A pragmatic approach to AI in HealthTech

A focus on empowering the Quality Assurance and Regulatory Affairs (QA/RA) professional

26 Aug 2025

Disclaimer

The analyses, their interpretation, and related information contained herein are made and provided subject to the assumptions, methodologies, caveats, and variables described in this report and are based on third party sources and data reasonably believed to be reliable. No warranty is made as to the completeness or accuracy of such third party sources or data.

As with any attempt to estimate future events, the forecasts, projections, conclusions, and other information included herein are subject to certain risks and uncertainties, and are not to be considered guarantees of any particular outcome.

Today’s presenters

Mike King
Senior Director,
Strategy and Commercialization

Mike is the Senior Director of Strategy and Commercialization within the Technology Solutions business of IQVIA.

- Responsible for optimizing business workflow across the Regulatory, Quality and Safety Solutions.
- 20+ years leading global teams in Regulatory Affairs and Quality Assurance across a range of therapeutic areas

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Anusha Gangadhara
Associate Director,
Product Owner

Anusha is the RIM Smart Product Manager and MedTech SME.

- Responsible for product definitions built from business requirements
- Define functionality of solutions to meet Global Regulations.
- 15+ years leading global teams in Regulatory Affairs and Quality Assurance.

Anusha.Gangadhara@iqvia.com

Todd Neal
Senior Product Manager,
IT Design & Development

Todd is the Senior Product Manager for a range of end-to-end processes in IQVIA’s Quality Management System solution

- Responsible for Complaint Management, Post-Market Surveillance and Supplier Management modules of
- 30+ years experience in Enterprise Software and in developing solutions for healthcare

Todd.Neal@iqvia.com

IQVIA TECHNOLOGIES

To what extent is AI used within your company QMS processes?

Please select the most suitable below:

1. No AI is used
2. We are considering the use of AI in some targeted QMS processes
3. Some of our QMS processes use AI, however we are looking to broaden its use
4. AI is used to a large extent, within appropriate processes and where suitable for the organization.

Navigating the world of QA/RA in the era of AI enabled solutions

Mike King
Senior Director, Strategy & Commercialization

IQVIA TECHNOLOGIES

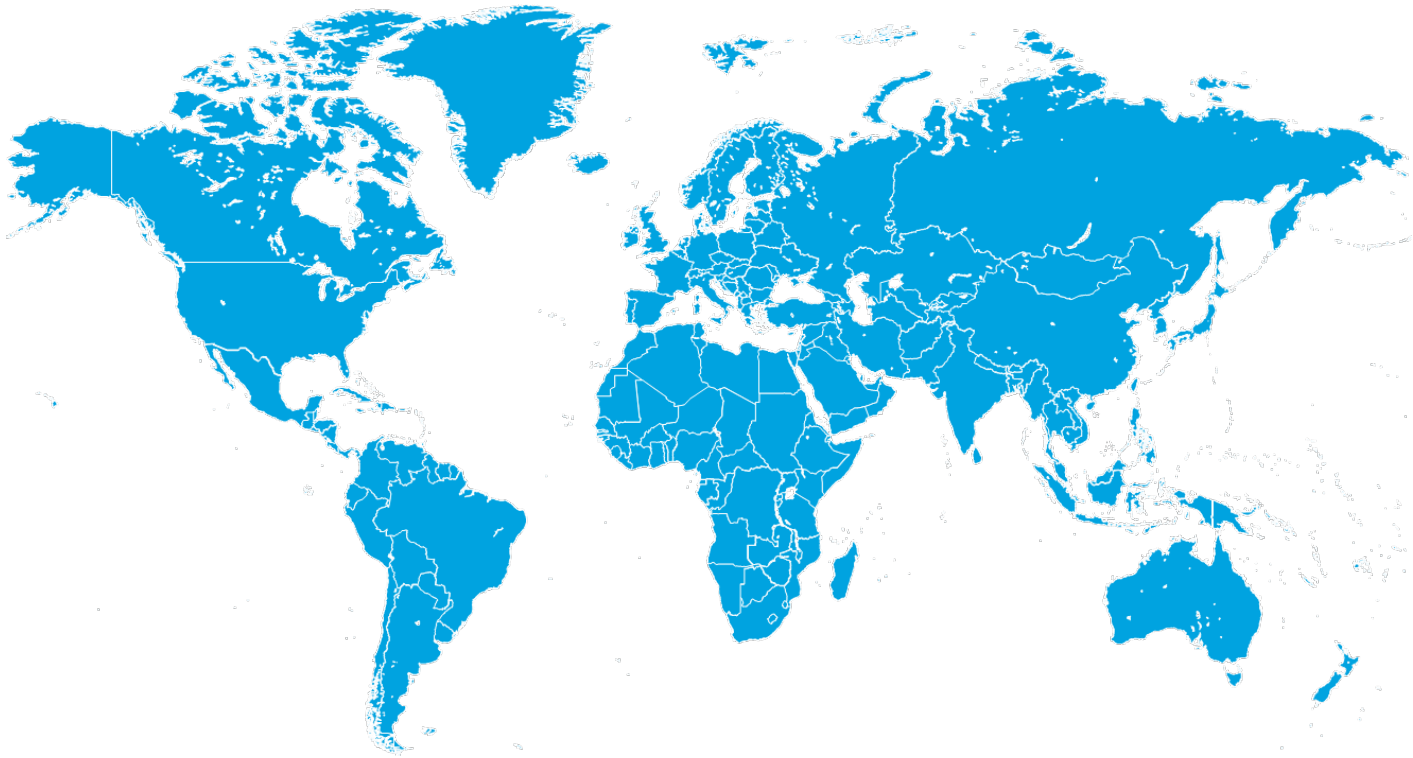
Global healthcare markets are progressively challenging

Use targeted AI solutions to drive a dual focus on patient safety and commercial performance

The problem statement:

MedTech and Pharma industries strive for global market access frameworks that are:

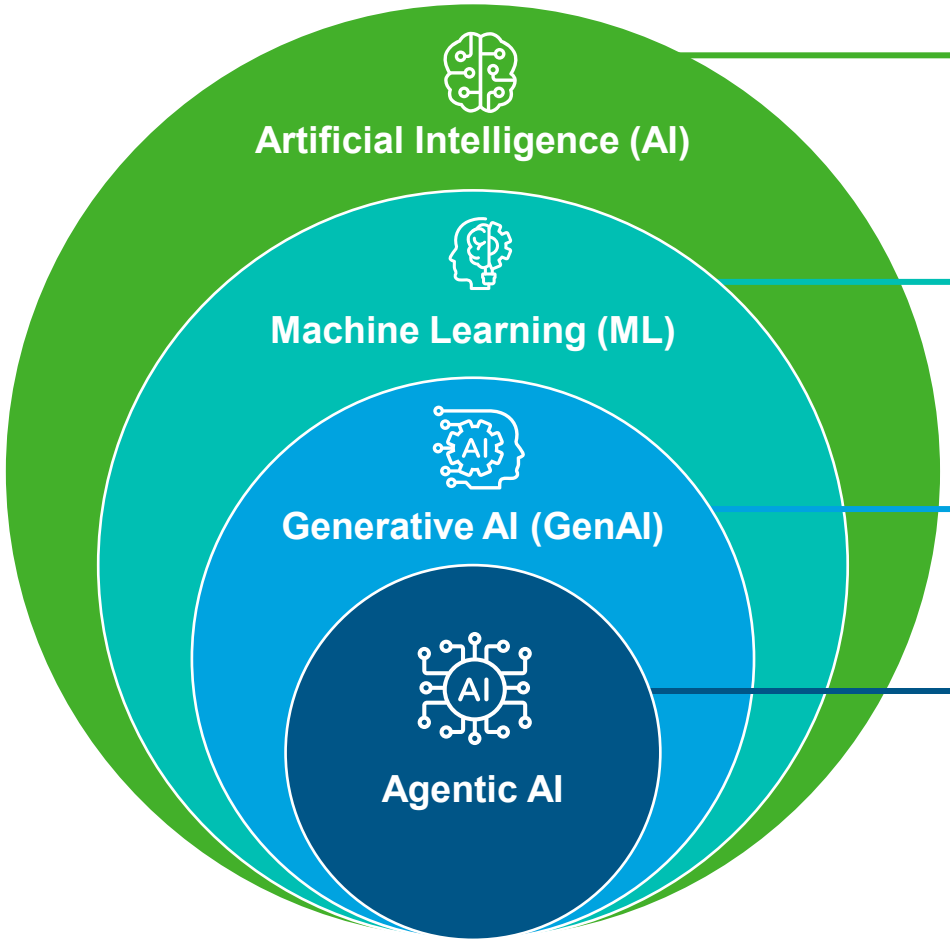
1. Aligned to commercial and strategic objectives
2. Efficient, timely and repeatable
3. Effective in adapting to global compliance process variations



IQVIA TECHNOLOGIES

Artificial Intelligence (AI) is a broad set of complementary methods

Be aware of the risk-benefit(s) of the different types of AI that are available



Artificial Intelligence (AI) is the theory and development of computer systems able to perform characteristic of **human intelligence**, such as computer vision, speech recognition, machine learning and more. *John McCarthy, 1956*

Machine Learning (ML) is the branch of AI concerned with the development and study of statistical algorithms that can learn from data, and generalize well to make **predictions** on unseen data without explicit instructions

Generative AI is a sub-set of ML/deep-learning models that can **generate** high-quality text, images, and answers based on data they were trained on

Agentic AI refers to **autonomous** AI agents able to understand, build, and perform complex workflows and business processes with limited direct human supervision. Agents don't replace point solutions; agents can orchestrate and operate point solutions in place of human capital

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Global AI regulations continue to advance

Maintain oversight of horizontal AI regulations alongside vertical healthcare regulations and standards

EU AI Act: The European Union's AI Act classifies AI applications by risk level, with stringent requirements for high-risk applications such as biometric identification and financial decisions. It emphasizes data governance, transparency, and human oversight.

US AI Guidelines: In the United States, the National Institute of Standards and Technology (NIST) has developed the AI Risk Management Framework, which provides guidelines for managing risks associated with AI systems, particularly in critical sectors like healthcare and finance.

UK AI Regulation: The UK has adopted a pro-innovation approach, allowing individual regulatory bodies to govern AI within their domains. This includes guidelines from the Financial Conduct Authority (FCA), the Information Commissioner's Office (ICO) along with MHRA guidelines. This cross-industry approach is particularly useful as it enables best practices to be shared across industries.

Japan: Japan has introduced the Bill on the Promotion of Research, Development and Utilization of Artificial Intelligence-Related Technologies (AI Bill), which was submitted to Parliament on February 28, 2025. This bill aims to position Japan as a leader in AI innovation by adopting a lighter regulatory approach compared to other countries.

South Korea: Introduced the AI Basic Act, which is set to take effect in January 2026. This act consolidates 19 separate AI-related regulatory proposals into a unified framework, making it the second comprehensive AI-specific legislation in the world, following the EU's AI Act.

China: Has implemented several AI-related regulations, focusing on data security, privacy, and ethical use of AI. The country has also published guidelines for AI development and deployment.

Navigate complexity by solutioning out from targeted use cases

Be specific and focused – a default fallback is legacy solutions and/ or personal herculean effort

Relevant

- What is my **QA/RA use case(s)?**
- What **process steps** are outputs are defined by regulations and standards?

Controlled

- What **healthcare verification & validation** requirements are required? (e.g. US 21 CFR)
- What other **regulations** apply? (e.g. EU AI Act, EU GDRP, Cyber security,…)

Cost Effective

- What **solutions** are available, inclusive of AI?
- What is the **risk benefit / value** of each?
- What is the **cost** to implement and maintain?

