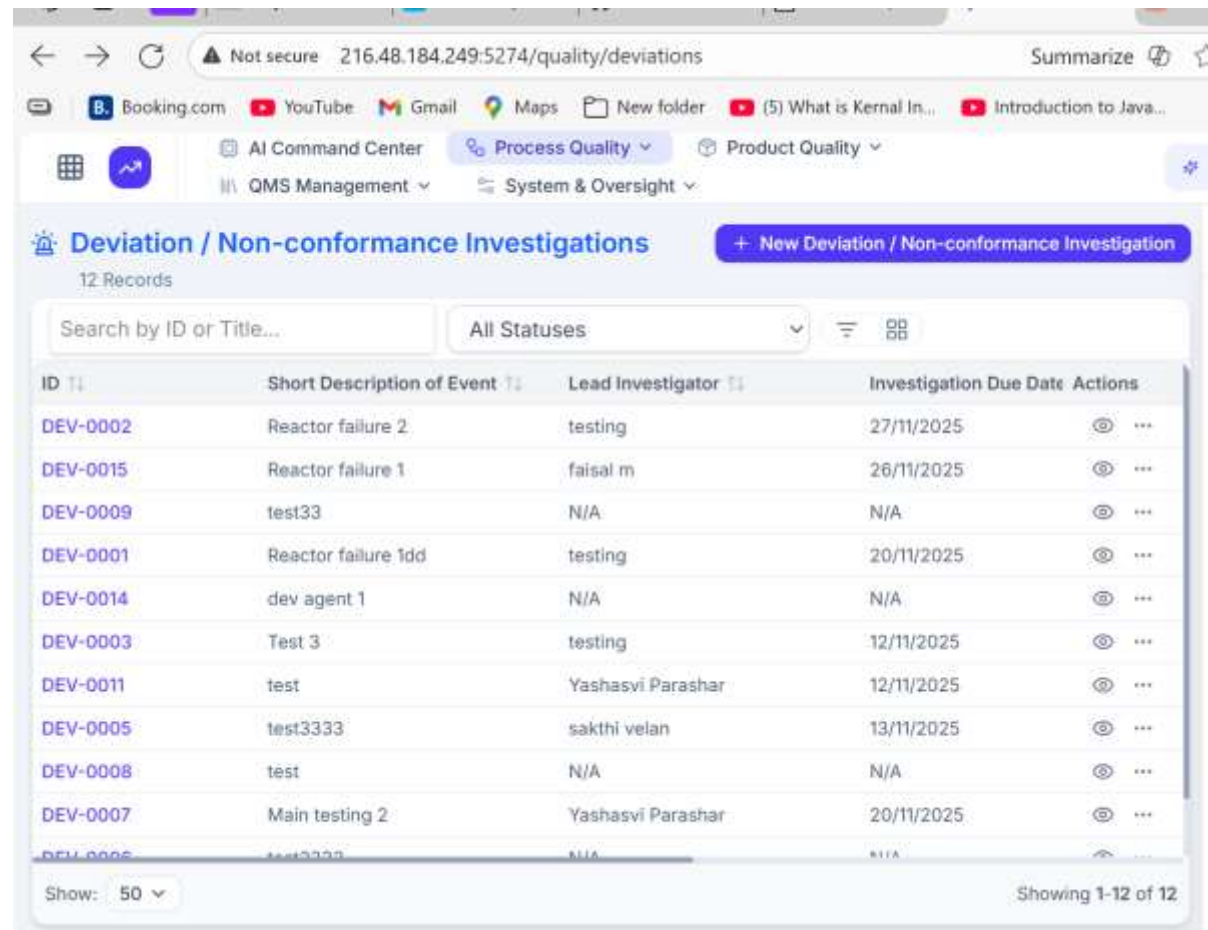


Task 2: QMS Modules in Supply Chain OS

Submitted by Lokesh Bheemagani

1. In-Process Quality: Deviation Management:

➤ DEV-0002 (Reactor Failure, Major Classification, Product Impact)



ID	Short Description of Event	Lead Investigator	Investigation Due Date	Actions
DEV-0002	Reactor failure 2	testing	27/11/2025	👁️ ...
DEV-0015	Reactor failure 1	faisal m	26/11/2025	👁️ ...
DEV-0009	test33	N/A	N/A	👁️ ...
DEV-0001	Reactor failure 1dd	testing	20/11/2025	👁️ ...
DEV-0014	dev agent 1	N/A	N/A	👁️ ...
DEV-0003	Test 3	testing	12/11/2025	👁️ ...
DEV-0011	test	Yashasvi Parashar	12/11/2025	👁️ ...
DEV-0005	test33333	sakthi velan	13/11/2025	👁️ ...
DEV-0008	test	N/A	N/A	👁️ ...
DEV-0007	Main testing 2	Yashasvi Parashar	20/11/2025	👁️ ...
DEV-0006	test3333	N/A	N/A	👁️ ...

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	Initiator
Nov 5, 2025, 10:07 AM	faisal m
Detected By	Source of Event
faisal m	Manufacturing
Deviation Classification Tags	GMP Area/Process Affected
Environmental, Personnel	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	Supporting Investigation Team
testing	a6c853d0-31c0-4d63-b882-530ec11c3400
Investigation Due Date	Deviation Classification
Nov 27, 2025	Major
Justification for Classification	
Repeat Deviation?	
No	
Preliminary Impact Assessment	
test	
Product Impact?	Overall Notification Required?
Yes	TBD
Severity (S)	Occurrence (O)
3 - Moderate	3 - Possible
Detectability (D)	Initial RPN (S x O x D)
3 - Low	27
Formal Risk Scoring Outcome	
Medium	

Generated on: 1/12/2025

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2. In-Product Quality: Recalls & Complaints:

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

AI Command Center | Process Quality | Product Quality | QMS Management | System & Oversight | Co-Pilot | Settings

FORM SECTIONS

1. Initiation & Triage

Recall Management: REC-0001
recall for pqc-0001 | Initiation & Triage

Save | Submit for Strategy Approval

Details | Discussion | Timeline | Audit Trail | Attachments | Review | Focus

1. Initiation & Triage

Recall Title *
recall for pqc-0001

Date Initiated *
dd-mm-yyyy

Initiated By *
Search users...

Recall Coordinator *
Search users...

Product Name *
Type in search...

Batch / Lot Number *
Select a batch...

Strength / Dosage

Unit Type
Select...

Product Type *
Select...

Supplier Involved? *
Select...

Recall Trigger Type *
Select...

Manufacturing Stages Affected
Add Manufacturing Stages Affected

STAGE NAME	ROLE IN FAILURE	DESCRIPTION	Actions
No entries.			

Collapse

➤ **Product Complaint:**

AI Command Center | Process Quality | Product Quality | QMS Management | System & Oversight | Co-Pilot | Settings

FORM SECTIONS

1. Complaint Intake

Product Complaint: PQC-0001
product complaint for supplier | Intake & Draft

Save | Submit for Triage

Complaint Title *
product complaint for supplier

Product Type *
PDF

Date Complaint Received *
dd-mm-yyyy

Date of Event *
dd-mm-yyyy

Source of Complaint *
Select...

Country of Complaint Origin *
Select an option...

Manufacturing Site *
Select...

Product Name *
API-KYZ-01

Batch / Lot Number *
XYZ-001A

Complaint Category *
Select...

Dosage/Strength

Unit Type
Select...

Sample Returned? *
Select...

Quantity Affected

Unit Type
Select...

Related Work Order ID

Complaint Description (Verbatim) *
B I T

Collapse

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:

