# REVOLUTIONIZING LIFE SCIENCE RECALLS

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# **AGENDA**















# LIFE SCIENCES RECALLS

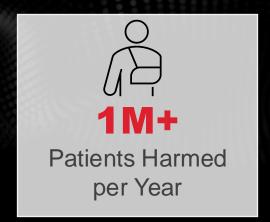




The primary reasons for pharmaceutical recalls are manufacturing defects, contamination and labeling errors.

The medical device sector typically accounts for a more significant percentage of U.S. recalls, with software issues a growing concern.





# **POLL**

Has your organization ever been involved in a product recall?

- A. Yes
- B. No
- C. N/A



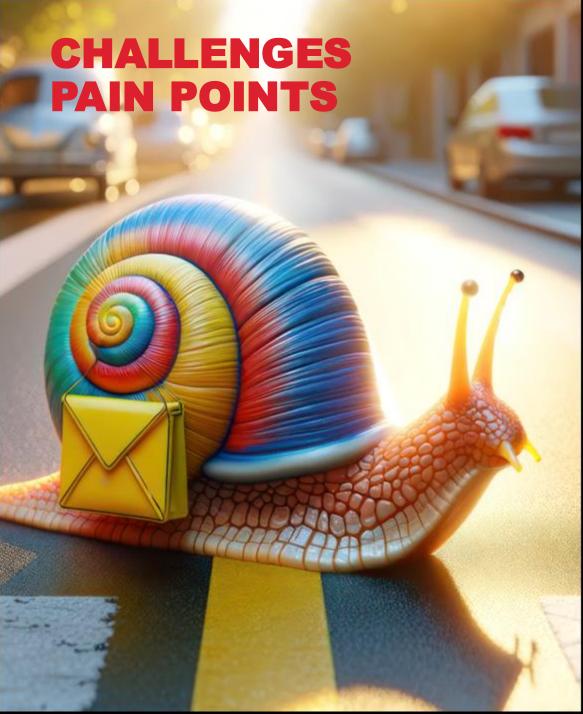






# WHAT IS YOUR COMPANY'S TOP CHALLENGE WITH RECALLS?

- 1. Deciding to initiate a recall
- 2. Gathering the consignee information
- 3. Notification process (sending, receiving)
- 4. Recall effectiveness and closure
- 5. We struggle with the entire process



### DATA

- Data integration with various data sources
- Lack of real-time visibility
- Data accuracy and compliance
- Delays due to siloed data sources
- Manual methods used with multiple SoR

# SENDING, TRACKING AND EFFECTIVENESS

- Compiling consignee information
- Tracking notifications and responses
- Effectiveness of recall and disposition

# KEEPING UP WITH COMPLIANCE

- Notification translations
- Managing compliance with multiple regulatory bodies across different countries

# HASSLE MAP

#### DETECT EMERGING SIGNALS

- · Mfg. failures
- Complaints
- CAPAs
- Audits
- · Field service calls
- Regulator communication

### SCOPE, IMPACT & BOUNDING

- Identify and qualify Quality issues
- · Affected product scope
- Patient Impact
- Product Impact
- Regulatory ImpactBusiness Impact

### RESPONSE DECISION TREE

- Create a response decision tree
- Analyze outcomes for each decision

### ESCALATION FOR DECISION MAKING

Iterative process

#### **DECISION TO ACT**

- Decision on postmarket action
- Identify the type of post-market action

#### **INITIATE RECALL**

 Initiate postmarket action

#### **SEND PHYSICAL MAIL**

 Sending notifications and tracking confirmation of received communication

#### **REVERSE LOGISTICS**

 Confirmation from received patients

#### **FIELD NOTIFICATION**

- Recall Advisory to healthcare providers and hospitals
- Recall notification to patients/device users
- Field action notifications to field action group team
- Tracking notification acknowledgment &
- Validating response

### **REGULATORY NOTIFICATION**

- Correspond with a regulatory authority on the effectiveness of the recall
- · Monitor recall status
- Monitor communication efficiency

### PREPARE COMMUNICATION

- · Consignee notice
- · Press release
- FAQ preparation, etc.
- Prepare communication packets
- Executive team notification and signoff

### COMPLETE CONSIGNEE LIST

- Identify batches of all devices
- Identify the location of all consignments in the supply chain
- Generate a list of all patients/users
- Connecting with different systems to gather the list and data
- Quality of data not assured

### CONFIRMATION OF PRODUCT RECIEVED

 Generate a list of tracked received at the manufacturing location

# REVERSE LOGISTICS EFFICIENCY

 Measure reverse logistics efficiency for the number of recalled devices vs. the list of devices identified.

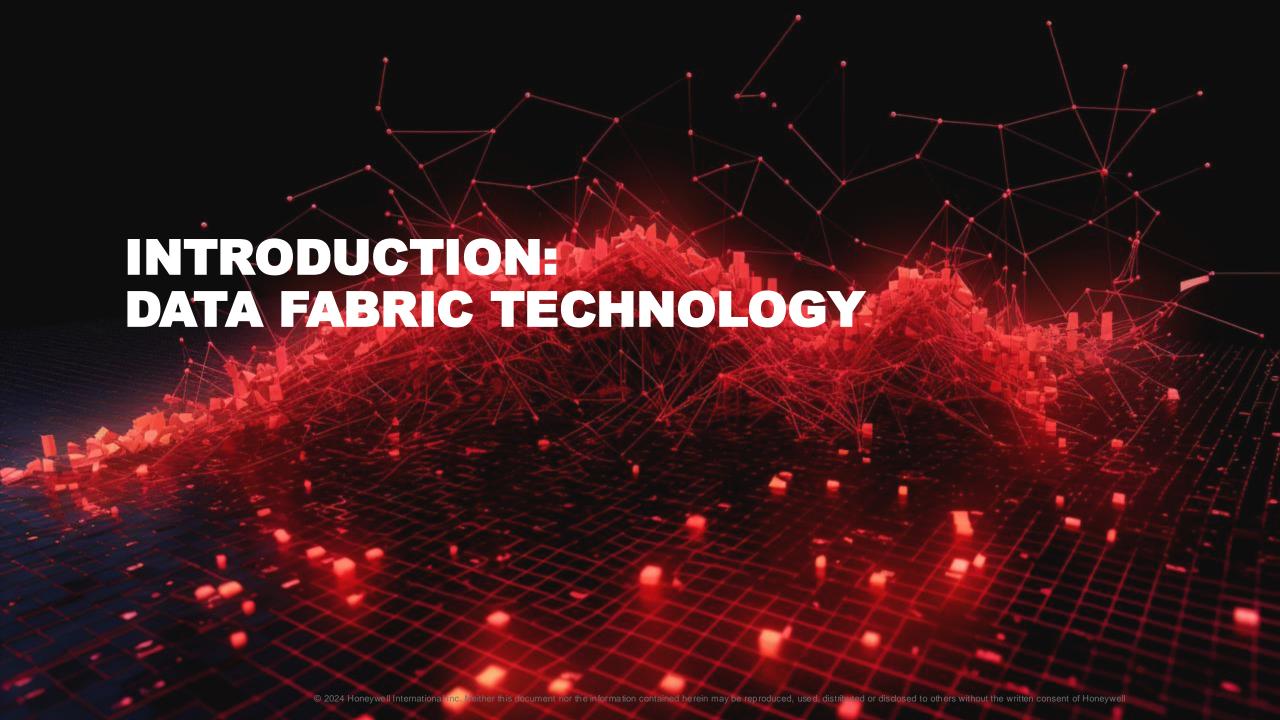
### PROOF OF AT-RISK PRODUCT RECALL

 Share the proof of at-risk recall with FDA/Regulators

#### PROOF OF ACTION

CLOSE RECALL

- Share the proof of specific
- Action/destruction for at-risk recalled devices



# **KEY TERMS**

### **1** Data Fabric

An architectural approach or set of services that provides consistent, secure, and scalable access to data across a wide variety of sources and environments

# Data Governance

Ensuring consistent data governance and security policies across all data sources

# **Data Integration**

Integrating data from various sources (cloud, on-premises, structured, unstructured) into a cohesive environment

# **Data Orchestration**

The automated management of data workflows, ensuring that data moves smoothly between systems and is available where and when it is needed

# 03 Data Lake

A centralized repository that stores all your structured and unstructured data at any scale

# Data Processing

Leverages automation and AI to manage and optimize data, such as automating data discovery, lineage tracking, and data quality management.

# DATA FABRIC TECHNOLOGY

**Business Apps** Connective **Data Fabric** 0 :::: **Example Data Sources** Cloud Data **QMS DMS TMS MES** DCS LIMS **CTMS ERP RIMS Databases** Stores

# BENEFITS OF A DATA FABRIC

Standardized end-to-end process from signal detection to recall effectiveness evaluation



#### **PROCESS AUTOMATION**

#### MINIMUM DEPARTMENTAL **DEPENDENCY**



#### **REGULATORY COMPLIANCE**

Automatically conduct complex analysis of data with configured reports that can be easily generated

Closed loop system that

enables documentation of

process improvement when

Connect to all relevant systems to automate the compilation of the consignee list