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Empowering QA/RA professionals with AI enabled solutions drives clear value

- Patient Outcomes
- Product Quality
- Commercial Performance

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Agentive AI: Transforming the role of QA/RA

Anusha Gangadhara
Associate Director, Product Owner

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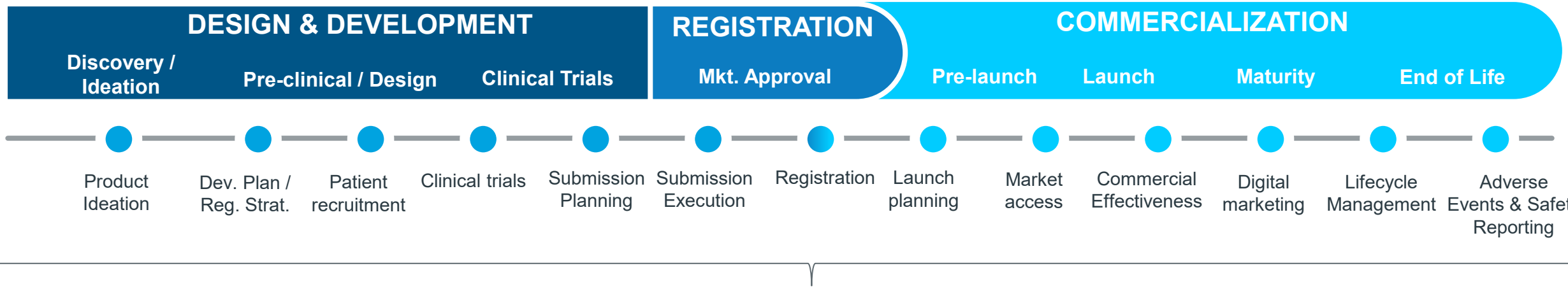
Harvesting the full product lifecycle – to power future workflow

Traceability and precedence through strong connected data frameworks across QA/RA systems

- Which countries should be targeted first for the global launch activities, which ones next?
- What is the optimal regulatory pathway enabling me to get to market faster?
- How can I optimize my lifecycle maintenance activities to maximize re-use and reduce workload of HA submissions?
- What procedure in which country? what is the submission timeline? what is the submision format, fee?, what pre-conditions apply? What documents can be resued?
- What documents must be submitted? must the document be legalised?

Harvesting the full product lifecycle – to power future workflow

AI Insights, impact assessment and predictive analysis need to stitch the full ecosystem



Product Metadata
Product definition as used in the global and in-country launches

SOPs & Evidences
Proof of Safety and efficacy details through the release cycle

Submissions
In-country regulatory content assembly and agency interactions

Registrations
Market approvals, expiry, renewals and commercial availability

Commercials
Product use monitoring, customer success, market history

Post Market
Complaints, adverse event and safety reports, non-compliance and CAPA

Built and tracked on Global and in-country Standards, Regulations and Governance

Need for validated ‘Dynamic Data’ throughout QA/RA processes

Transformation from manual to automated intelligence

Global lists

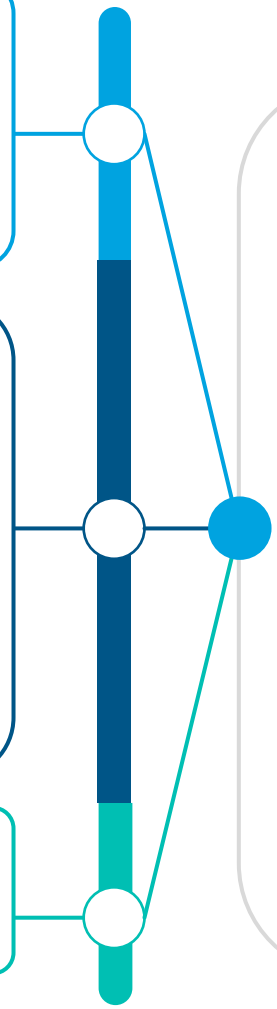
- Change details to global documents + ISO/IEC
- Standards to product characteristics
- Product Characteristics + ISO/IEC
- Complaint codes (IMDRF) to global documents

Country lists

- Agency (notified bodies included) & submission types
- Language, climatic zone
- Country to risk classification per regulation
- Submission templates – 50+ countries for Medical Devices
- License validity period per country
- Reference markets
- PMS activities list
- Initial submission fee + timeline
- Legal representative/sponsor requirement

IMDRF Global STED mapping

- STED-EU-FDA
- Automapping to country Templates



Process Examples

- **Impact Assessment to identify affected**
  - Products
  - Processes
  - In-country registrations
  - Global documents
- **Global registration planning**
  - Driven by impact assessment
  - Triggered by change management, standards or regulation changes and complaints
  - Insights on reference markets and delta submission requirements for market expansion
- **Drive In-country registration and submission build**
  - In-country registration planning with average timelines and fee estimation
  - Insights from precedence data on agency interactions and affected areas
  - Track and plan renewals and expiry
  - Use global submission documents to drive population of regional content

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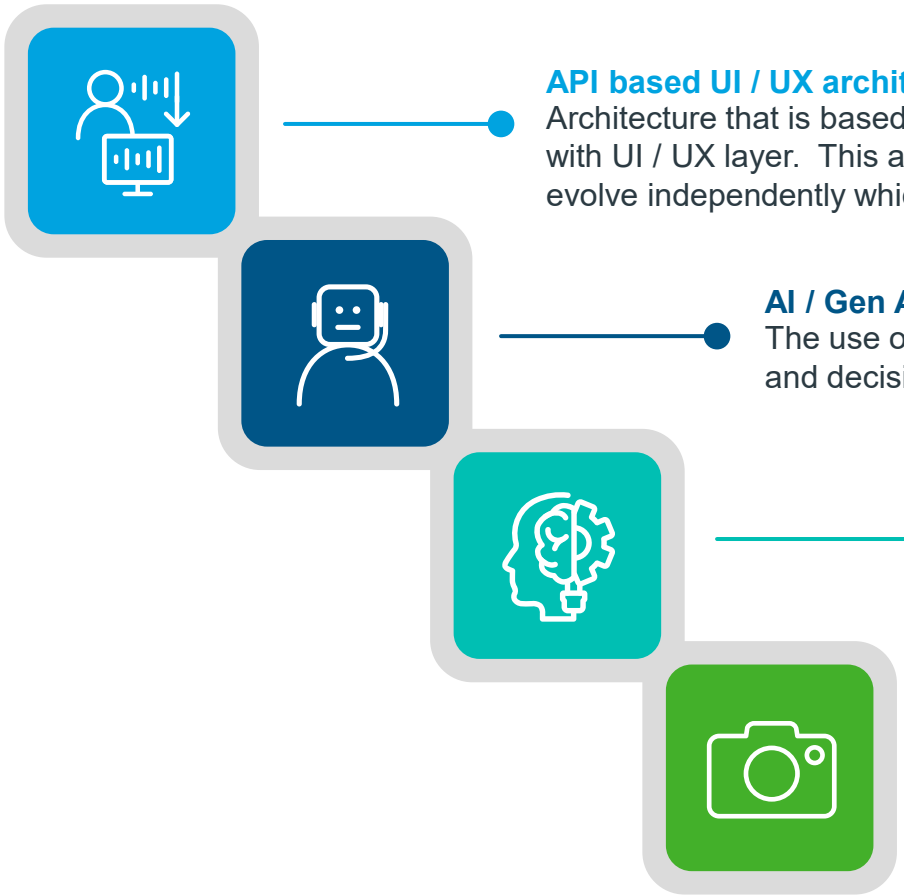
Building AI features as core platform capabilities

Enhancing QA/RA's focus on patient safety, product quality and commercial performance



API based UI / UX architecture
Architecture that is based on API business components interacting with UI / UX layer. This allows the UI / UX layer to advance and evolve independently which accelerates innovation for the UX layer

AI / Gen AI
The use of AI and Gen AI to accelerate the content creation and decision making process for end users

Progressive Web App (PWA)
As a Progressive Web App, the UI will run natively in browsers as well as on mobile device with offline capability

Microsoft Azure
Maximizing the technologies provided by Microsoft accelerates the innovation provided in our QA / RA solutions

- Gen AI prompts
- NLP (100+ languages)
- Similar event recognitions using precedence
- Intelligent summarization
- Intelligent recommendation assistant
- Decision tree-based recommendation
- Text and Image ingestion

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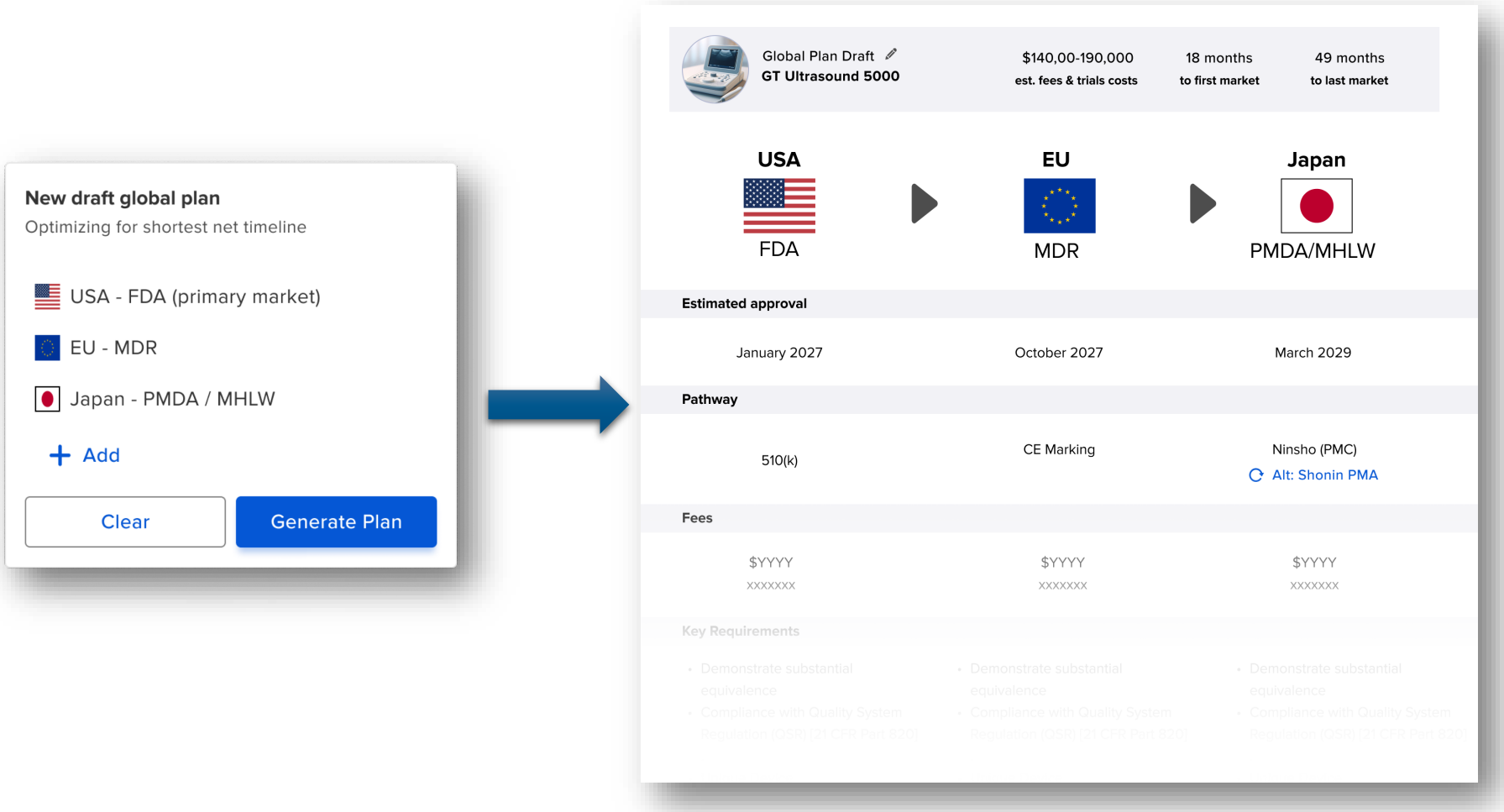
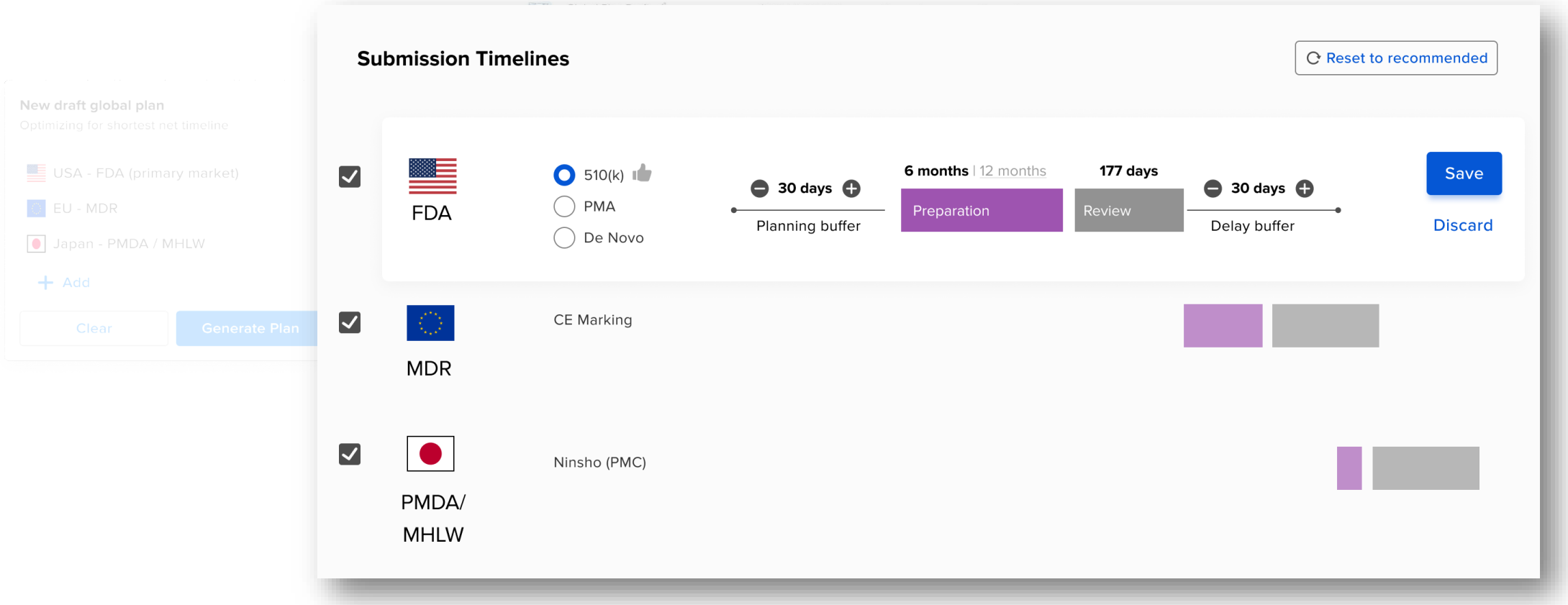
Using AI in defining and building dynamic QA/RA workflows

Define the problem statement & build the workflow using regulatory intelligence and precedence



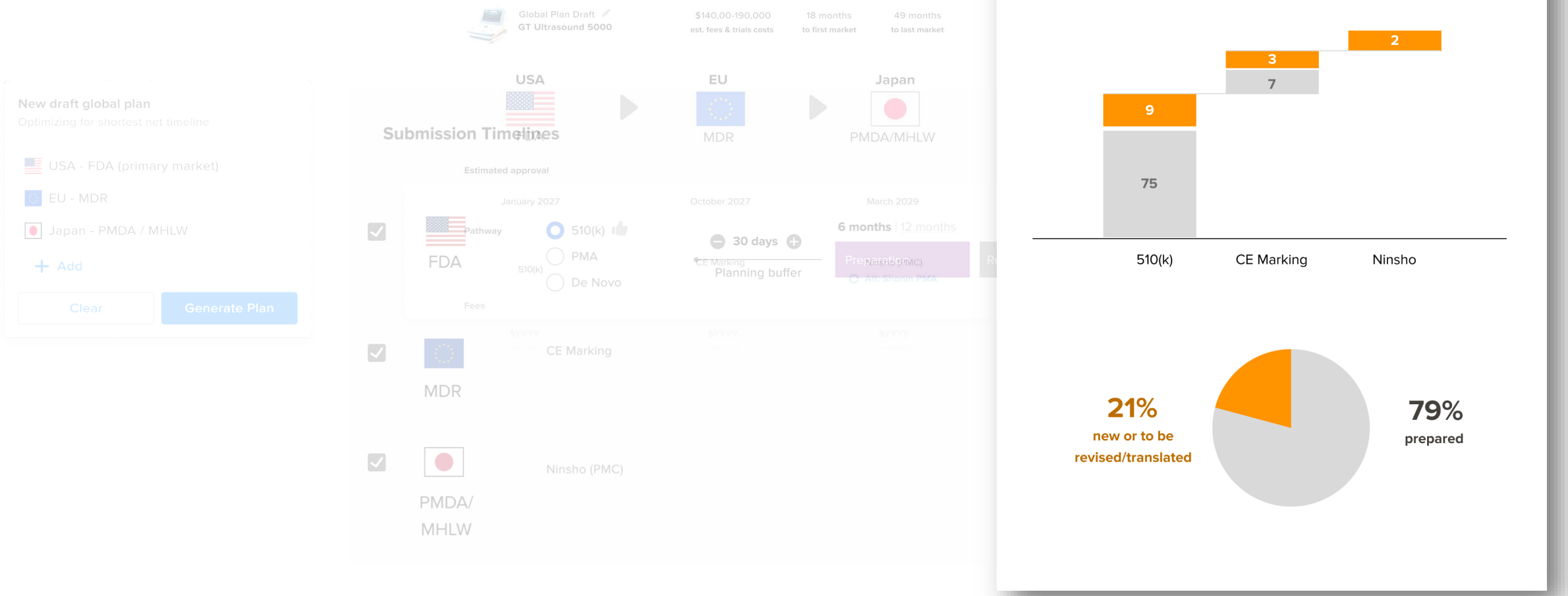
Using AI in defining and building dynamic QA/RA workflows

Optimize precedence and recommendations to accommodate current scenarios



Using AI in defining and building dynamic QA/RA workflows

Insights and impact assessments to define tasks and actions



SmartSolve® eQMS Demonstration

Todd Neal
Senior Product Manager, IT Design & Development

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Complaint Handling

Drive improved quality, volume and consistency whilst accelerating timeliness

Case Intake

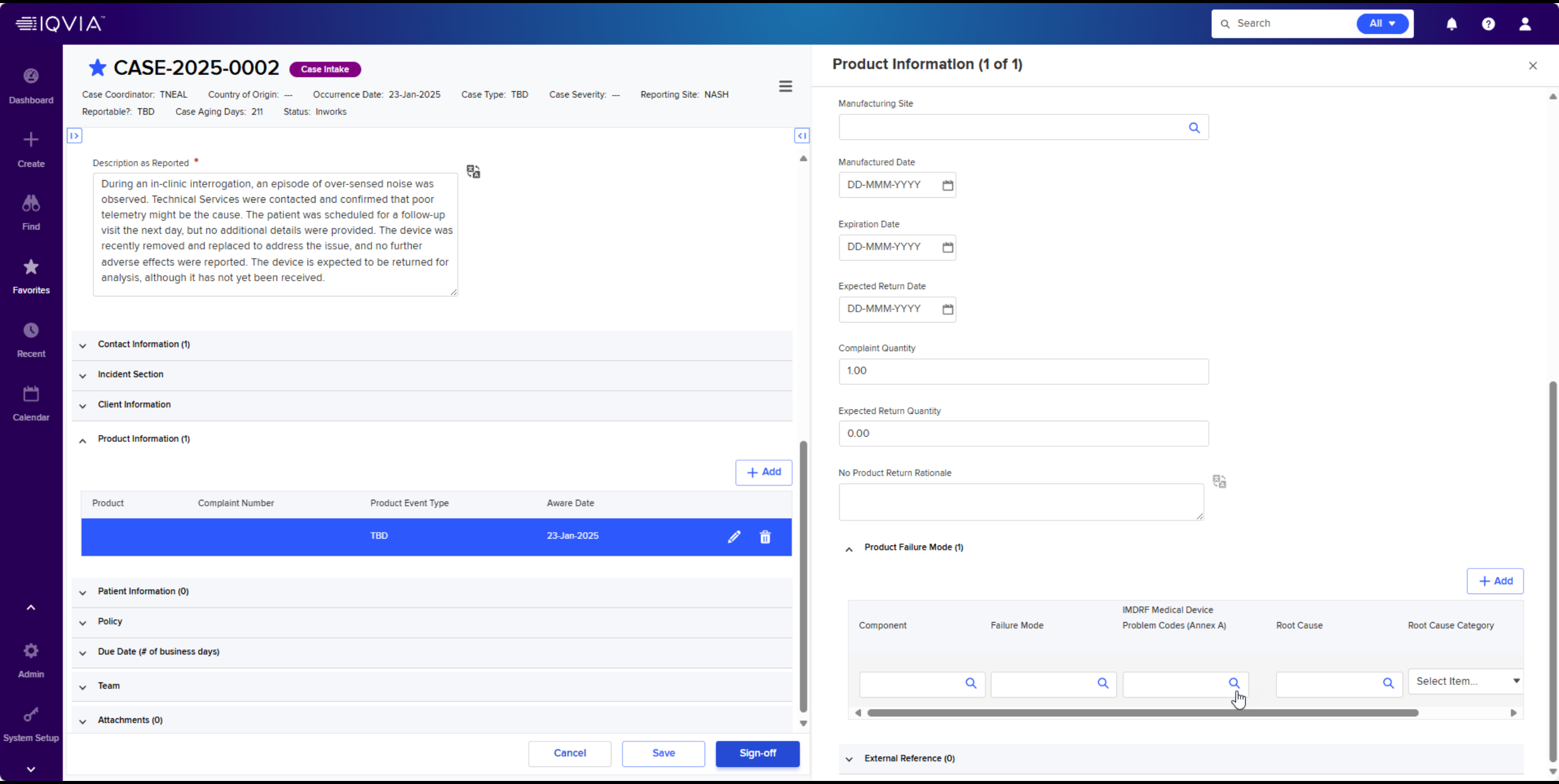
- Utilising **NLP AI** to automate case intake
- Supports a variety of data sources

Adverse Event Reports

- Utilising **Gen AI** to improve in US MDR coding
- Trained using 5 years of US MAUDE data

Language

- Embedded **translation capabilities**
- Enter and review information in different languages


IQVIA
Search
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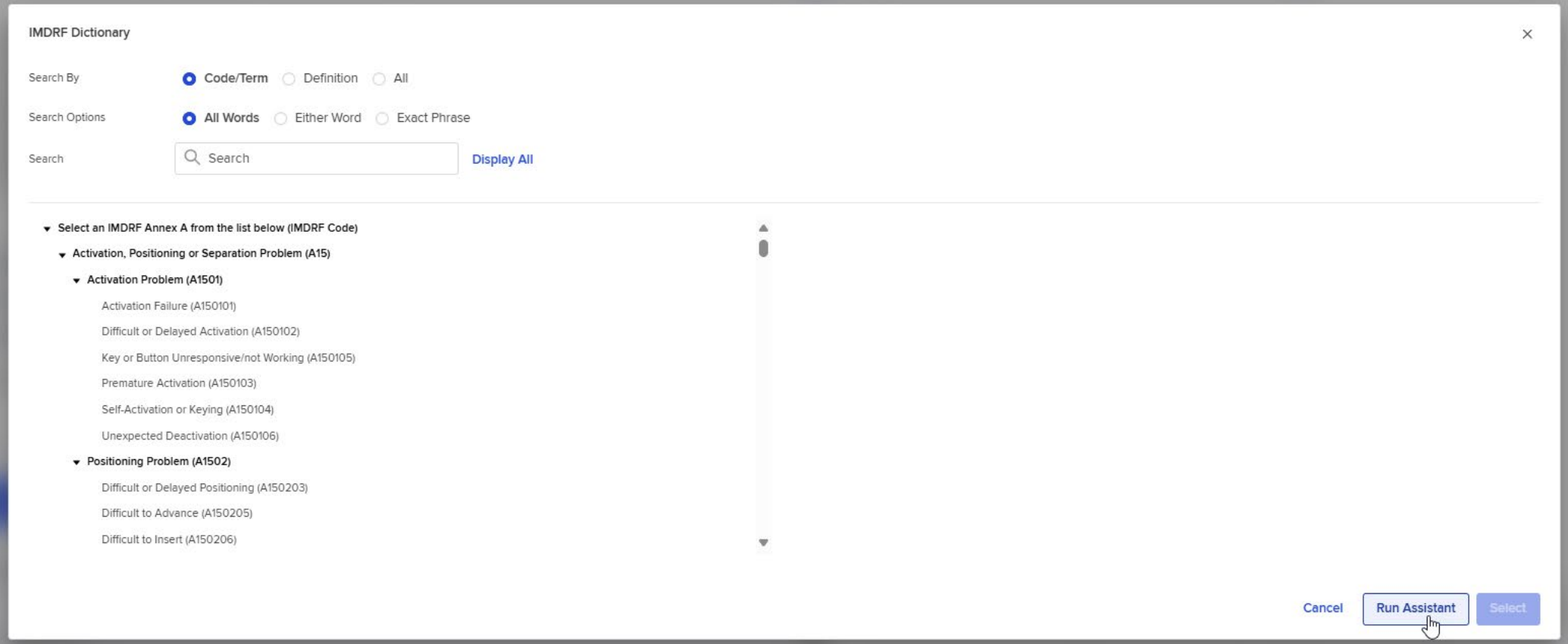
Dashboard
Create
Find
Favorites
Recent
Calendar
Admin
System Setup
CASE-2025-0002
Case Intake
Case Coordinator: TNEAL
Country of Origin: ---
Occurrence Date: 23-Jan-2025
Case Type: TBD
Case Severity: ---
Reporting Site: NASH
Reportable?: TBD
Case Aging Days: 211
Status: Inworks
Description as Reported *
During an in-clinic interrogation, an episode of over-sensed noise was observed. Technical Services were contacted and confirmed that poor telemetry might be the cause. The patient was scheduled for a follow-up visit the next day, but no additional details were provided. The device was recently removed and replaced to address the issue, and no further adverse effects were reported. The device is expected to be returned for analysis, although it has not yet been received.
Contact Information (1)
Incident Section
Client Information
Product Information (1)
+ Add
Product
Complaint Number
Product Event Type
Aware Date
TBD
23-Jan-2025
Patient Information (0)
Policy
Due Date (# of business days)
Team
Attachments (0)
Cancel
Save
Sign-off
Product Information (1 of 1)
Manufacturing Site
Manufactured Date
DD-MMM-YYYY
Expiration Date
DD-MMM-YYYY
Expected Return Date
DD-MMM-YYYY
Complaint Quantity
1.00
Expected Return Quantity
0.00
No Product Return Rationale
Product Failure Mode (1)
+ Add
Component
Failure Mode
IMDRF Medical Device Problem Codes (Annex A)
Root Cause
Root Cause Category
Select Item...
External Reference (0)


IMDRF Dictionary
Search By
Code/Term
Definition
All
Search Options
All Words
Either Word
Exact Phrase
Search
Search
Display All
Select an IMDRF Annex A from the list below (IMDRF Code)
Activation, Positioning or Separation Problem (A15)
Activation Problem (A1501)
Activation Failure (A150101)
Difficult or Delayed Activation (A150102)
Key or Button Unresponsive/not Working (A150105)
Premature Activation (A150103)
Self-Activation or Keying (A150104)
Unexpected Deactivation (A150106)
Positioning Problem (A1502)
Difficult or Delayed Positioning (A150203)
Difficult to Advance (A150205)
Difficult to Insert (A150206)
Cancel
Run Assistant
Select

IMDRF Dictionary

Search By: Code/Term | Definition | All

Search Options: All Words | Either Word | Exact Phrase

Search: Search | Display All

- Select an IMDRF Annex A from the list below (IMDRF Code)
  - Activation, Positioning or Separation Problem (A15)
    - Activation Problem (A1501)
      - Activation Failure (A150101)
      - Difficult or Delayed Activation (A150102)
      - Key or Button Unresponsive/not Working (A150105)
      - Premature Activation (A150103)
      - Self-Activation or Keying (A150104)
      - Unexpected Deactivation (A150106)
    - Positioning Problem (A1502)
      - Difficult or Delayed Positioning (A150203)
      - Difficult to Advance (A150205)
      - Difficult to Insert (A150206)

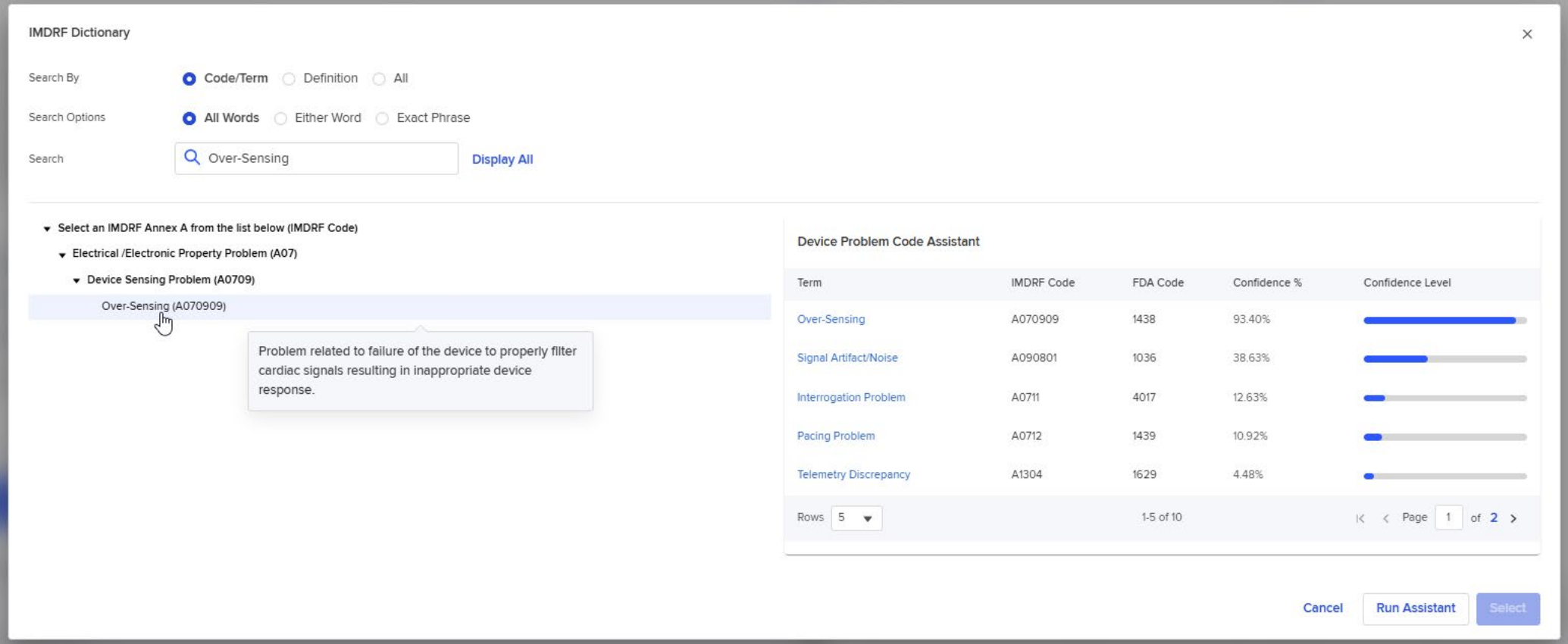
Device Problem Code Assistant

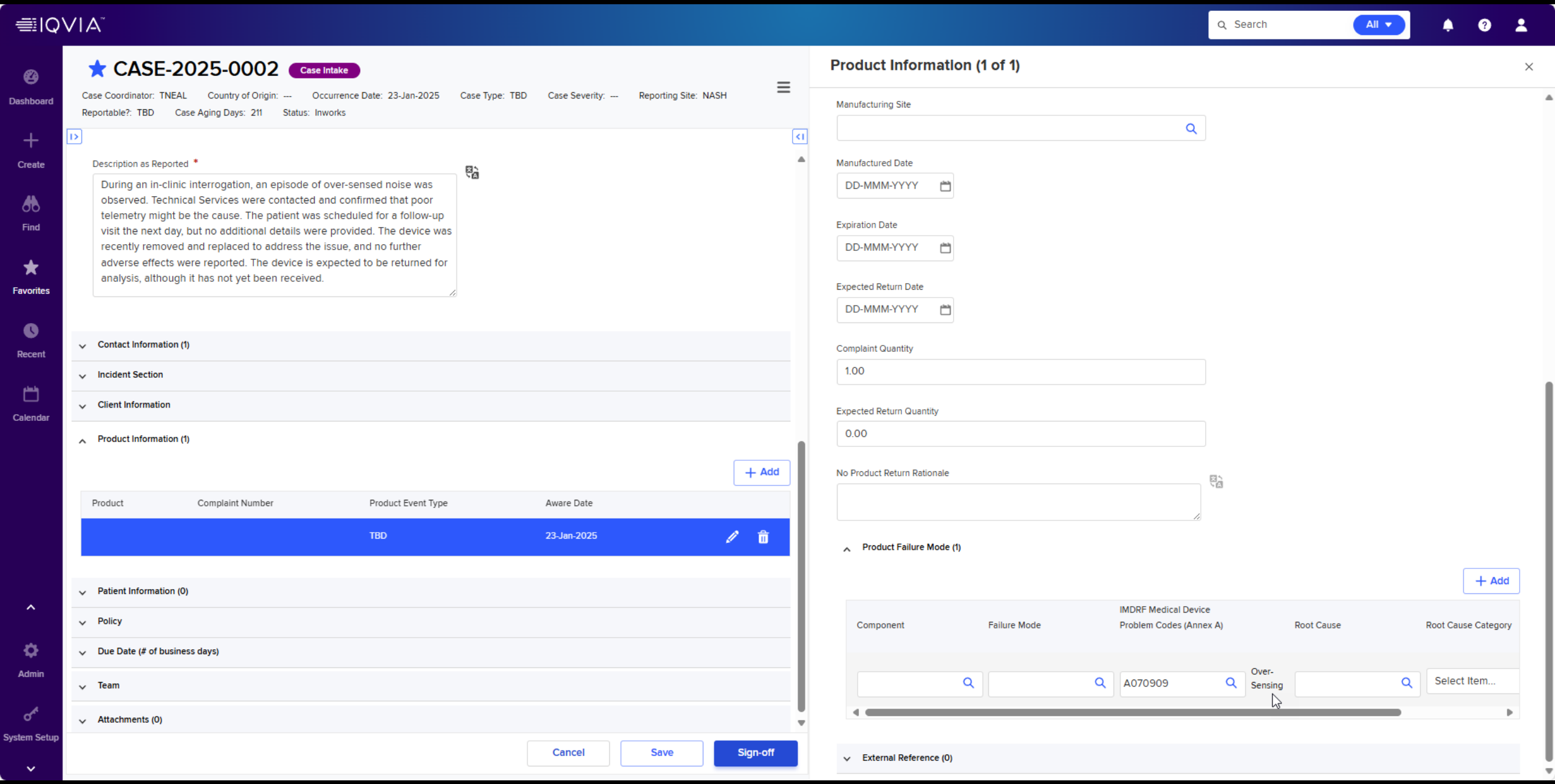
Term	IMDRF Code	FDA Code	Confidence %	Confidence Level
Over-Sensing	A070909	1438	93.40%	
Signal Artifact/Noise	A090801	1036	38.63%	
Interrogation Problem	A0711	4017	12.63%	
Pacing Problem	A0712	1439	10.92%	
Telemetry Discrepancy	A1304	1629	4.48%	

Rows 5 | 1-5 of 10 | Page 1 of 2

Cancel | Run Assistant | Select

This response contains AI generated content. Please review for accuracy.


IMDRF Dictionary
Search By
Code/Term
Definition
All
Search Options
All Words
Either Word
Exact Phrase
Search
Over-Sensing
Display All
Select an IMDRF Annex A from the list below (IMDRF Code)
Electrical /Electronic Property Problem (A07)
Device Sensing Problem (A0709)
Over-Sensing (A070909)
Problem related to failure of the device to properly filter cardiac signals resulting in inappropriate device response.
Device Problem Code Assistant
Term
IMDRF Code
FDA Code
Confidence %
Confidence Level
Over-Sensing
A070909
1438
93.40%
Signal Artifact/Noise
A090801
1036
38.63%
Interrogation Problem
A0711
4017
12.63%
Pacing Problem
A0712
1439
10.92%
Telemetry Discrepancy
A1304
1629
4.48%
Rows
5
1-5 of 10
Page
1
of
2
Cancel
Run Assistant
Select


IQVIA
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CASE-2025-0002
Case Intake
Case Coordinator: TNEAL
Country of Origin: ---
Occurrence Date: 23-Jan-2025
Case Type: TBD
Case Severity: ---
Reporting Site: NASH
Reportable?: TBD
Case Aging Days: 211
Status: Inworks
Description as Reported *
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Contact Information (1)
Incident Section
Client Information
Product Information (1)
+ Add
Product
Complaint Number
Product Event Type
Aware Date
TBD
23-Jan-2025
Patient Information (0)
Policy
Due Date (# of business days)
Team
Attachments (0)
Cancel
Save
Sign-off
Product Information (1 of 1)
Manufacturing Site
Manufactured Date
DD-MMM-YYYY
Expiration Date
DD-MMM-YYYY
Expected Return Date
DD-MMM-YYYY
Complaint Quantity
1.00
Expected Return Quantity
0.00
No Product Return Rationale
Product Failure Mode (1)
+ Add
Component
Failure Mode
IMDRF Medical Device Problem Codes (Annex A)
Root Cause
Root Cause Category
A070909
Over-Sensing
Select Item...
External Reference (0)

CASE-2024-0020-1

Product: DP | Country of Origin: UNITED STATES | Reportable?: Yes | Complaint Coordinator: TNEAL | Reporting Site: NASH | Aware Date: 11-Dec-2024 | Complaint Aging Days: 254 | Case Severity: Serious Injury | Status: Inworks

Back to Records | Task | Action | Print | Edit Forms

Task Status | Errors (0)

- Start — 11-Dec-2024
- Verify Complaint — 13-Dec-2024
- Investigate Complaint — 17-Jan-2025 — Active
- Prompt Additional Regulatory Report
- Void Additional Regulatory Report
- Evaluate Regulatory — 13-Dec-2024
- Evaluate Product
- External Evaluation
- Ad Hoc
- Verify Complaint Closure

Detail | Similar Cases | Product History Review | Investigation | Product Evaluation | Regulatory | Notes | Attachments | Cross References | Activity (6)

Complaint Information

Case Number	CASE-2024-0020
Product	DP
Product Name	Demo Product
Aware Date	11-Dec-2024
Occurrence Date	11-Dec-2024
Lot Number	---
Lot Reference Number	---
UDI-DI Number	---
UDI-DI Issuing Entity	---
Basic UDI-DI	---
Basic UDI-DI Issuing Entity	---
Eudamed ID	---
Eudamed ID Issuing Entity	---
Eudamed-DI	---
Eudamed-DI Issuing Entity	---
Unit of Use UDI-DI	---
Unit of Use UDI-DI Issuing Entity	---
UDI/UPC Number	---
Expected Return Quantity	0
Decontamination Hold	No
Actual Quantity Returned	0
Actual Quantity Retained	---
Manufacturing Site	---
Manufactured Date	---
Expiration Date	---
Description Summary	Patient experienced adverse event possibly due to battery depletion

Failure Mode as Reported (0)

Component	Failure Mode	IMDRF Medical Device Problem Codes (Annex A)	Root Cause	Root Cause Category	Primary Code

No data to display

AI found similar cases with 80% or greater confidence. Click here to view in Detail panel. Don't show again

CASE-2024-0020-1

Product: DP | Country of Origin: UNITED STATES | Reportable?: Yes | Complaint Coordinator: TNEAL | Reporting Site: NASH | Aware Date: 11-Dec-2024 | Complaint Aging Days: 254 | Case Severity: Serious Injury | Status: Inworks

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- External Evaluation
- Ad Hoc
- Verify Complaint Closure

AI has identified previous case(s) that may be similar to the current based on their description summary.

Record Number	Product	Occurrence Date	Description Summary	Confidence %	AI Creation Date
CASE-2024-0011	DP	11-Dec-2024	Patient experienced adverse event possibly due to battery depletion	100%	11-Dec-2024
CASE-2024-0019	DP	11-Dec-2024	adverse event potentially due to battery discharge	89.65%	12-Dec-2024
CASE-2024-0004	DP	10-Dec-2024	adverse event potentially due to battery discharge.	89.65%	11-Dec-2024
CASE-2024-0018	DP	11-Dec-2024	Patient reported fainting due to premature battery depletion	89.01%	12-Dec-2024
CASE-2024-0017	DP	11-Dec-2024	Patient reported dizziness, possibly related to battery	85.56%	12-Dec-2024
CASE-2024-0012	DP	11-Dec-2024	Patient reported dizziness, possibly related to battery	85.56%	11-Dec-2024
CASE-2024-0010	DP	11-Dec-2024	Patient reported dizziness due to battery drain	85.19%	11-Dec-2024
CASE-2024-0015	DP	11-Dec-2024	Patient experienced lightheadedness and palpitations. It was found that the pacemaker's battery had depleted, leading to insufficient pacing.	79.97%	12-Dec-2024
CASE-2024-0014	DP	11-Dec-2024	Patient reported episodes of fatigue and chest discomfort. Investigation revealed a malfunction in the pacemaker's battery, causing it to intermittently stop working.	77.87%	12-Dec-2024
CASE-2024-0013	DP	11-Dec-2024	Patient experienced dizziness and shortness of breath due to the pacemaker's battery failure. The device was unable to maintain the required heart rate.	76.35%	12-Dec-2024
CASE-2024-0016	DP	11-Dec-2024	Patient suffered from weakness and irregular heartbeats due to a depleted pacemaker battery. The device failed to provide consistent pacing.	74.44%	12-Dec-2024

Dashboard
Create
Find
Favorites
Recent
Calendar
Admin
System Setup

CASE-2024-0020-1

Product: DP | Country of Origin: UNITED STATES | Reportable?: Yes | Complaint Coordinator: TNEAL | Reporting Site: NASH | Aware Date: 11-Dec-2024 | Complaint Aging Days: 254 | Case Severity: Serious Injury | Status: Inworks

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Task | Action | Print | Edit Forms

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- **Start** — 11-Dec-2024
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Detail | Similar Cases | Product History Review | Investigation | Product Evaluation | Regulatory | Notes | Attachments | Cross References | Activity (6)

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CASE-2024-0013	DP	11-Dec-2024	Patient experienced dizziness and shortness of breath due to the pacemaker's battery failure. The device was unable to maintain the required heart rate.	76.35%	12-Dec-2024
CASE-2024-0016	DP	11-Dec-2024	Patient suffered from weakness and irregular heartbeats due to a depleted pacemaker battery. The device failed to provide consistent pacing.	74.44%	12-Dec-2024

https://dev-wopi.pilgrimasp.com/112024R3INTUPD/Reroute.aspx?EntityName=SS_CASE&ItmId=00000000000000002149264149&EntityType=SS_CASE&FormKey=SS_CASE_DETAIL&Token=eyJ0eXAiOiJKV1QiLCJhbGciOiJIUzI1NiJ9.eyJMSUNFTINFIjoie1wiTG9nZ2VkT25PcmdJZFwiOlwiMDAwMDAwMDAwMDAwMDAwMDAwMDAwMDAwMFwiLFwiQ3VycmV...

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CASE-2024-0008-1 Investigate Complaint

Product: DP | Country of Origin: UNITED STATES | Reportable?: TBD | Complaint Coordinator: TNEAL | Reporting Site: NASH | Aware Date: 10-Dec-2024 | Complaint Aging Days: 255 | Case Severity: Serious Injury
Status: Inworks

Task | Action | Print | Attachment | Edit Forms

Task Status | Errors (0)

- Start — 10-Dec-2024
- Verify Complaint — 10-Dec-2024
- Plan Investigation — 10-Dec-2024
- Investigate Complaint — 14-Jan-2025 — Active
- Approve Regulatory Evaluation
- Evaluate Product
- External Evaluation
- Ad Hoc
- Verify Complaint Closure
- Verify Regulatory

Investigate Complaint Task Information

Investigation Information

Product Information

Investigation Subtasks (4)

Note: To add or reopen subtasks, select 'Manage Investigation Subtasks' from the Action menu.

Activity	Assigned To / Completed By	Due Date / Completed Date	Status
Safety Investigation	TNEAL	10-Dec-2024	Completed
Manufacturing Investigation	TNEAL	10-Dec-2024	Completed
Quality Control Investigation	TNEAL	10-Dec-2024	Completed
Distribution Investigation	TNEAL	10-Dec-2024	Completed

Note: Click 'Add' to record investigation results without routing a subtask. To add subtasks, select 'Manage Investigation Subtasks' from the Action menu.

Additional Results of Investigation

IMDRF Cause Investigation: Type of Investigation (Annex B)

Investigation Tools (0)

Failure Mode as Reported (0)

Root Cause Analysis

Cancel | Save | Sign-off

Detail | Similar Cases | Product History Review | Investigation | Product Evaluation | Regula

Investigation Information

Investigation Subtasks

Safety Investigation (1 of 4)

Instructions: Assess the immediate and long-term risks to patients who may have been injected with the contaminated solution

Result of Investigation:

Risk Assessment of Particulate Contamination
Scientific Literature Review indicate injected glass particles >50 microns can cause local tissue damage (granulomas, abscesses) and systemic complications (embolism, organ damage). Documented cases of similar incidents in the past have resulted in serious patient harm.

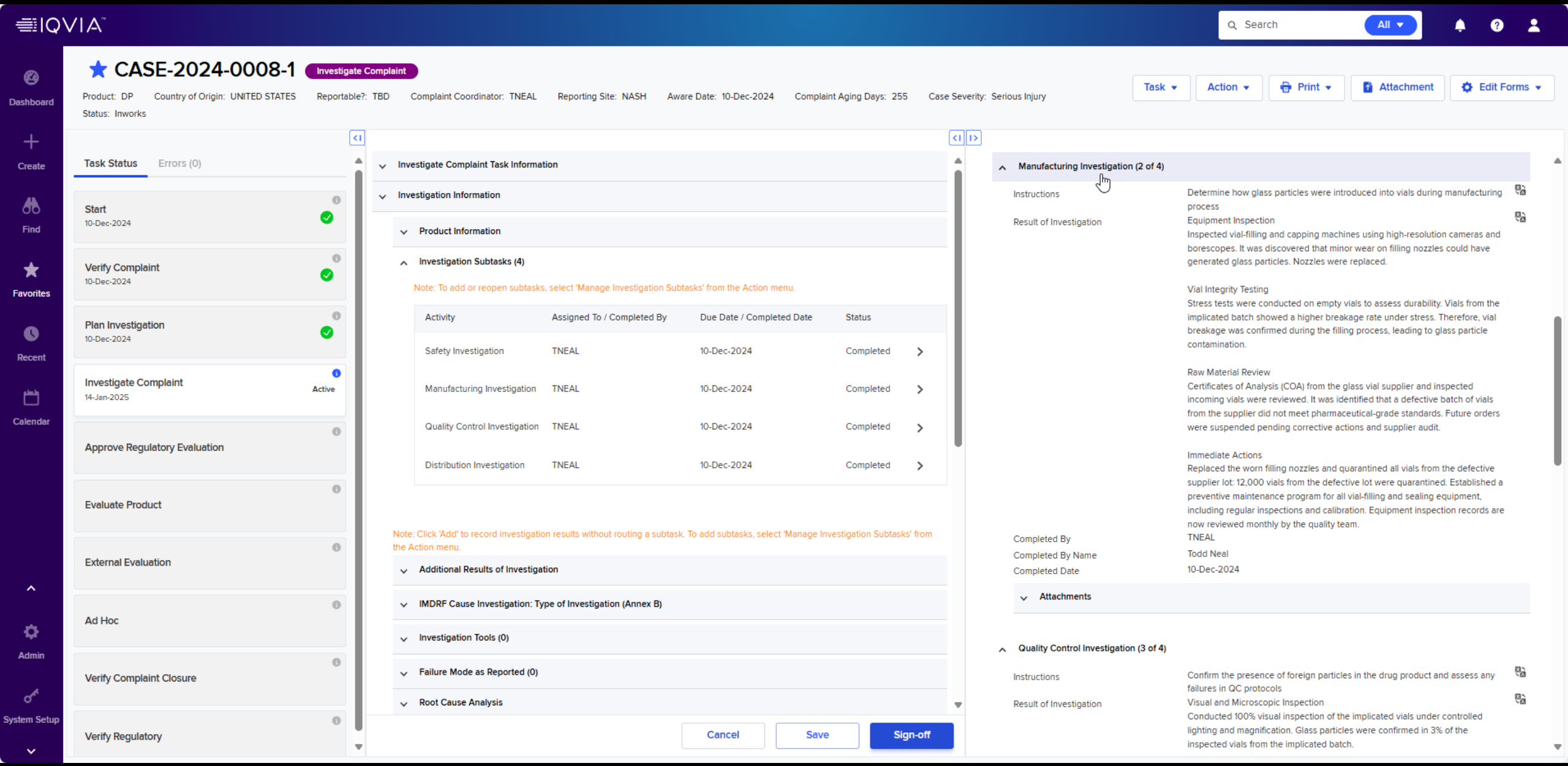
Patient Records Review
Medical records of 12 patients who received Drug Y from the implicated batch were reviewed. Two patients showed signs of local inflammation at the injection site, while one patient exhibited signs of phlebitis. There was found a correlation between inflammation cases with the presence of glass particles. No severe systemic events were reported, but early signs of tissue irritation were found.

Expert Consultation
Toxicologist and Vascular Specialist confirmed the risk of embolism if glass particles enter the bloodstream and advised immediate recall. Experts provided written recommendations for patient monitoring and recall procedures.

Immediate Actions
Notified healthcare providers of the issue, issued a recall of the affected batches, and instructed facilities to inspect vials before use. Recall Notice sent to all distributors and hospitals. A helpline was established for healthcare providers to report findings or concerns.

Completed By: TNEAL
Completed By Name: Todd Neal
Completed Date: 10-Dec-2024

Attachments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CASE-2024-0008-1
Investigate Complaint
Product: DP
Country of Origin: UNITED STATES
Reportable?: TBD
Complaint Coordinator: TNEAL
Reporting Site: NASH
Aware Date: 10-Dec-2024
Complaint Aging Days: 255
Case Severity: Serious Injury
Status: Inworks
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Task Status
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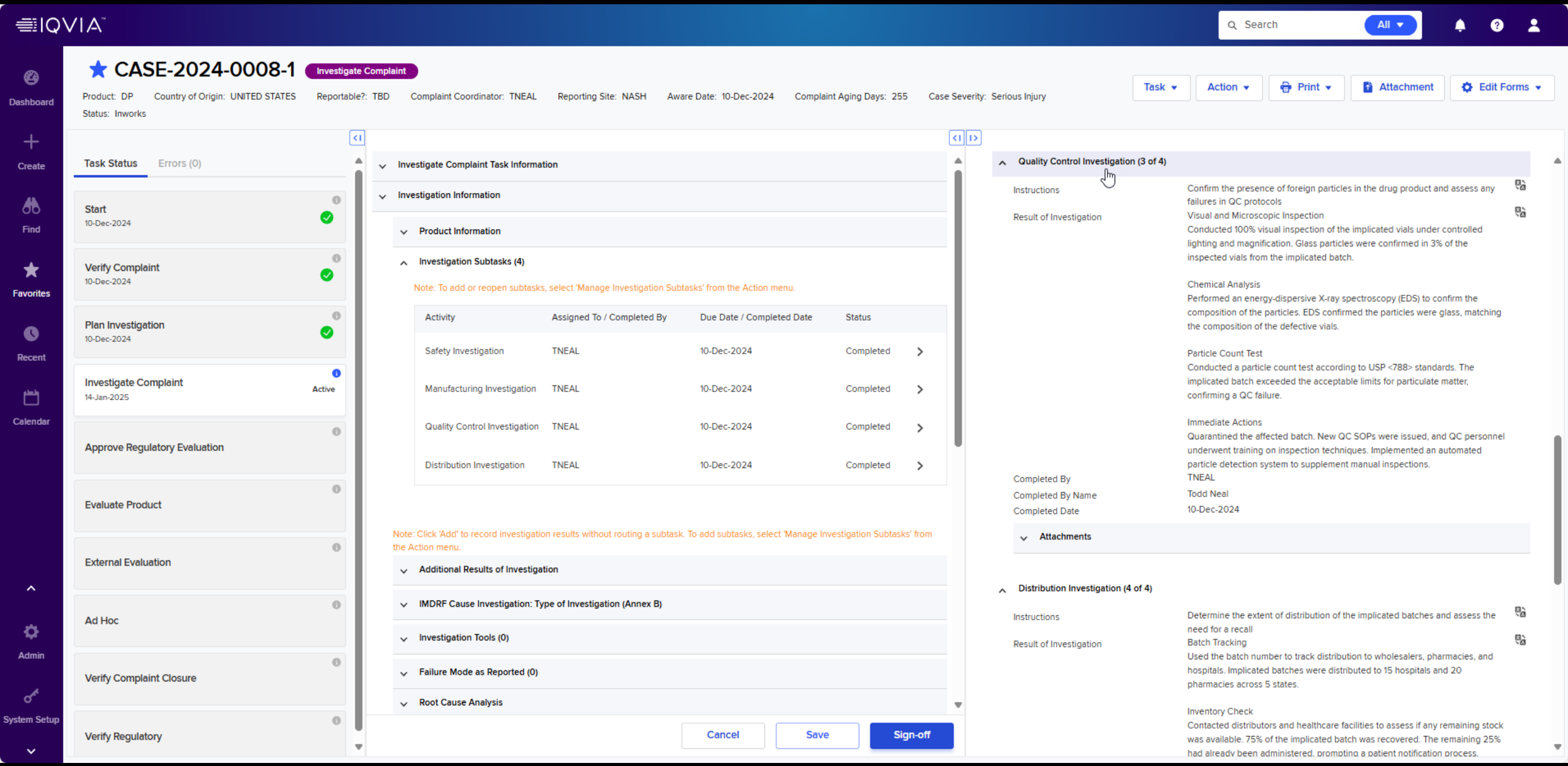
Start
10-Dec-2024
Verify Complaint
10-Dec-2024
Plan Investigation
10-Dec-2024
Investigate Complaint
14-Jan-2025
Active
Approve Regulatory Evaluation
Evaluate Product
External Evaluation
Ad Hoc
Verify Complaint Closure
Verify Regulatory
Investigate Complaint Task Information
Investigation Information
Product Information
Investigation Subtasks (4)
Note: To add or reopen subtasks, select 'Manage Investigation Subtasks' from the Action menu.
Activity
Assigned To / Completed By
Due Date / Completed Date
Status
Safety Investigation
TNEAL
10-Dec-2024
Completed
Manufacturing Investigation
TNEAL
10-Dec-2024
Completed
Quality Control Investigation
TNEAL
10-Dec-2024
Completed
Distribution Investigation
TNEAL
10-Dec-2024
Completed
Note: Click 'Add' to record investigation results without routing a subtask. To add subtasks, select 'Manage Investigation Subtasks' from the Action menu.
Additional Results of Investigation
IMDRF Cause Investigation: Type of Investigation (Annex B)
Investigation Tools (0)
Failure Mode as Reported (0)
Root Cause Analysis
Cancel
Save
Sign-off
Manufacturing Investigation (2 of 4)
Instructions
Determine how glass particles were introduced into vials during manufacturing process
Result of Investigation
Equipment Inspection
Inspected vial-filling and capping machines using high-resolution cameras and borescopes. It was discovered that minor wear on filling nozzles could have generated glass particles. Nozzles were replaced.
Vial Integrity Testing
Stress tests were conducted on empty vials to assess durability. Vials from the implicated batch showed a higher breakage rate under stress. Therefore, vial breakage was confirmed during the filling process, leading to glass particle contamination.
Raw Material Review
Certificates of Analysis (COA) from the glass vial supplier and inspected incoming vials were reviewed. It was identified that a defective batch of vials from the supplier did not meet pharmaceutical-grade standards. Future orders were suspended pending corrective actions and supplier audit.
Immediate Actions
Replaced the worn filling nozzles and quarantined all vials from the defective supplier lot: 12,000 vials from the defective lot were quarantined. Established a preventive maintenance program for all vial-filling and sealing equipment, including regular inspections and calibration. Equipment inspection records are now reviewed monthly by the quality team.
Completed By
TNEAL
Completed By Name
Todd Neal
Completed Date
10-Dec-2024
Attachments
Quality Control Investigation (3 of 4)
Instructions
Confirm the presence of foreign particles in the drug product and assess any failures in QC protocols
Result of Investigation
Visual and Microscopic Inspection
Conducted 100% visual inspection of the implicated vials under controlled lighting and magnification. Glass particles were confirmed in 3% of the inspected vials from the implicated batch.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CASE-2024-0008-1
Investigate Complaint
Product: DP
Country of Origin: UNITED STATES
Reportable?: TBD
Complaint Coordinator: TNEAL
Reporting Site: NASH
Aware Date: 10-Dec-2024
Complaint Aging Days: 255
Case Severity: Serious Injury
Status: Inworks
Task
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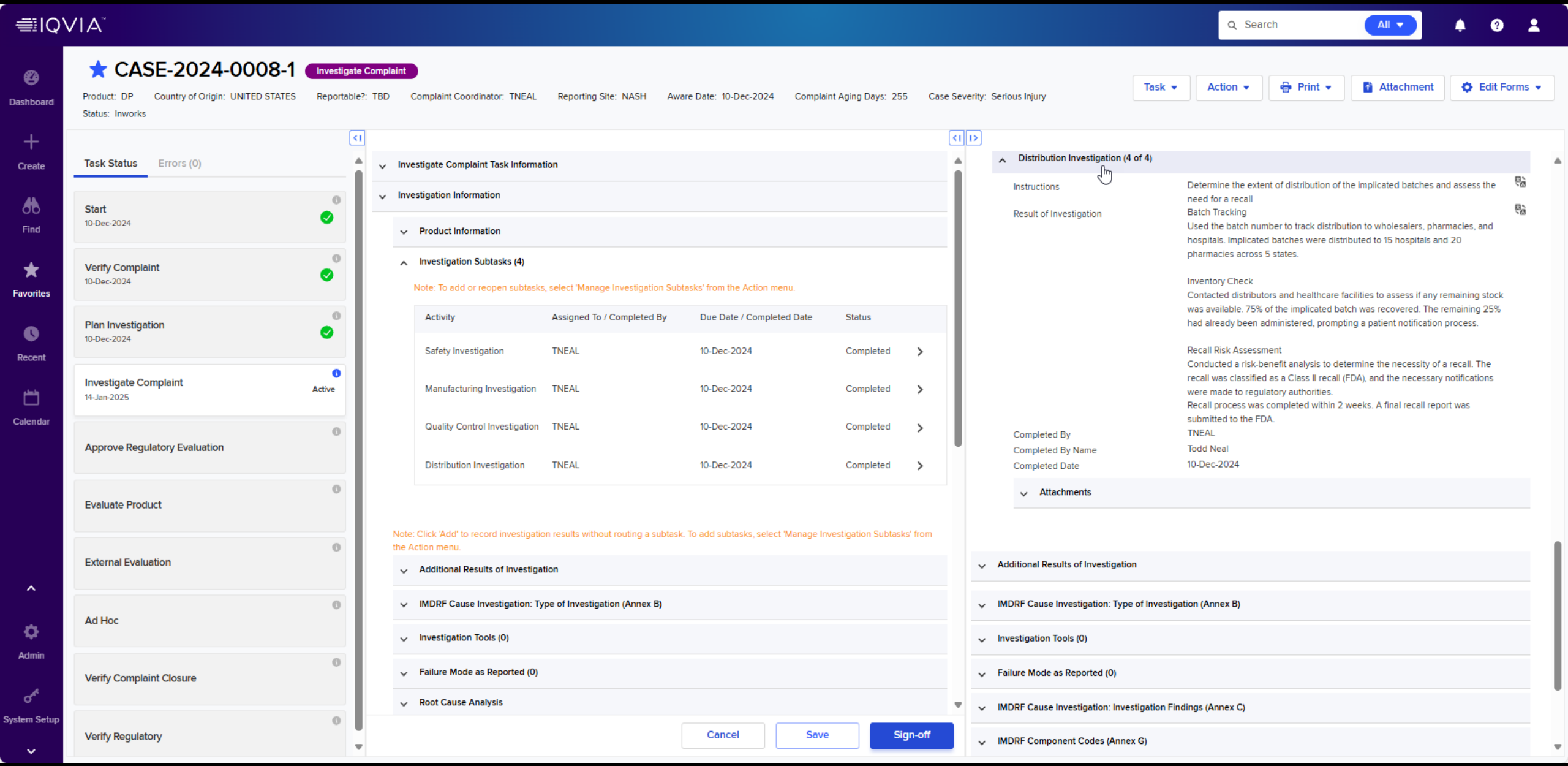
Task Status
Errors (0)
Start
10-Dec-2024
Verify Complaint
10-Dec-2024
Plan Investigation
10-Dec-2024
Investigate Complaint
14-Jan-2025
Active
Approve Regulatory Evaluation
Evaluate Product
External Evaluation
Ad Hoc
Verify Complaint Closure
Verify Regulatory
Investigate Complaint Task Information
Investigation Information
Product Information
Investigation Subtasks (4)
Note: To add or reopen subtasks, select 'Manage Investigation Subtasks' from the Action menu.
Activity
Assigned To / Completed By
Due Date / Completed Date
Status
Safety Investigation
TNEAL
10-Dec-2024
Completed
Manufacturing Investigation
TNEAL
10-Dec-2024
Completed
Quality Control Investigation
TNEAL
10-Dec-2024
Completed
Distribution Investigation
TNEAL
10-Dec-2024
Completed
Note: Click 'Add' to record investigation results without routing a subtask. To add subtasks, select 'Manage Investigation Subtasks' from the Action menu.
Additional Results of Investigation
IMDRF Cause Investigation: Type of Investigation (Annex B)
Investigation Tools (0)
Failure Mode as Reported (0)
Root Cause Analysis
Cancel
Save
Sign-off
Quality Control Investigation (3 of 4)
Instructions
Confirm the presence of foreign particles in the drug product and assess any failures in QC protocols
Result of Investigation
Visual and Microscopic Inspection
Conducted 100% visual inspection of the implicated vials under controlled lighting and magnification. Glass particles were confirmed in 3% of the inspected vials from the implicated batch.
Chemical Analysis
Performed an energy-dispersive X-ray spectroscopy (EDS) to confirm the composition of the particles. EDS confirmed the particles were glass, matching the composition of the defective vials.
Particle Count Test
Conducted a particle count test according to USP <788> standards. The implicated batch exceeded the acceptable limits for particulate matter, confirming a QC failure.
Immediate Actions
Quarantined the affected batch. New QC SOPs were issued, and QC personnel underwent training on inspection techniques. Implemented an automated particle detection system to supplement manual inspections.
Completed By
TNEAL
Completed By Name
Todd Neal
Completed Date
10-Dec-2024
Attachments
Distribution Investigation (4 of 4)
Instructions
Determine the extent of distribution of the implicated batches and assess the need for a recall
Result of Investigation
Batch Tracking
Used the batch number to track distribution to wholesalers, pharmacies, and hospitals. Implicated batches were distributed to 15 hospitals and 20 pharmacies across 5 states.
Inventory Check
Contacted distributors and healthcare facilities to assess if any remaining stock was available. 75% of the implicated batch was recovered. The remaining 25% had already been administered, prompting a patient notification process.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CASE-2024-0008-1
Investigate Complaint
Product: DP
Country of Origin: UNITED STATES
