



A Proactive Approach to Inspection Readiness

Harnessing Automated EHS for Safety and Compliance

Stephanie Ojeda

Director of Product Management, Life Sciences & Manufacturing
AssurX

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Agenda

- Challenges in EHS Incident Management
- Root Cause Analysis: A Deep Dive
- Importance of Standardization
- Benefits of an Automated QMS
- Best Practices for EHS Incident Management
- Integrating Risk Assessment Techniques
- Use Case: Adopting a Proactive Approach to EHS Inspections
- Q&A

Hello! I'm Stephanie!

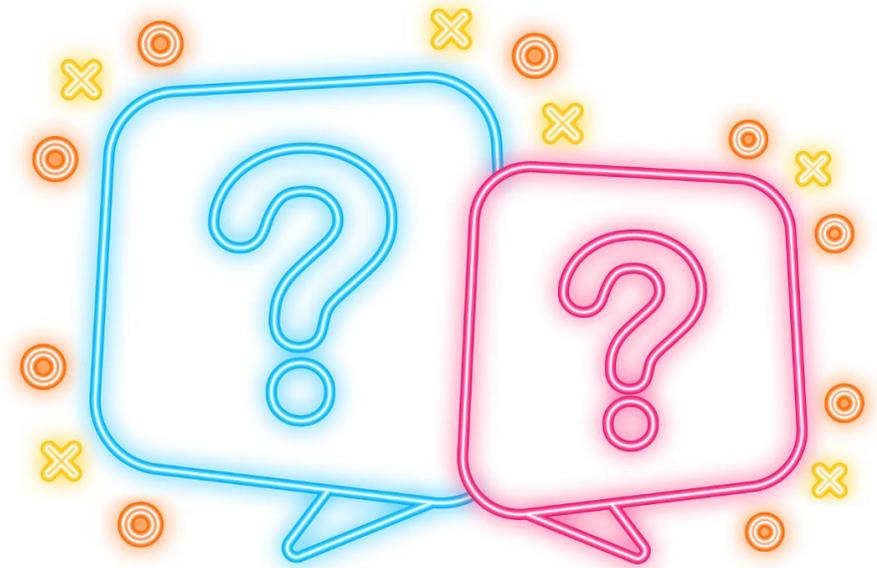
- **St. Louis University**
 - B.S. in Chemistry
- **15+ years of Quality Management Experience**
 - Biotech, Pharma, Medical Device, Food & Beverage, General Manufacturing
- **ASQ Certified Quality Auditor**
- **ISO 13485 Lead Auditor**
- **Lean Six Sigma Green Belt**



Poll Time!

What is your biggest challenge when it comes to EHS Incident Management?

- Lack of timely incident reporting
- Communication breakdowns
- Data discrepancies and inconsistencies
- Resource allocation issues
- Insufficient documentation
- Something else



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
 - Perceived Consequences
 - Inadequate Reporting Channels



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
 - Perceived Consequences
 - Encourage an open reporting culture, i.e. anonymous reporting
 - Inadequate Reporting Channels
 - Implement user-friendly reporting systems



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
 - Silos and Departmental Barriers
 - Lack of Standardized Communication Protocols



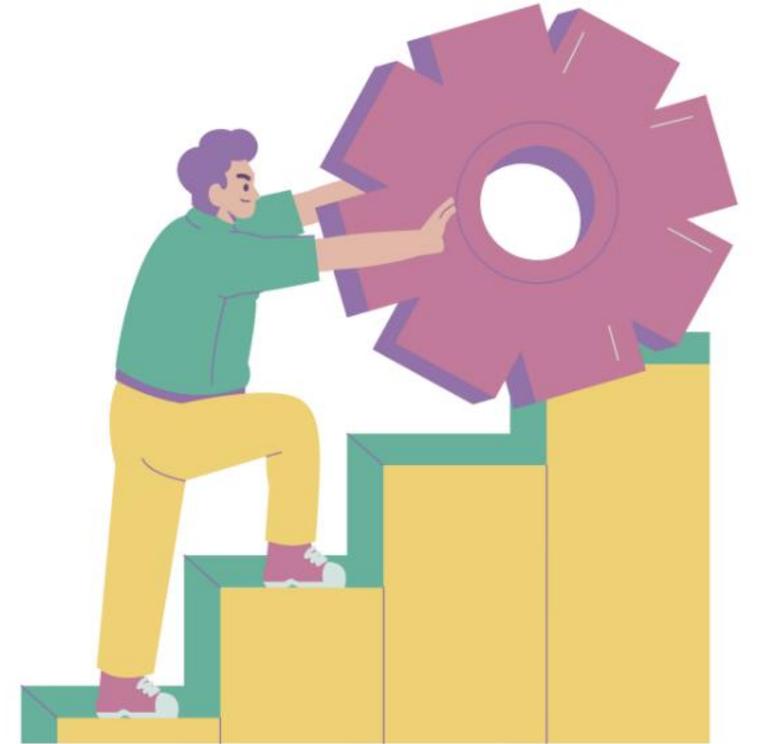
Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
 - Silos and Departmental Barriers
 - Conduct training to promote cross-functional communication
 - Lack of Standardized Communication Protocols
 - Establish clear guidelines for incident reporting



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
 - Multiple Data Sources
 - Lack of Standardized Data Capture



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
 - Multiple Data Sources
 - Integrate data sources to create a centralized incident management system
 - Lack of Standardized Data Capture
 - Incorporate validation checks to ensure accuracy



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
- Resource Allocation Issues
 - Geographical Disparities
 - Competing Priorities



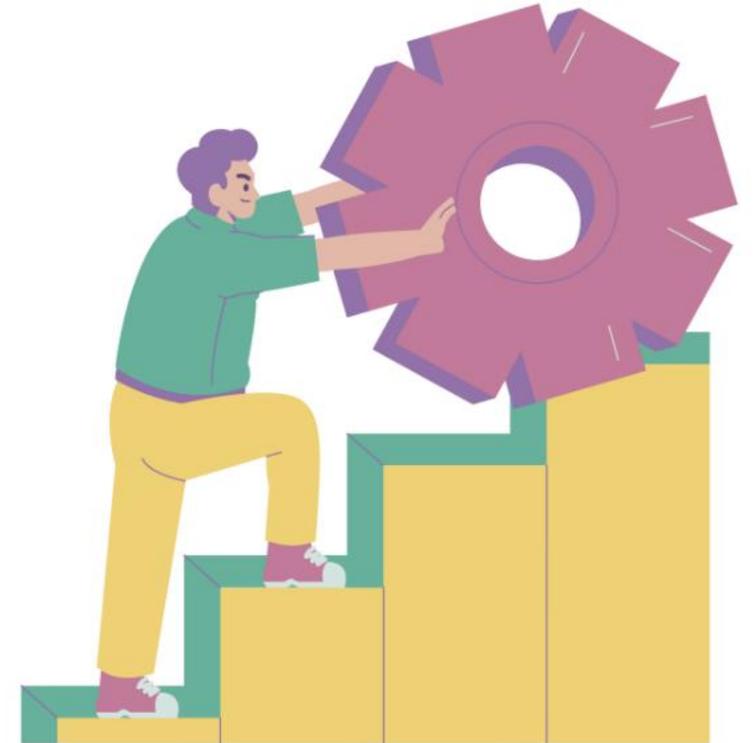
Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
- Resource Allocation Issues
 - Geographical Disparities
 - **Improve collaboration and communication channels**
 - Competing Priorities
 - **Advocate for effective prioritization and planning**



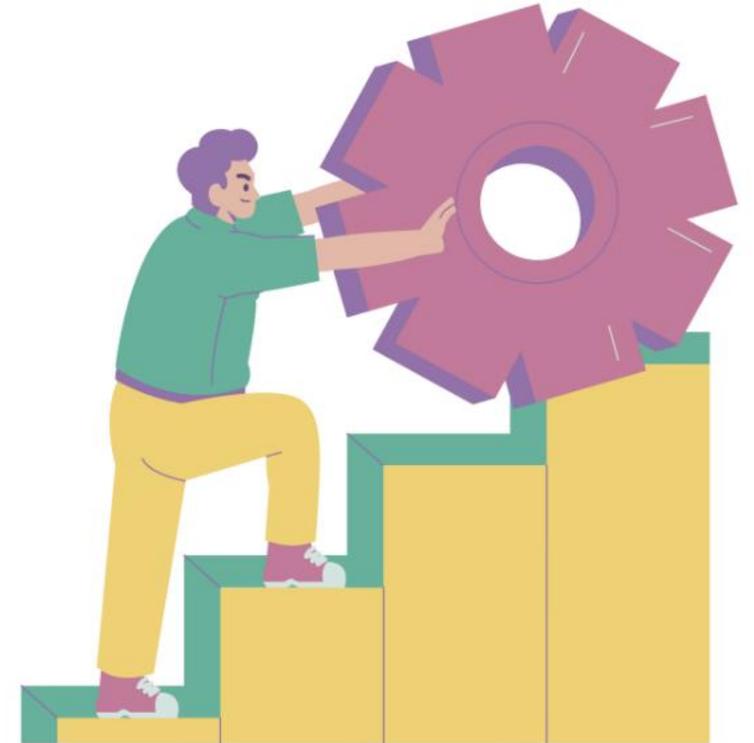
Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
- Resource Allocation Issues
- Insufficient Documentation
 - Lack of Comprehensive Incident Details
 - Failure to Capture Root Causes



Challenges in EHS Incident Management

- Lack of Timely Incident Reporting
- Communication Breakdowns
- Data Discrepancies and Inconsistencies
- Resource Allocation Issues
- Insufficient Documentation
 - Lack of Comprehensive Incident Details
 - Utilize standardized incident reporting systems
 - Failure to Capture Root Causes
 - Highlight the role of documentation in root cause analysis

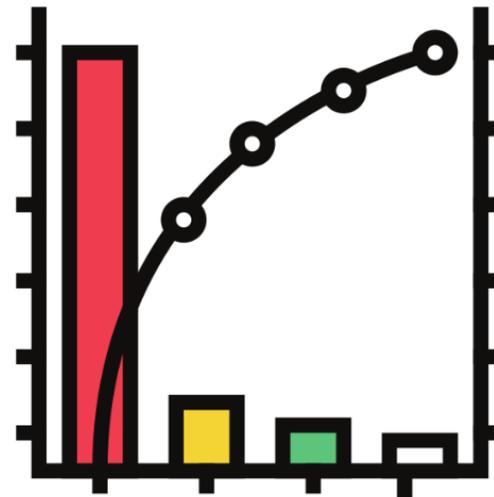
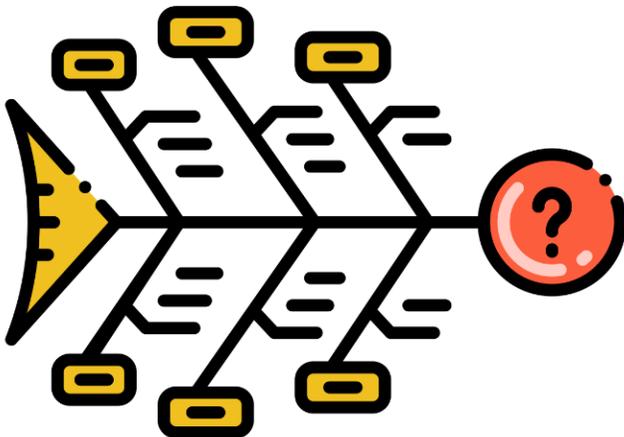


Root Cause Analysis: A Deep Dive



Steps in Root Cause Analysis

- Identify the Problem
- Collect Data
- Identify the Root Cause
- Analyze the Root Cause
- Develop Corrective and Preventive Actions



Importance of Standardization

- Consistency in Incident Reporting
 - Uniform data collection
 - Defined incident categories



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
 - Common language and understanding
 - Cross-functional collaboration



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
- Clarity in Roles and Responsibilities
 - Role definition in incident response
 - Role-specific training processes



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
- Clarity in Roles and Responsibilities
- Reduced Variability in Incident Responses
 - Consistent procedures across incidents
 - Minimized ad hoc decision-making



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
- Clarity in Roles and Responsibilities
- Reduced Variability in Incident Responses
- Streamlined Investigation Processes
 - Clear sequence of investigation steps
 - Consistent data collection methods



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
- Clarity in Roles and Responsibilities
- Reduced Variability in Incident Responses
- Streamlined Investigation Processes
- Adaptability to Changing Regulations
 - Continuous review and updating
 - Regular training on updated procedures



Importance of Standardization

- Consistency in Incident Reporting
- Efficient Communication Across Teams
- Clarity in Roles and Responsibilities
- Reduced Variability in Incident Responses
- Streamlined Investigation Processes
- Adaptability to Changing Regulations
- Enhanced Data Integrity
 - Consistent information format
 - Unified data storage and retrieval



Poll Time!

How are you currently managing your EHS Incidents?

- Paper-based/File-based
- Automated QMS
- Homegrown solution
- Other



What is Quality Management System (QMS) Software?

- An electronic Quality Management System (eQMS) helps companies streamline and automate their quality management processes
- Serves as a centralized repository for managing quality-related data, documentation, and workflows
- Key features of an eQMS:
 - Document Management
 - EHS Incident Management
 - Training Management
 - Corrective & Preventive Actions
 - Non-Conformance Management
 - Audit Management
 - Risk Management
 - Supplier Management
 - Reporting & Analytics

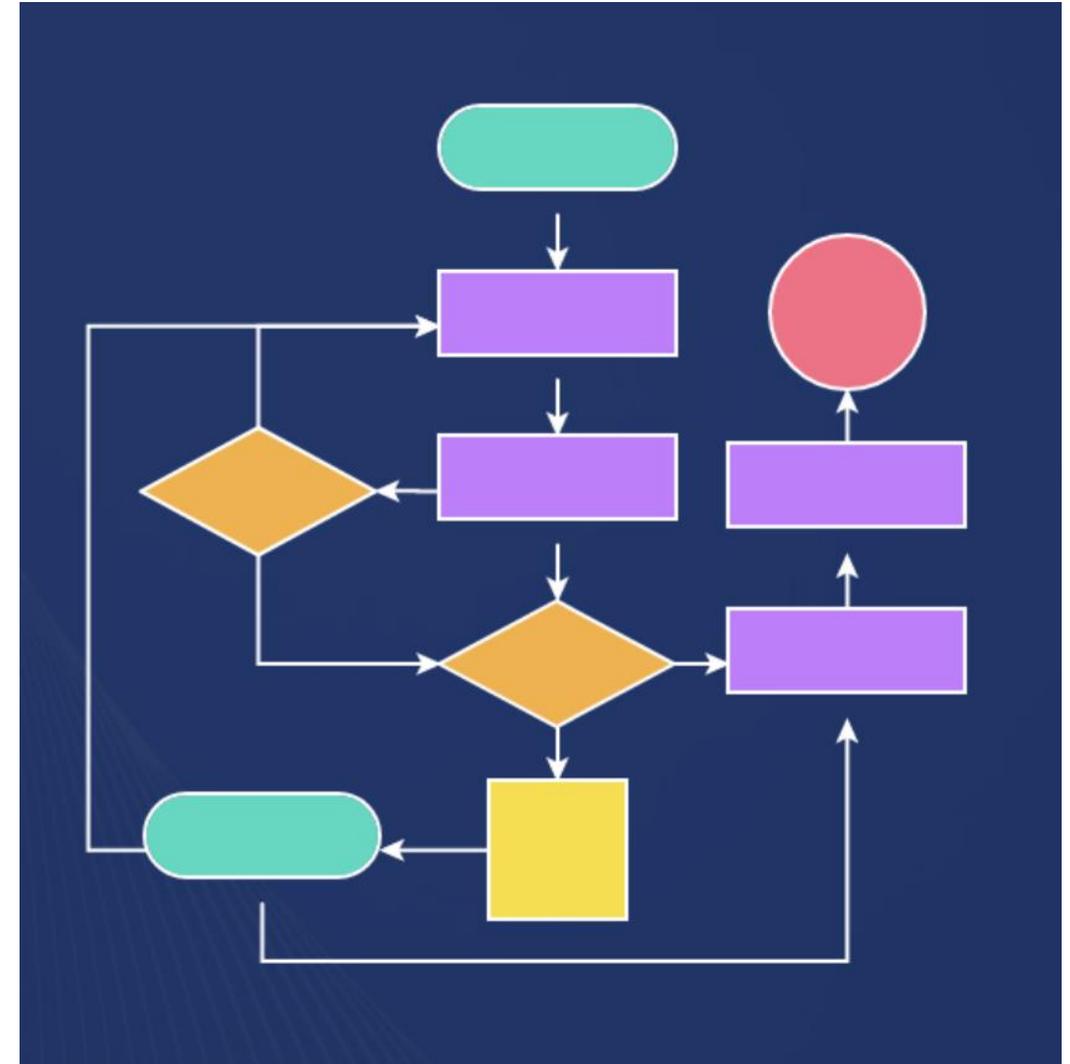
Benefits of an Automated QMS

- **Organization & Accessibility**
 - Documents, training files, and other electronic records are stored in a centralized location
 - Improved document traceability
 - Control access to sensitive documents and information as needed



Benefits of an Automated QMS

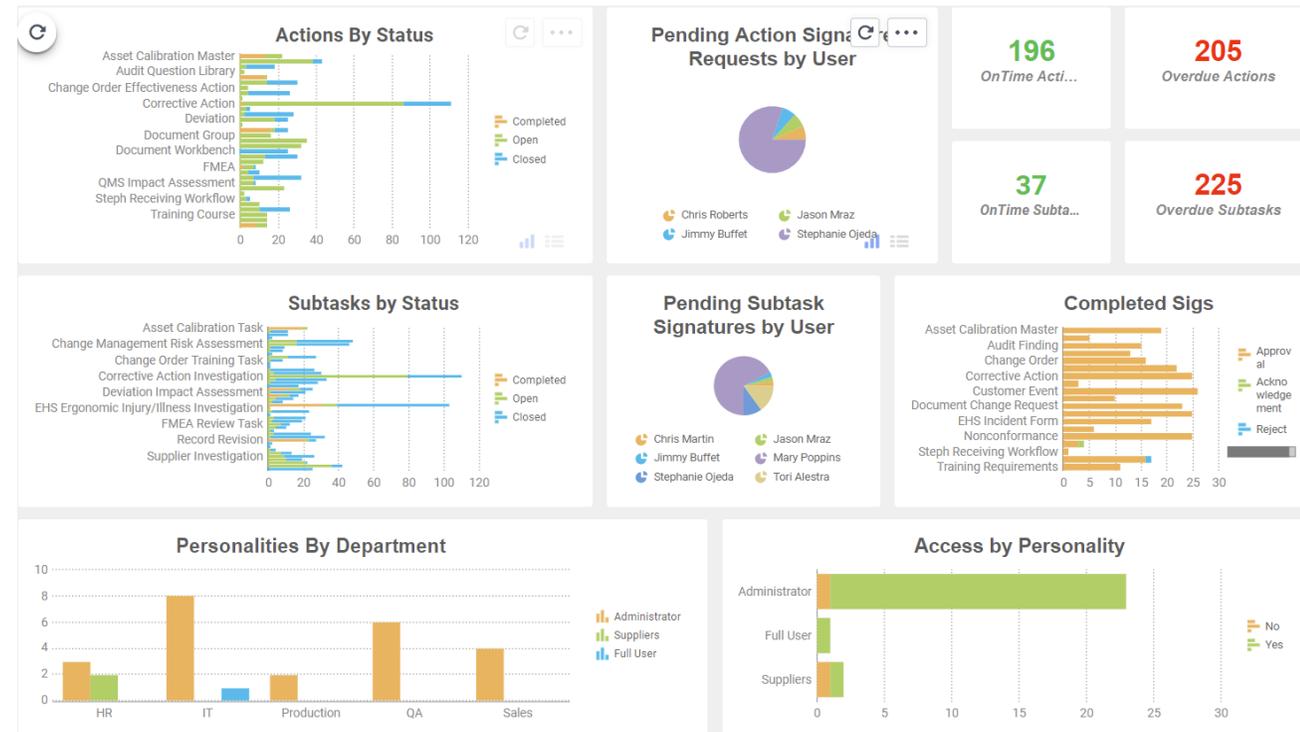
- Automation Potential
 - Increase efficiency through elimination of manual and repetitive tasks
 - Improve real-time insights, allowing for ability to make informed decisions quickly
 - Increase competitive advantage through improvement of efficiencies and responsiveness to issues and potential risks



Benefits of an Automated QMS

- **Metrics & KPI Reporting**

- Utilize your data in a powerful way by generating charts, graphs, reports
- Streamlined access to real-time and historical data, enabling data-driven decision making
- Establish alerts and notifications based on user-defined quality metrics



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
 - Regular training sessions
 - Integration of EHS in onboarding programs



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
 - Define quantifiable metrics (i.e. # of near misses reported)
 - Involve employees in establishment of KPIs



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
- Scenario Planning for High-Risk Activities
 - Create realistic and plausible scenarios
 - Develop response protocols for each scenario



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
- Scenario Planning for High-Risk Activities
- Incident Simulation Exercises
 - Involve cross-functional teams
 - Post-exercise debriefing



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
- Scenario Planning for High-Risk Activities
- Incident Simulation Exercises
- Integration of Technology for Incident Tracking
 - Create a centralized incident database
 - Implement alerts, notifications, and escalations



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
- Scenario Planning for High-Risk Activities
- Incident Simulation Exercises
- Integration of Technology for Incident Tracking
- Regular Audits and Inspections
 - Risk-based auditing approach
 - Thorough documentation and recordkeeping



Best Practices: EHS Incident Management

- Employee Training and Awareness Programs
- Establishment of Key Performance Indicators (KPIs)
- Scenario Planning for High-Risk Activities
- Incident Simulation Exercises
- Integration of Technology for Incident Tracking
- Regular Audits and Inspections
- Feedback Loops for Continuous Improvement
 - Incident debriefings and reviews
 - Anonymous feedback mechanisms



