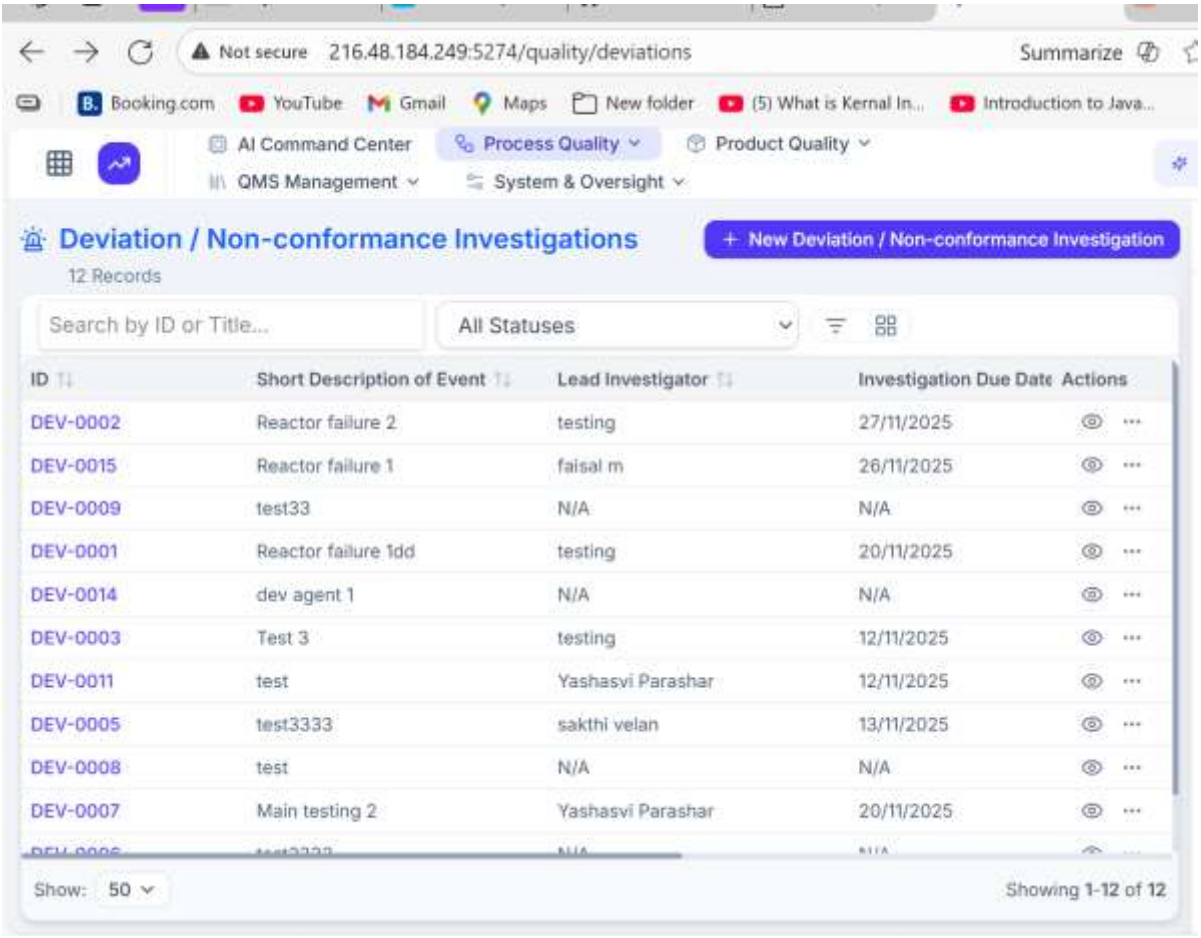
Task 2: QMS Modules in Supply Chain OS

Submitted by Lokesh Bheemagani

1. **In-Process Quality: Deviation Management:**
   - **DEV-0002 (Reactor Failure, Major Classification, Product Impact)**



The Deviation List View showing "Overdue"

Deviation / Non-conformance Investigation DEV-0002

Status	Initiator	Confidentiality
Effectiveness Check Pending	faisal m	Confidential Quality Record