Reportable?: TBD
Complaint Coordinator: TNEAL
Reporting Site: NASH
Aware Date: 10-Dec-2024
Complaint Aging Days: 255
Case Severity: Serious Injury
Status: Inworks
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Investigate Complaint Task Information
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Investigation Subtasks (4)
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Activity
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Due Date / Completed Date
Status
Safety Investigation
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10-Dec-2024
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Manufacturing Investigation
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10-Dec-2024
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Quality Control Investigation
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Distribution Investigation
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Note: Click 'Add' to record investigation results without routing a subtask. To add subtasks, select 'Manage Investigation Subtasks' from the Action menu.
Additional Results of Investigation
IMDRF Cause Investigation: Type of Investigation (Annex B)
Investigation Tools (0)
Failure Mode as Reported (0)
Root Cause Analysis
Cancel
Save
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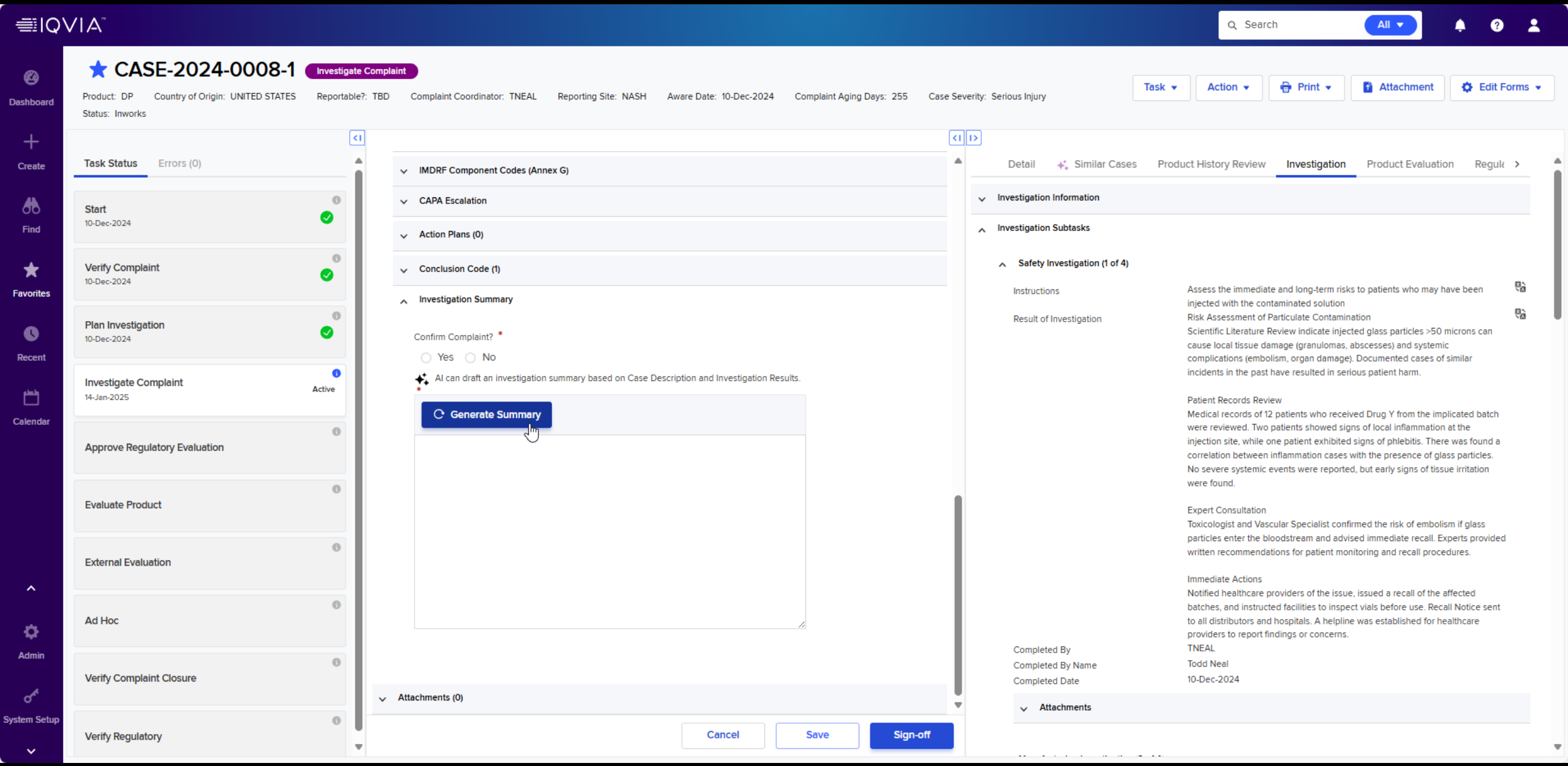
Distribution Investigation (4 of 4)
Instructions
Determine the extent of distribution of the implicated batches and assess the need for a recall
Result of Investigation
Batch Tracking
Used the batch number to track distribution to wholesalers, pharmacies, and hospitals. Implicated batches were distributed to 15 hospitals and 20 pharmacies across 5 states.
Inventory Check
Contacted distributors and healthcare facilities to assess if any remaining stock was available. 75% of the implicated batch was recovered. The remaining 25% had already been administered, prompting a patient notification process.
Recall Risk Assessment
Conducted a risk-benefit analysis to determine the necessity of a recall. The recall was classified as a Class II recall (FDA), and the necessary notifications were made to regulatory authorities.
Recall process was completed within 2 weeks. A final recall report was submitted to the FDA.
Completed By
TNEAL
Completed By Name
Todd Neal
Completed Date
10-Dec-2024
Attachments
Additional Results of Investigation
IMDRF Cause Investigation: Type of Investigation (Annex B)
Investigation Tools (0)
Failure Mode as Reported (0)
IMDRF Cause Investigation: Investigation Findings (Annex C)
IMDRF Component Codes (Annex G)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IMDRF Component Codes (Annex G)
CAPA Escalation
Action Plans (0)
Conclusion Code (1)
Investigation Summary
Confirm Complaint? *
Yes
No
AI can draft an investigation summary based on Case Description and Investigation Results.
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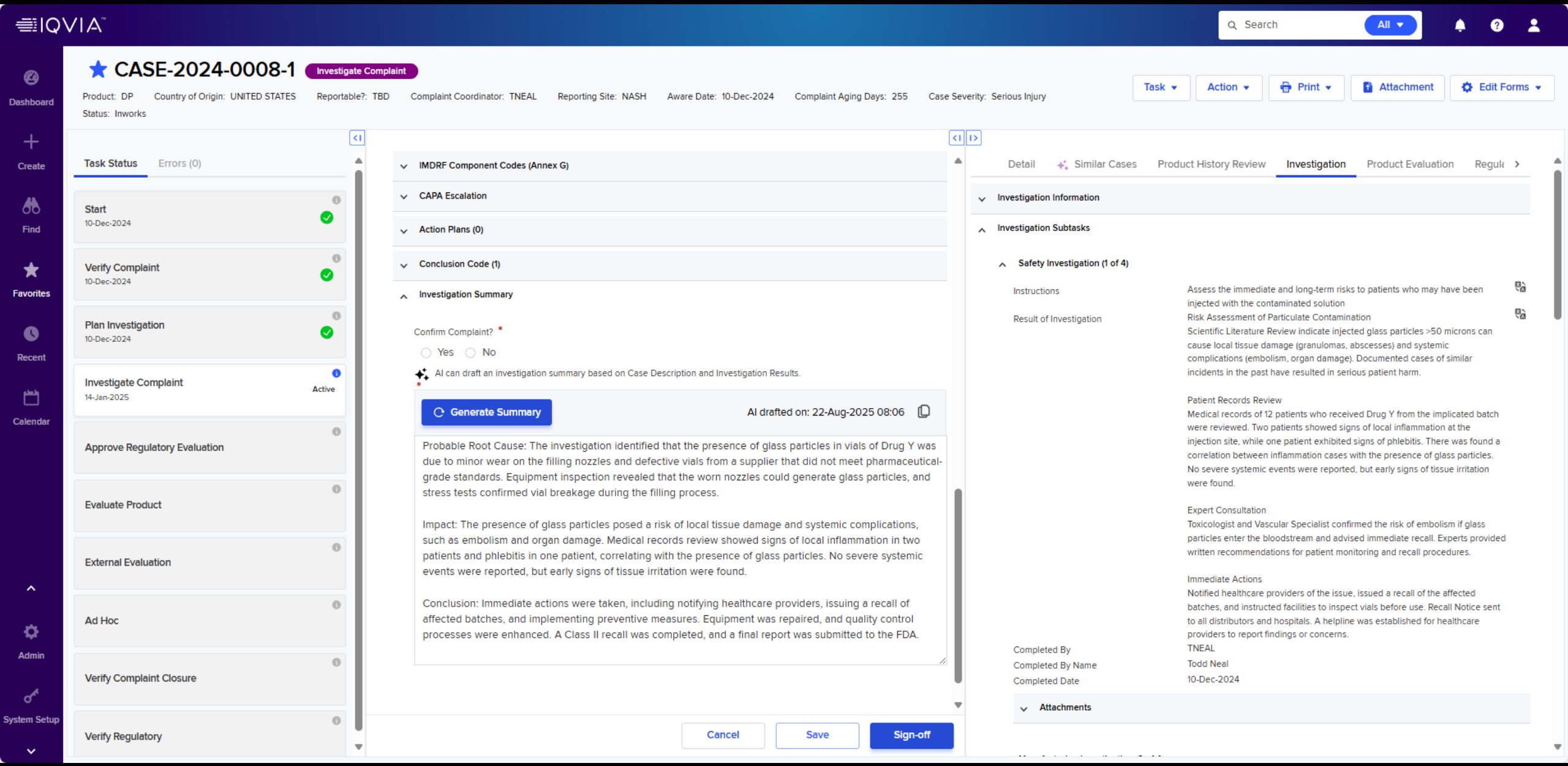
Safety Investigation (1 of 4)
Instructions
Assess the immediate and long-term risks to patients who may have been injected with the contaminated solution
Result of Investigation
Risk Assessment of Particulate Contamination
Scientific Literature Review indicate injected glass particles >50 microns can cause local tissue damage (granulomas, abscesses) and systemic complications (embolism, organ damage). Documented cases of similar incidents in the past have resulted in serious patient harm.
Patient Records Review
Medical records of 12 patients who received Drug Y from the implicated batch were reviewed. Two patients showed signs of local inflammation at the injection site, while one patient exhibited signs of phlebitis. There was found a correlation between inflammation cases with the presence of glass particles. No severe systemic events were reported, but early signs of tissue irritation were found.
Expert Consultation
Toxicologist and Vascular Specialist confirmed the risk of embolism if glass particles enter the bloodstream and advised immediate recall. Experts provided written recommendations for patient monitoring and recall procedures.
Immediate Actions
Notified healthcare providers of the issue, issued a recall of the affected batches, and instructed facilities to inspect vials before use. Recall Notice sent to all distributors and hospitals. A helpline was established for healthcare providers to report findings or concerns.
Completed By
TNEAL
Completed By Name
Todd Neal
Completed Date
10-Dec-2024
Attachments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Verify Complaint Closure
Verify Regulatory
IMDRF Component Codes (Annex G)
CAPA Escalation
Action Plans (0)
Conclusion Code (1)
Investigation Summary
Confirm Complaint? *
Yes
No
AI can draft an investigation summary based on Case Description and Investigation Results.
Generate Summary
AI drafted on: 22-Aug-2025 08:06
Probable Root Cause: The investigation identified that the presence of glass particles in vials of Drug Y was due to minor wear on the filling nozzles and defective vials from a supplier that did not meet pharmaceutical-grade standards. Equipment inspection revealed that the worn nozzles could generate glass particles, and stress tests confirmed vial breakage during the filling process.
Impact: The presence of glass particles posed a risk of local tissue damage and systemic complications, such as embolism and organ damage. Medical records review showed signs of local inflammation in two patients and phlebitis in one patient, correlating with the presence of glass particles. No severe systemic events were reported, but early signs of tissue irritation were found.
Conclusion: Immediate actions were taken, including notifying healthcare providers, issuing a recall of affected batches, and implementing preventive measures. Equipment was repaired, and quality control processes were enhanced. A Class II recall was completed, and a final report was submitted to the FDA.
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Investigation Subtasks
Safety Investigation (1 of 4)
Instructions
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Result of Investigation
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Expert Consultation
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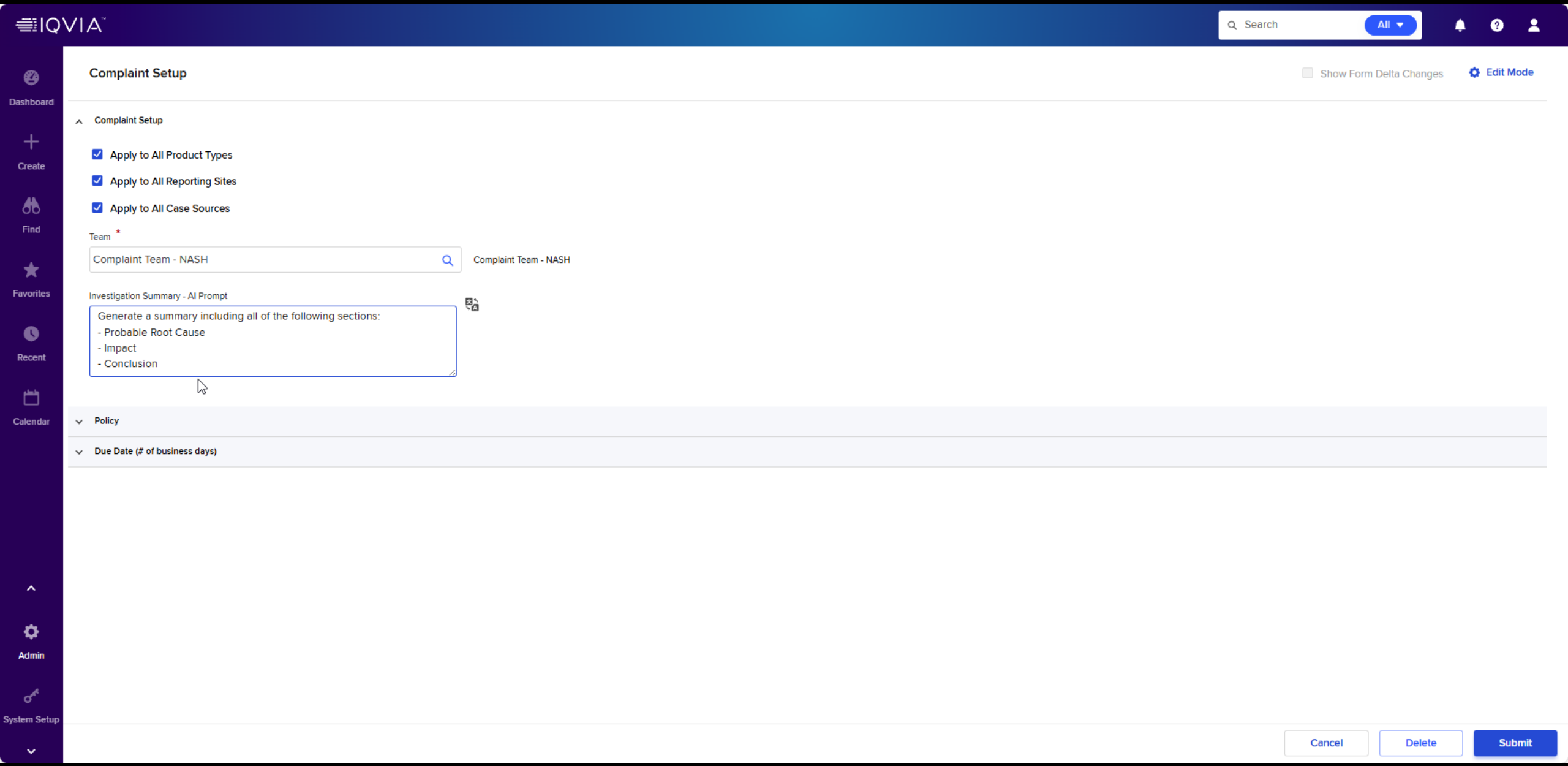
TNEAL
Completed By Name
Todd Neal
Completed Date
10-Dec-2024
Attachments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Apply to All Case Sources
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Complaint Team - NASH
Complaint Team - NASH
Investigation Summary - AI Prompt
Generate a summary including all of the following sections:
- Probable Root Cause
- Impact
- Conclusion
Policy
Due Date (# of business days)
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