Manage regulation guidelines with a fully validated and digital solution



#### **EASY REPORT CREATION**

a recall is closed



#### **IMPROVE EFFICIENCY & DECISION MAKING**



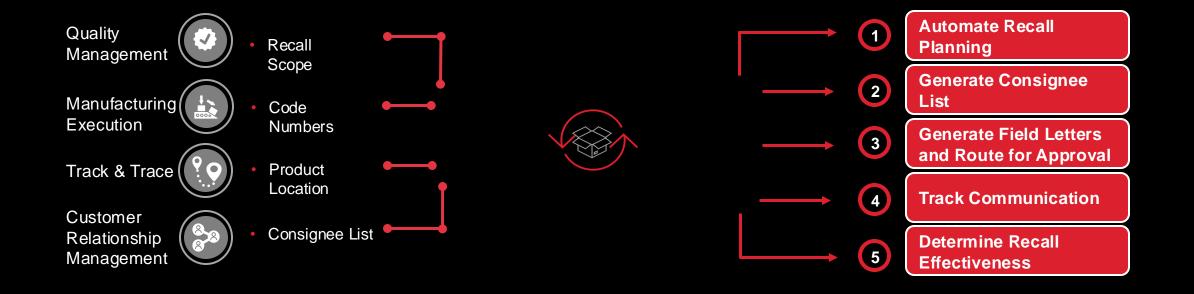
Streamlined processes, intelligent workflows and automation for faster, more informed decision-making



#### **CONTINUOUS PROCESS IMPROVEMENT**

Creates a feedback loop to learn from mistakes, improve processes and ultimately produce safer and higherquality products

# **UNLOCKING THE VALUE**



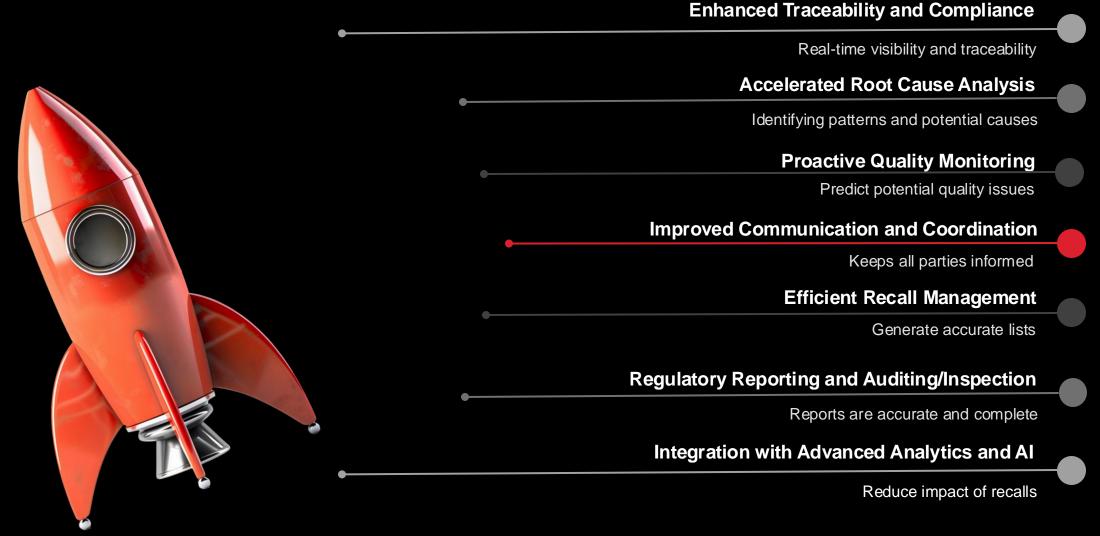
### **Business Challenges Addressed**

- Detect emerging recall signals, reducing recall impact
- Efficiency gain in the recall process resulting in a decrease in costs
- Transparency and accuracy in the recall process to support regulatory agencies
- Reduce brand, legal and regulatory fine exposure



