FACULTY OF COMPUTING
UTM Johor Bahru

SECJ 2203: Software Engineering
Project Assignment
Semester 01, 2025/2026

Mark Distribution:

Assessment	Week (Briefing)	CLO & Mark	Deliverables/Task	Week (Submit)
Assignment 1 (A1)	W3	CLO1: 5%	**Deliverables**: Project Proposal	W5
Assignment 2 (A2)	W5	CLO1: 7%	**Deliverables**: System Requirements Specification	W7
Assignment 3 (A3)	W9	CLO2: 15%	**Deliverables**: System Design Document	W12
Assignment 4 (A4)	W12	CLO2: 13%	**Deliverables**: System Testing Document	W15
Video on Leadership		CLO3: 6%	Reflection videos on leadership must be done individually. The video must be uploaded to the ePortfolio system. Every member in the team must experience leading the group at least for one assignment. **4 members per group is the most ideal**.	W15
Peer Review – Teamwork		CLO3: 4%	Every member in the group must rate the other teammate from the aspect of teamworking using the teamXplore tool for each assignment.	W5, W7, W12, W15

Case Study: Development of "QMS-Flow" - An Integrated Software for ISO 9001:2015 Document Control and Quality Management

Abstract

This case study outlines the analysis, design, and functional requirements for **"QMS-Flow,"** a web-based software solution designed to help organizations manage their Quality Management System (QMS) in compliance with the ISO 9001:2015 standard. The primary challenge faced by many companies is the burdensome, error-prone, and inefficient nature of manual, paper-based, or spreadsheet-driven QMS processes. QMS-Flow aims to solve this by providing an integrated, automated, and centralized platform covering critical QMS modules, including Audit Management, Change Control, Corrective Actions, and more.

1. Introduction & Problem Statement

Company XYZ Sdn. Bhd. is a medium-sized manufacturing firm based in Malaysia that produces high-precision electronic components. They are ISO 9001:2015 certified, which is crucial for retaining their key international clients. However, their current QMS relies on a combination of shared network drives, spreadsheets, and manual paper trails.

This has led to several significant problems:

- **Audit Inefficiency:** Internal audits are difficult to schedule and track. Audit findings are recorded in separate documents, making it hard to ensure follow-up actions are completed.
- **Lack of Document Control:** Multiple versions of Standard Operating Procedures (SOPs) exist, causing confusion on the factory floor. There is no formal "locking" mechanism for documents under review.
- **Poor Traceability:** Tracking customer complaints, corrective actions (CAPAs), and employee training records is a manual, time-consuming process. It's nearly impossible to link a customer complaint to a specific corrective action and subsequent employee retraining.
- **Compliance Risk:** Missed equipment calibration dates and poor record-keeping for management reviews have been flagged as minor non-conformities in external audits, posing a risk to their certification.[1]

The management of Company XYZ has decided to invest in a dedicated software solution to digitize their entire QMS process, ensuring compliance, improving efficiency, and providing management with real-time visibility.

2. Proposed Solution: The "QMS-Flow" System

The proposed solution is **QMS-Flow**, a centralized, web-based application built on a modern technology stack. The system will provide role-based access to employees, managers, and quality assurance personnel. Its core design philosophy is to create a single source of truth for all QMS-related activities.

The system will be composed of several interconnected modules, each addressing a specific clause or requirement of the ISO 9001:2015 standard.

3. System Modules & Functionality

The QMS-Flow system is designed with a modular architecture. Below are the core modules and their functionalities.

3.1 Audit Management

This module facilitates the planning, execution, and follow-up of internal and external audits.

- **Audit Schedules:** Quality managers can create an annual audit plan, scheduling audits for different departments or processes with assigned auditors and dates.[2]
- **Audit Checklists:** Users can create reusable audit checklists from templates based on specific ISO 9001:2015 clauses or internal procedures.
- **Audit Findings:** During an audit, auditors can log findings directly into the system, classifying them as Conformity, Observation, or Non-Conformity (Minor/Major).
- **Assign Findings:** Each finding can be assigned to a specific user (e.g., a department head) with a target completion date for corrective action. The system sends automated email reminders as deadlines approach.

3.2 Change Control

This module ensures that any changes to critical documents or processes are formally reviewed, approved, and recorded.

- **Document Repository:** A centralized repository for all controlled documents (SOPs, Work Instructions, Policies).
- **Version Control:** The system automatically handles versioning (e.g., v1.0, v1.1, v2.0) upon approval of changes.
- **Review & Approval Workflow:** When a user requests a change, the document is automatically "locked" (read-only for others). It then enters a predefined approval workflow, notifying reviewers and approvers.
- **Audit Trail:** Every action—view, download, change request, approval—is logged with a user and timestamp.

3.3 Management Review

This module automates the process of conducting and documenting management review meetings as required by the standard.

- **Meeting Scheduler:** Schedule management review meetings and send automated email invitations to all required attendees.
- **Agenda Management:** Assign agenda items (e.g., review of quality objectives, audit results, customer feedback) to different individuals.
- **Minutes & Action Items:** Record meeting minutes directly in the system and assign action items from the discussion to users with target dates.

3.4 Customer Complaints

This module provides a systematic way to handle customer feedback and complaints.

- **Complaint Logging:** Any employee can log a customer complaint with details like customer name, product, complaint nature, and date.
- **Investigation & Assignment:** The Quality Manager can assign the complaint to a user for investigation. A target date for resolution is set, and email alerts are triggered.
- **Link to Corrective Actions:** A complaint can be directly linked to a new or existing Corrective Action in the CAPA module to ensure the root cause is addressed.

3.5 Corrective Actions (CAPA)

This is a central module for managing non-conformities and implementing preventive measures.

- **CAPA Initiation:** Corrective actions can be initiated from an audit finding, a customer complaint, or as a standalone action.
- **Root Cause Analysis (RCA):** The system guides users through RCA methodologies (e.g., 5 Whys, Fishbone Diagram).
- **Custom Form Builder:** A **drag-and-drop interface** allows administrators to create custom forms for different types of CAPAs, ensuring all necessary information is captured.
- **Effectiveness Verification:** After implementation, the system schedules a follow-up task to verify that the corrective action was effective.

3.6 Employee Training

This module manages employee competencies and training records.

- **Training Matrix:** Add training requirements for specific roles, departments, or individual employees.
- **Record Keeping:** Log all completed trainings, including details like trainer, date, and training materials.
- **Evaluation & Effectiveness:** Track post-training evaluations to ensure competency was achieved. The system can flag when refresher training is due.

3.7 Device & Equipment Management

This module serves as a central registry for all company equipment and devices.

- **Equipment Registry:** Use ready-made forms to add all devices/equipment with unique IDs, location, manufacturer details, and supplier information.
- **Document Linking:** Link relevant documents like user manuals, purchase orders, or maintenance procedures to each equipment entry.

3.8 Calibrations

This module ensures that monitoring and measuring equipment remains accurate and reliable.

- **Calibration Scheduling:** Add equipment to the system and define its required calibration frequency (e.g., annually, semi-annually).
- **Method Definition:** Define the standard calibration method to be used for each type of device.
- **Record & Alerts:** Record calibration results (Pass/Fail), upload calibration certificates, and set automated alerts to notify personnel before the next calibration is due.

4. Conclusion & Expected Outcomes

The implementation of **QMS-Flow** at Precision Manufacturing is expected to yield significant benefits:

- **Enhanced Compliance:** Automation and alerts will drastically reduce the risk of non-conformance with the ISO 9001:2015 standard.
- **Increased Efficiency:** Digitizing workflows will save hundreds of man-hours currently spent on manual paperwork, tracking, and follow-ups.
- **Improved Visibility & Decision Making:** Centralized dashboards will provide management with a real-time overview of the QMS health, from overdue CAPAs to pending document approvals.
- **Stronger Quality Culture:** By making QMS processes more accessible and transparent, the system will foster a greater sense of ownership and accountability among all employees.

This case study demonstrates how a well-engineered software solution can transform a complex, compliance-driven process like management from a bureaucratic burden into a strategic advantage.