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
 - Systematic process of identifying, evaluating, and prioritizing potential hazards to prevent incidents and improve safety



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
 - View risk assessments as an interconnected component rather than an isolated activity



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
- Proactive Identification of Hazards
 - By identifying risks proactively, organizations can address issues before they escalate into incidents



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
- Proactive Identification of Hazards
- Quantitative and Qualitative Risk Analysis
 - Quantitative: involves numerical assessments & assigning values to risks
 - Qualitative: considers factors such as severity, likelihood, and potential impact



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
- Proactive Identification of Hazards
- Quantitative and Qualitative Risk Analysis
- Prioritizing Risks Based on Severity
 - Assess the consequences of an incident, considering factors like injuries, property damage, environmental impact, etc.



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
- Proactive Identification of Hazards
- Quantitative and Qualitative Risk Analysis
- Prioritizing Risks Based on Severity
- Continuous Review and Update of Risk Assessments
 - Risks and associated factors can change due to various internal and external influences



Integrating Risk Assessment Techniques

- Understanding Risk Assessments
- Incorporating Risk into EHS Incident Management
- Proactive Identification of Hazards
- Quantitative and Qualitative Risk Analysis
- Prioritizing Risks Based on Severity
- Continuous Review and Update of Risk Assessments
- Employee Involvement in Risk Identification
 - Recognizing and leveraging frontline worker expertise is essential for a comprehensive and accurate risk assessment



Use Case: Adopting a Proactive Approach to EHS Inspections

Goal:

- Adopt a proactive approach to EHS inspections

Challenges:

- Delayed Incident Reporting
- Scattered Documentation
- Ineffective Training
- Unknown Risks



Use Case: Adopting a Proactive Approach to EHS Inspections

EHS Management

15 OSHA Reportable

14 My Incident Forms

9 My EHS Tasks

14 Late EHS Incidents

2 EHS Needing Approval

[+ Add EHS Incident](#)

Open Incidents

INCIDENT TYPE INCIDENT DATE FROM INCIDENT DATE TO

TASKS	INCIDENT NUMBER	ENTRY DATE	DATE OF INCIDENT	TYPE OF INCIDENT	WORKFLOW STAGE	PLANNED DUE DATE
+	EHS-2023-032	11/01/2023	11/01/2023	Injury / Illness	Investigation	11/22/2023
+	EHS-2023-031	10/02/2023	10/02/2023	Injury / Illness	Quality Review	10/23/2023
+	EHS-2023-029	06/27/2023	06/26/2023	Injury / Illness	Quality Review	07/18/2023
+	EHS-2023-025	03/30/2023	03/30/2023	Injury / Illness	Investigation	04/20/2023
+	EHS-2023-024	03/30/2023	03/30/2023	Injury / Illness	OCC Health Review	04/20/2023
+	EHS-2023-023	03/22/2023	03/22/2023	Injury / Illness	OCC Health Review	04/12/2023

Initiative Taken:

- Implementation of EHS Incident Management system

Use Case: Adopting a Proactive Approach to EHS Inspections

Document Management

2

Documents in Draft

1

Documents Needing Approval

0

DCRs Needing Approval

1

Released Documents

0

Documents Expiring

[+ Add DCR](#) [+ Add Document Master](#) [+ Add Record Master](#) [+ Add Document Type](#) [+ Add Document Group](#)

Effective Documents

TYPE

HISTORY	DOCUMENT MASTER	REVISION	REVISION#	TYPE	TITLE	DOC/REC #
	1011	1402	1.0	EHS Documents	EHS Incident Analysis	EHS-00001
	1012	1403	1.0	EHS Documents	EHS Incident Reporting	EHS-00002
	813	1364	8.0	QA SOP	HPLC Calibration	QAS-00002
	918	1357	2.0	Production SOP	Production Procedure Line A	PROS-00002
	928	1284	1.0	Production SOP	Production Procedure Line B	PROS-00003
	916	1321	4.0	QA SOP	QA Inspection	QAS-00003

Initiative Taken:

- Establishment of centralized repository to house standardized processes

Use Case: Adopting a Proactive Approach to EHS Inspections

Documents Or Records In This Group

CATEGORY ▾	DOC/REC # ▾	TYPE ▾	DOCUMENT NUMBER ▾	TITLE ▾	NEXT REVIEW ▾	REMOVE FROM GROUP ▾
Document	EHS-00001	EHS Documents	EHS-00001	EHS Incident Analysis	12/27/2024	Delete
Document	EHS-00002	EHS Documents	EHS-00002	EHS Incident Reporting	12/27/2024	Delete

Document Security

EDIT ITEM ▾	SECURITY TYPE ▾	NAME ▾	ACCESS ▾	REMOVE ITEM ▾
Edit	Department	QA	Manage	Remove

▼ TYPE DETAILS

Document/Record Type*	EHS Documents	Prefix*	EHS
Category*	Document x ▾ ↻	Revision Format*	Numeric x ▾
Status*	<input checked="" type="radio"/> Open <input type="radio"/> Completed <input type="radio"/> Closed		
Department	QA		
Type Owner	Stephanie Ojeda		
Periodic Review Type	Year x ▾	Periodic Review Increment	1
Release Notifications	Stephanie Ojeda x Michael Jordan x		

Initiative Taken:

- Establishment of centralized repository to house standardized processes

Use Case: Adopting a Proactive Approach to EHS Inspections

TITLE ▾	TYPE ▾	CATEGORY ▾
EHS Inspection Training	Classroom	General
Root Cause Analysis 101	Classroom	General

All Open Sessions For This Course

TITLE ▾	DATE ▾	START TIME ▾	END TIME ▾	LOCATION ▾	TRAINER ▾	CAPACITY ▾	ATTENDEES ▾	REMAINING SPOTS ▾
Fall Session 2023	12/30/2023	7:00 AM	7:30 AM	Conference Room A	Stephanie Ojeda	10	2	8
Winter Session	1/8/2024	7:00 AM	8:00 AM	Zoom Call	Stephanie Ojeda	15	0	15

Exam Template Questions

QUESTION ▾	TYPE ▾	ANSWERS ▾	CORRECT ANSWER ▾
When should safety incidents be reported?	Multiple Choice	A) Never B) Within 2 weeks C) Within 48 hours D) Immediately E)	Immediately
Is safety important?	Yes/No	Yes/No	Yes
OSHA forms are never needed.	True/False	True/False	F

Initiative Taken:

- Training and awareness programs

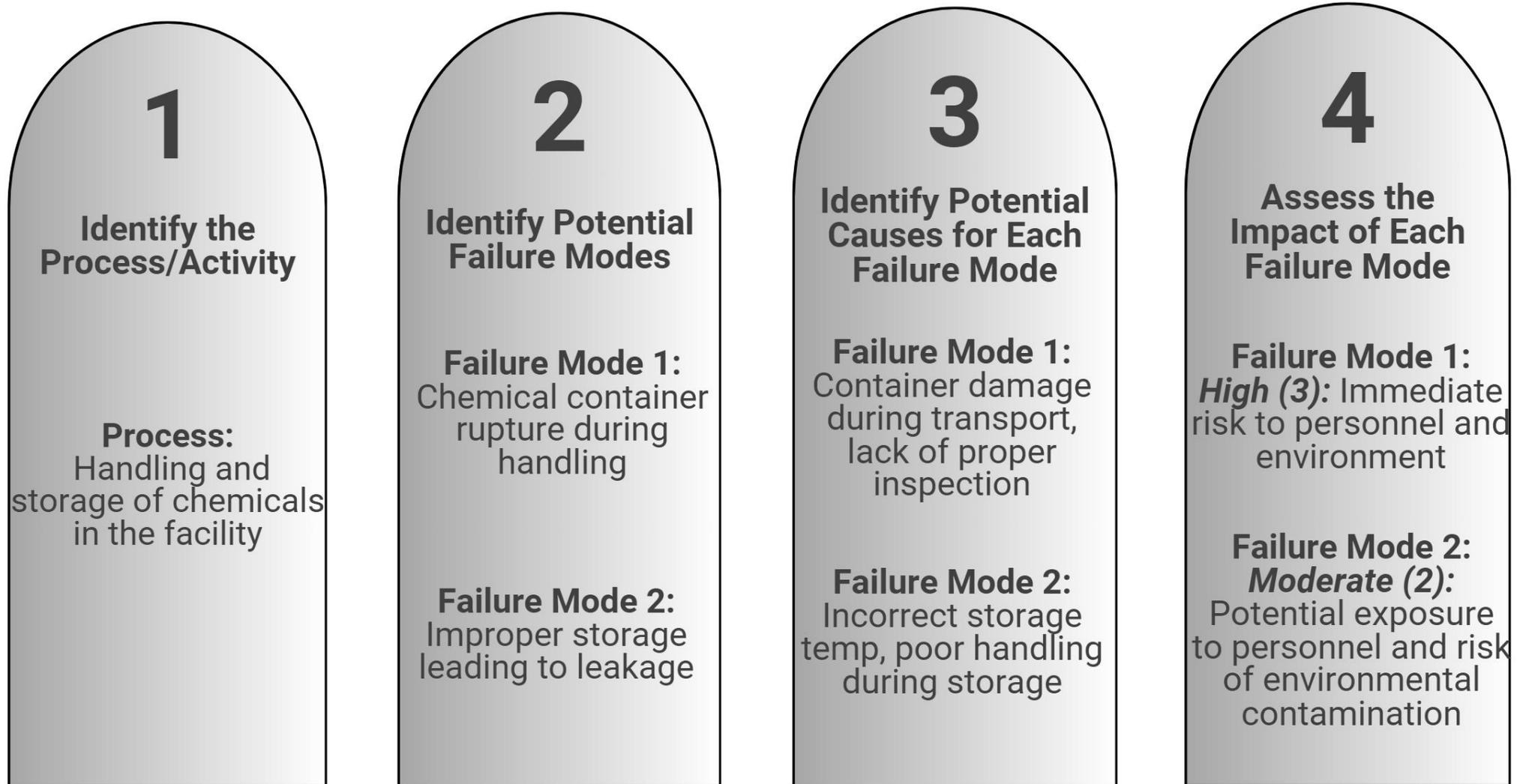
Use Case: Adopting a Proactive Approach to EHS Inspections