1. Event Details

Short Description of Event
Reactor failure 2

Date & Time of Discovery
Nov 5, 2025, 10:07 AM

Initiator
faisal m

Detected By
faisal m

Source of Event
Manufacturing

Deviation Classification Tags
Environmental, Personnel

GMP Area/Process Affected
QC Micro Lab, API Manufacturing

Area/Department Owner
faisal m

Detailed Description
NA

Immediate Actions Taken
NA

Interim Containment Actions
NA

2. QA Triage & Impact Assessment

Lead Investigator
testing

Supporting Investigation Team
a6c853d0-31c0-4d63-b882-530ec11c3400

Investigation Due Date
Nov 27, 2025

Deviation Classification
Major

Justification for Classification

Repeat Deviation?
No

Preliminary Impact Assessment
test

Product Impact?
Yes

Overall Notification Required?
TBD

Severity (S)
3 - Moderate

Occurrence (O)
3 - Possible

Detectability (D)
3 - Low

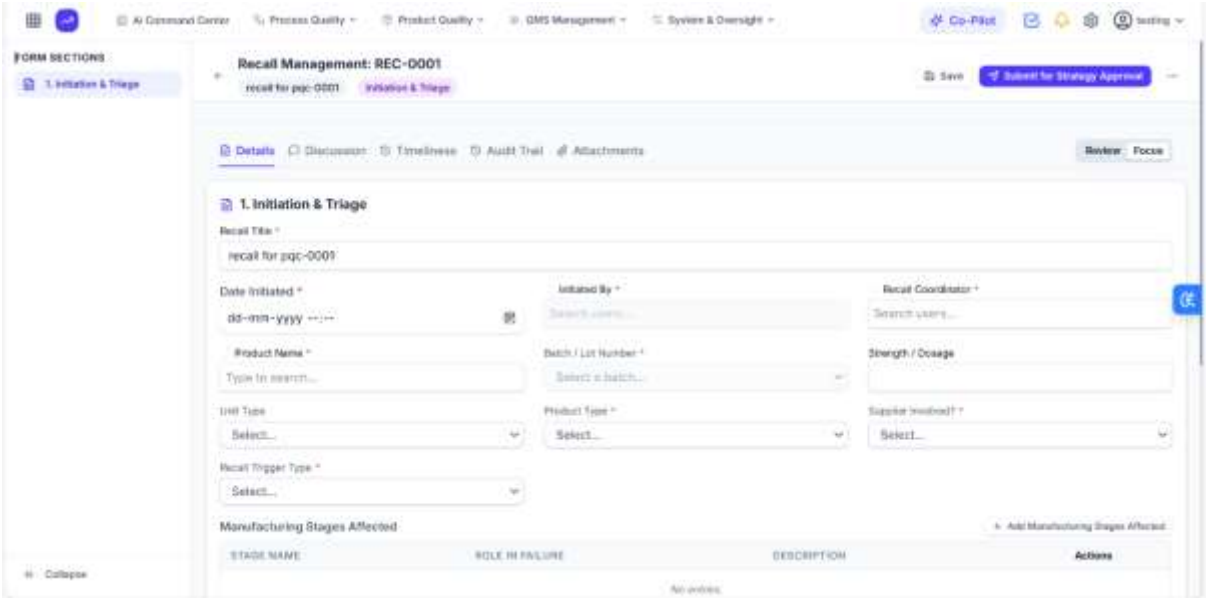
Initial RPN (S x O x D)
27

Formal Risk Scoring Outcome
Medium

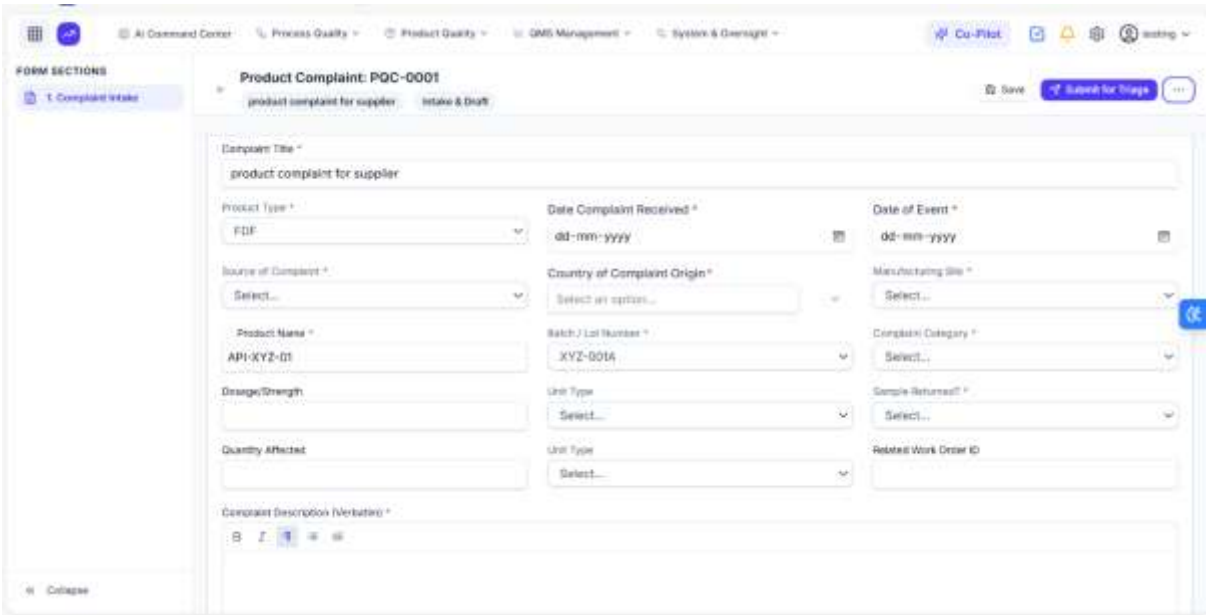
Generated on: 1/12/2025 Page 1 of 2

2. In-Product Quality: Recalls & Complaints:

- **Complaint PQC-0001 triggered Recall REC-0001 for batch XYZ-001A**
- **Recall Initiation:**



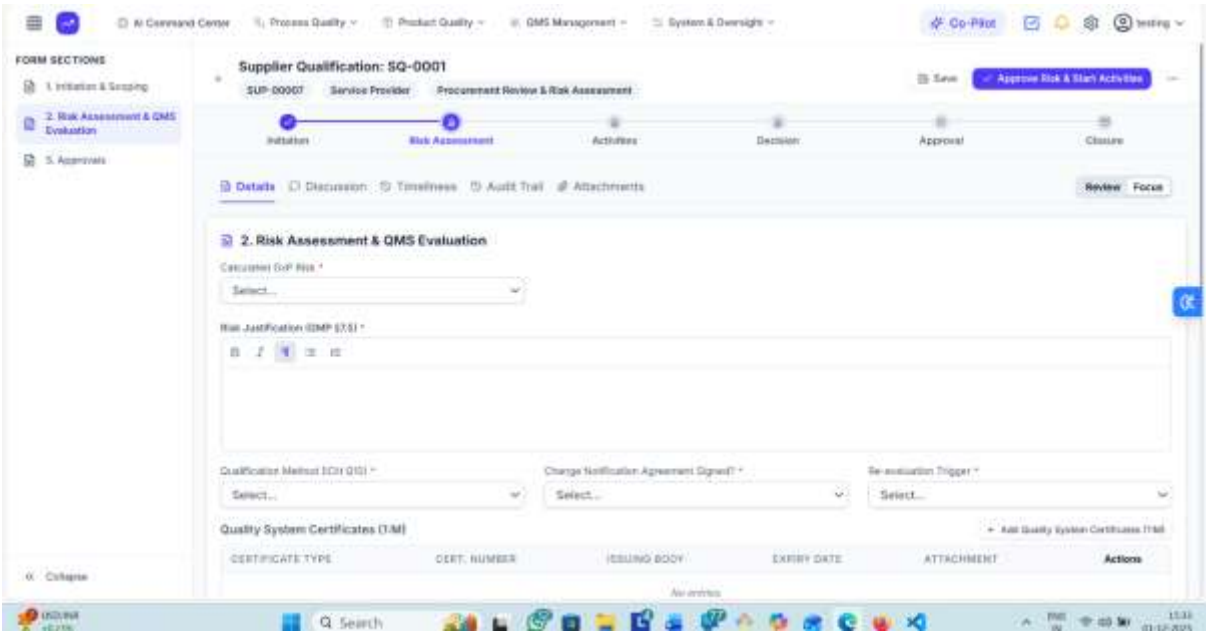
- **Product Complaint:**



3. Supplier Quality Management:

- **Supplier SUP-00007 and the requirement for "Data Integrity Agreements"**

- **Supplier Risk Assessment:**



4. Role Perspectives: QA vs. Production:

QA Officer	Production Manager
Compliance Guardian	Output Owner
Focus: Audit readiness, Patient Safety (SAE-0001 reporting deadlines)	Focus: Speed, Efficiency (Fixing DEV-0002 to restart the reactor)

5. End-to-End Quality Flow: