Master Course Group Project: The Living Quality System Challenge
Course Title: "Can Your Lab Survive the Next Auditor?" **Weight:** 25% of the Total Course Grade **Platform Partner:** Online Quality Management System

1. Project Overview & Philosophy:

In clinical laboratory medicine, "quality" is frequently taught as a static, bureaucratic exercise. Technologists are trained to view compliance as a mountain of physical paper logs, binder-bound SOPs, and a frantic scramble to clean up the lab once a year before an accreditation survey (CAP, CBAHI, or ISO). This legacy approach is a liability. It creates a "reactive" culture, leads to severe transcription errors, and compromises patient safety.

The Living Quality System Challenge redefines the role of the Laboratory Quality Officer. In this term-long group project, student teams will act as the **Laboratory Quality & Governance Unit** for a **Clinical Lab**. Using a digital platform, each team will transform fragmented, paper-based operational logs, SOPs, and incident reports into a live, cohesive, and continuously audit-ready **Digital Quality Operating System**.

2. Team Mission & Core Tasks:

Each student team (3–4 students per group) will be provisioned with a dedicated workspace on the **Online QMS** platform. Over the course of the semester, your team must execute the following five project phases:

Phase 1: Document Control & Standard Mapping

- **The Task:** Take the provided raw clinical materials (including a technical procedure for Blood Culture Reporting, a calibration log, and a staff training record) and upload them to the online Document Control module.
- **Accreditation Mapping:** Classify and digitally link these documents to the relevant national and international standards, specifically:
  - **CBAHI Hospital Laboratory Standards (LB.17 - Safety, LB.25 - Critical Results, LB.31 - QMS)**
  - **CAP Accreditation Checklist Requirements (GEN.20375 - Document Control, GEN.20377 - Record Retention)**
  - **ISO 15189 Quality and Competence Standards**

Phase 2: Incident Creation & Logging

- **The Task:** Select one realistic, pre-analytical or analytical clinical incident from the provided case file, examples include:
  - ***Case A:*** A 24-hour delay in reporting a preliminary positive blood culture for a NICU patient because the paper result slip was lost in a physical tracking rack dispute.
  - ***Case B***: A critical bedside barcode printing bypass in the pediatric ward, where nurses "batch-printed" labels at a centralized station, resulting in a patient misidentification and a corrupted LIS timestamp.
- **System Logging:** Log this incident in the QMS Incident Module, complete with specimen IDs, timestamps, affected departments (e.g., ICU, Emergency), and the clinical impact.

Phase 3: Root Cause Analysis (RCA) & Evidence Linkage

- **The Task:** Conduct a rigorous, professional Root Cause Analysis within the Online QMS platform.
- **Methodology:** Utilize the **5 Whys** and **Cause-and-Effect (Fishbone) Diagram** tools.
- **The Digital Linkage:** You must prove your hypotheses by linking evidence from your workspace. Link the incident directly to the flawed SOP (Phase 1), the staff's training record (or lack thereof), and the relevant committee minutes where the workflow was discussed.

Phase 4: Corrective and Preventive Action (CAPA) Design

- **The Task:** Formulate a comprehensive, actionable CAPA plan on the Online QMS platform to ensure this incident can never recur.
- **Requirements:** Your CAPA must explicitly define:
  - The **Immediate Corrective Action** (the containment phase).
  - The **Preventive Action** (system/process redesign, e.g., implementing an HIS software-level hard stop to prevent batch-printing).
  - The designated **Owner** (e.g., Microbiology Supervisor, CNO) and a realistic **Time-Bound Deadline**.
  - The **Follow-Up Evidence Criteria** (how you will prove to an auditor that the CAPA is closed and effective).

Phase 5: Predictive Quality Intelligence

- **The Task:** Move beyond reactive compliance. Use the Online QMS Analytics module to generate a "Quality Intelligence Insight."
- **Prompt:** Ask yourselves: *"What early warning signals in our daily operational data (e.g., refrigerator temperature fluctuations, LIS timestamp gaps, or staff punch-clock deviations) could have predicted this incident before it harmed a patient?"* Propose a set of live dashboard indicators for the Laboratory Director.