Initiative Taken:

- Integration of risk assessment techniques

Failure Modes & Effects Analysis



Failure Modes & Effects Analysis

5

Assess Likelihood of Each Failure Mode

Failure Mode 1: Moderate (2):
Occasional lapses in training and inspection

Failure Mode 2: Low (1): Regular training and monitoring in place

6

Assess Detection Capability

Failure Mode 1: High (3): Difficult to detect in early stages

Failure Mode 2: Moderate (2): Visible signs and regular checks

7

Calculate RPN
Impact x Likelihood x Detection

Failure Mode 1:
Impact - 3
Likelihood - 2
Detection - 3
 $3 \times 2 \times 3 = 18$

Failure Mode 2:
Impact - 2
Likelihood - 1
Detection - 2
 $2 \times 1 \times 2 = 4$

8

Prioritize Actions Based on RPN

Action 1:
Enhance training programs to reduce likelihood of container rupture

Action 2:
Implement additional containment measures to reduce risk of improper storage

Use Case: Adopting a Proactive Approach to EHS Inspections

Benefits:

- Improved incident response time
- Faster document retrieval
- Customized training programs
- Effective use of RCA and Risk Assessment methodologies



Summary

- Proactive EHS Management is Crucial
 - Helps prevent incidents
 - Protects employee well-being
 - Ensure compliance with regulations



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
 - Identification and reporting of risks
 - Utilization of frontline workers' insights



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
- Standardization Enhances Incident Management
 - Ensures consistency & clarity in roles
 - Reduces variability in responses



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
- Standardization Enhances Incident Management
- Risk Assessment Techniques Improve Decision-Making
 - Quantitative & qualitative analyses help with understanding of potential hazards
 - Take advantage of tools like FMEA



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
- Standardization Enhances Incident Management
- Risk Assessment Techniques Improve Decision-Making
- Root Cause Analysis Enhances Understanding
 - Understand factors contributing to incidents
 - Address underlying issues and prevent future occurrences



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
- Standardization Enhances Incident Management
- Risk Assessment Techniques Improve Decision-Making
- Root Cause Analysis Enhances Understanding
- Training and Awareness Foster a Proactive Culture
 - Create a proactive reporting culture
 - Ongoing awareness initiatives helps maintain a focus on safety



Summary

- Proactive EHS Management is Crucial
- Employee Involvement is Key
- Standardization Enhances Incident Management
- Risk Assessment Techniques Improve Decision-Making
- Root Cause Analysis Enhances Understanding
- Training and Awareness Foster a Proactive Culture
- Continuous Improvement through Feedback
 - Continuous improvement via feedback loops
 - Helps redefine incident management strategies over time



A group of business professionals in a meeting, clapping and smiling, overlaid with a red tint. The image shows several people in business attire, including a man in a suit and glasses in the foreground, and a woman in a light-colored blouse in the middle ground. They are all smiling and clapping, suggesting a positive event or presentation. The background is slightly blurred, focusing attention on the people in the foreground.

Q&A



Thank you!

Stephanie Ojeda
Email: sojeda@assurx.com

For more information, visit us at:
<https://www.assurx.com/enterprise-quality-management-software>