#### **UNIFIED DATA**

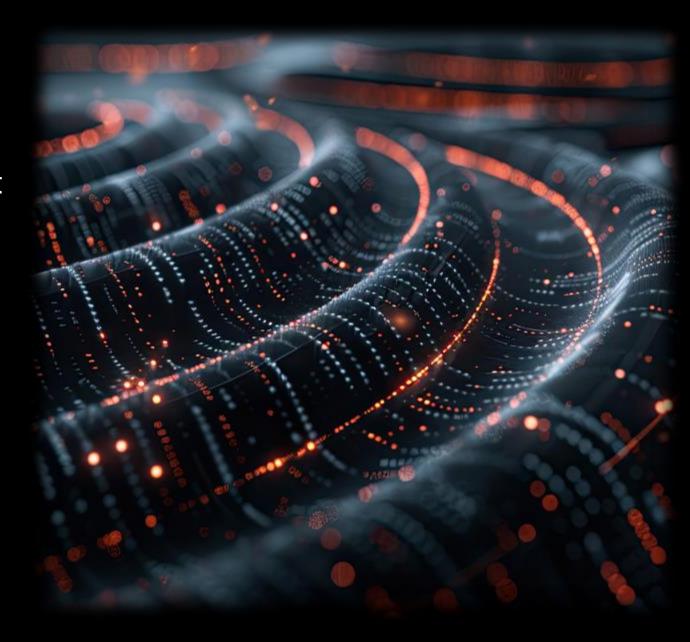
### **USE CASES**

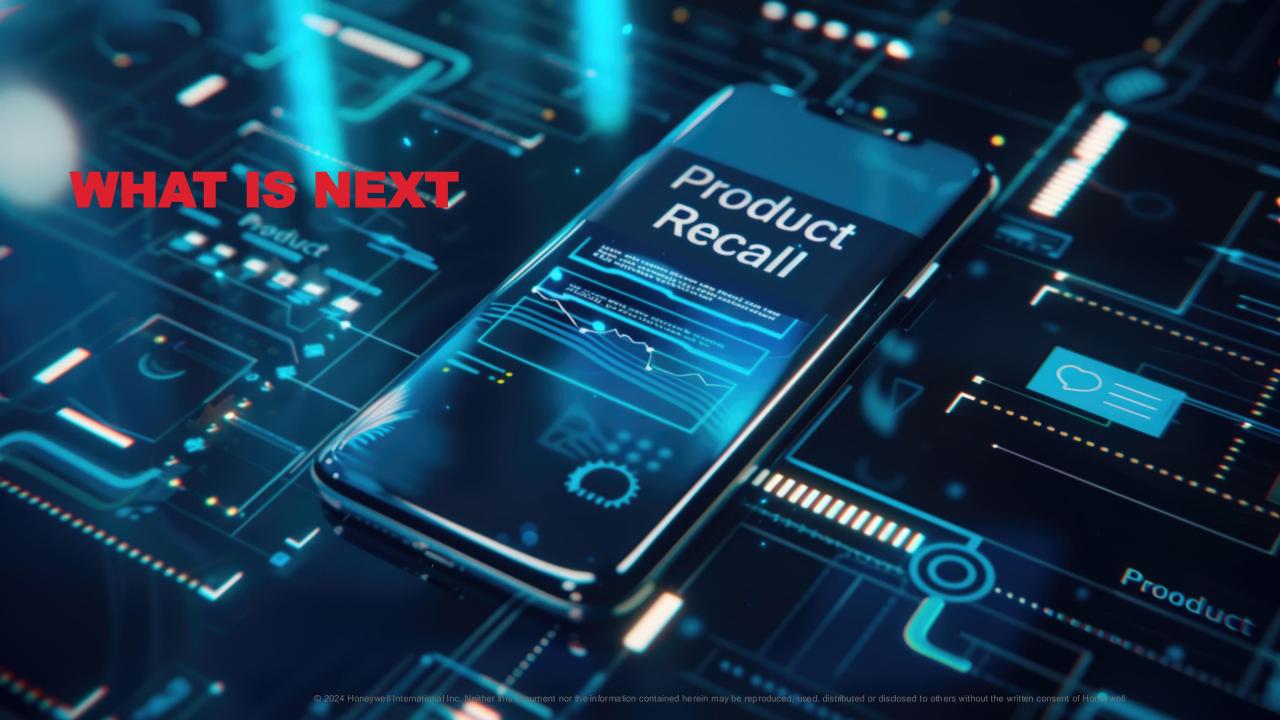




# **SHOW ME THE DATA**

- Where you are and where you want to go
- Understanding what systems and files are needed and used
- Communication \*\*Clear\*\*
- Staffing (training, gaps)
- Data Governance





### POLL

What are the biggest challenges you foresee in adopting this technology?

- A. Lack of skilled personnel and expertise
- B. Resistance to change within the organization
- C. Data privacy and security
- D. No challenges

# CONCLUSION







### **CALL TO ACTION**

Assess your current systems and begin planning your fabric adoption to stay ahead in a rapidly evolving industry

### STRATEGIC IMPORTANCE

Adopting data fabric is not just a technical upgrade but a strategic necessity for future-proofing your organization's recall processes

### RECAP OF KEY BENEFITS

Data fabric enhances data accuracy, speeds up response times and helps ensure compliance, which is crucial for recall management

#### **FUTURE PROOF RECALL WITH A FABRIC**