3. The Creative Climax: "Can Your Lab Survive the Next Auditor?"

At the end of the semester, static presentations are prohibited. Instead, your team will participate in a **Live Mock Audit Simulation**. An experienced Laboratory Auditor (your instructor) will log directly into your group's **QMS workspace** in real time and stress-test your system. The auditor will pick random points in your incident-to-improvement storyline and demand immediate, digitized proof:

1. *"You had a critical patient misidentification in the NICU. Show me the exact version of the Specimen Collection SOP that was active on the day of that incident."*
2. *"You state the nurse was retrained. Show me her verified, digitally signed training record for handheld barcode scanning."*
3. *"Your CAPA states you implemented a printer blocking software rule. Show me the IT validation record proving this interface change was tested before go-live (CAP GEN.43022)."*
4. *"If your Microbiology supervisor leaves tomorrow, how does this Online QMS system preserve the 'institutional memory' of this CAPA so the error doesn't repeat?"*

4. Deliverables & Submission Checklist

Each team must submit a single, comprehensive digital package containing:

1. **Fully Configured QMS Workspace:** Documents uploaded, standards mapped, incident logged, and CAPA active.
2. **The Incident-to-Improvement Storyline:** A 2-page narrative tracing the entire lifecycle of your chosen case (from initial clinical error to final CAPA closure).
3. **Executive Dashboard Presentation:** A 5-minute pitch to the Hospital Executive Committee (HEC) presenting your "Predictive Quality Intelligence" dashboard.
4. **Relational Reflection Essay:** A 500-word team essay addressing: *"How does transitioning from a paper-based, reactive compliance model to a digital, AI-assisted quality operating system change the professional role and daily work of the Laboratory Quality Officer?"*

5. Grading and Rubric (100% Scale)

Area	*Weight*	*Exceeded Expectations*	*Met Expectations*	*Not Met*
Document Control & Mapping	**20%**	All SOPs and files are uploaded with flawless metadata. Mapping to CAP, CBAHI, and ISO standards is complete, accurate, and scientifically justified.	Most documents are mapped correctly, but minor metadata is missing or mapping to standards lacks clear clinical justification.	Incomplete document upload, or incorrect standard mapping that violates regulatory guidelines.
Incident Analysis & CAPA Quality	**25%**	Incident is logged with high clinical realism. RCA (5 Whys/Fishbone) is deep, identifying systemic design flaws rather than individual blame. CAPA is highly actionable, time-bound, and includes robust follow-up evidence.	Incident logging is clear. RCA is completed, but relies moderately on "individual blame" (e.g., "the nurse made a mistake") rather than system re-engineering.	Shallow RCA or unfeasible CAPA that does not prevent recurrence.
Evidence Linkage & Audit Readiness	**20%**	Team demonstrates absolute audit-readiness during the live simulation. Every auditor request is retrieved in under 15 seconds through flawless digital linkage.	Team is mostly audit-ready, but experiences minor delays or lacks direct evidence linkage for some training/SOP records.	Major failure to produce requested evidence during the mock audit, resulting in critical compliance citations.
Learning & Knowledge Retention	**20%**	The Online QMS system is effectively configured as "organizational memory." Lessons learned are clearly documented, and the workflow is designed to survive staff turnover.	Lessons learned are documented, but are stored as static text rather than being structurally integrated into the workflow.	No evidence of knowledge retention or institutional memory configuration.
Creativity & Presentation	**15%**	HEC presentation is highly professional and persuasive. Proposes innovative, high-impact dashboard indicators to predict and prevent future clinical risks.	Presentation is clear and covers the necessary slides, but dashboard indicators are standard or lack predictive insight.	Poor presentation quality, or generic metrics that add no value to the Hospital Executive Committee.