

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**Situation / Problem-**

Tastybite India currently lacks an automated and integrated system to monitor, control, and document the sterilization process in retort machines. This manual approach is time-consuming, prone to errors, and inefficient in meeting regulatory compliance standards.

**Purpose Statement (Goals):**

The purpose of this project is to analyze, design, and implement a Retort Sterilization Application to enhance operational efficiency, ensure regulatory compliance, and improve product quality through automation and real-time monitoring.

**Project Objectives:**

* **Automated Process Control:** Implement a solution to control and monitor sterilization cycles precisely.
* **Data Logging and Traceability:** Ensure comprehensive data recording for regulatory compliance and audits.
* **User-friendly Interface:** Provide an interactive dashboard for operators and supervisors.
* **System Integration:** Enable seamless integration with hardware (PLCs, IoT devices) and enterprise systems (ERP, LIMS).
* **Compliance Adherence:** Meet FDA, WHO, and other relevant regulatory standards.

**Success Criteria:**

* **Enhanced Data Accessibility:** Improve availability and accessibility of sterilization cycle records, logs, and reports.
* **Reduced Downtime:** Minimize system-related delays through efficient automation.
* **Improved Operational Efficiency:** Ensure faster cycle processing and reduced manual intervention.
* **Regulatory Compliance:** Successfully pass regulatory audits with the system-generated reports.

 **Objectives**

1. **Automated Process Control:**
	* Replace manual control of retort machines with an automated system to regulate temperature, pressure, and sterilization duration.
	* Implement real-time adjustments for deviations during sterilization**.**
2. **Data Logging and Traceability:**
	* Log each cycle's sterilization data (temperature, pressure, time).
	* Maintain batch traceability by linking sterilization data to product batches**.**
3. **User-friendly Interface:**
	* Develop an interactive dashboard for operators to monitor and control processes.
	* Provide role-based access for supervisors, operators, and maintenance teams.
4. **Integration:**
	* Seamlessly connect with existing hardware (retort machines, sensors, PLCs).
	* Enable ERP and LIMS integration for data sharing across departments**.**
5. **Compliance Adherence:**
	* Incorporate features to meet regulatory standards (e.g., FDA, HACCP).
	* Provide validation tools for process qualification and audits.

 **Methods/Approach**

**1. Requirement Analysis**

* Conduct interviews with stakeholders:
	+ Operators: Understand pain points in the current process.
	+ QA Teams: Identify data requirements for compliance.
	+ Regulatory Experts: Ensure all compliance standards are addressed**.**
* Develop a comprehensive Requirements Specification Document:
	+ Functional requirements: Cycle programming, alarms, reporting.
	+ Non-functional requirements: Performance, security
	+ Integration requirements: Hardware ( IoT devices) and software (ERP/LIMS).

**2. Solution Design and Selection**

* Finalize the system architecture:
	+ Frontend: Operator dashboard, admin panel.
	+ Backend: Process control, data storage, reporting.
	+ Database: Structured schema for batch data and historical logs**.**

**3. Prototyping and Development**

* Build prototypes for critical features:
	+ Process control module.
	+ Real-time monitoring and alarms.
	+ Reporting interface**.**
* Develop and integrate:
	+ Frontend, Backend Database: Design schemas for batch data, cycle logs, and audit trails.
	+ Test prototypes in a controlled environment.

**4. Implementation and Training**

* Deploy the system in a phased manner:
	+ Pilot implementation on one retort machine.
* Train stakeholders:
	+ Operators: On using the new dashboard and alarms.
	+ Technical Staff: On troubleshooting and maintenance.

**5. Go Live**

* Conduct final validation tests with all stakeholders.
* Launch the system and monitor performance for a defined stabilization period

**Resources:**

**Project Team:**

* Business Analyst (Requirement gathering, design documentation).
* Developers (Frontend, backend, database, integration).
* QA Testers (Validation and compliance testing).
* Project Manager (Overall coordination).

**Business Stakeholders**-

* Project team members from Tastybite India (operations, QA, IT teams).
* External consultants for system integration.
* **Time:**

Project implementation within **5 months** max.

* 1 month for requirement gathering.
* 0.5 months for design.
* 2 months for development and prototyping.
* 1 month for testing and training.
* 0.5 months for deployment and stabilization.
* **Budget:**

 **Estimated Costs:25,00,000**

* Hardware: Rs. 12,00,000.
* Software licenses: Rs. 3,00,000.
* Development, Training and Services: Rs. 10,00,000

**Deliverables Summary**

1. Requirements Specification Document
2. System Design Document
3. Prototype and Pilot Implementation
4. Training Manuals(operational)
5. Final Application with Documentation
6. Compliance Reports