

### Quality Management

Johan Hoffmann Product Manager



### Advanced Quality Management

- Integrated advanced quality capabilities throughout the entire supply chain.
- Ensure compliance with regulations and boost product quality and customer satisfaction.
- Foster continuous improvements and risk mitigations with a feedback-driven approach.
- Minimize the reliance on third-party quality management solutions.

Public preview 10.0.44 (April 2025)

General available 10.0.45 (September 2025)



#### **Continuous improvement**

CAPA Management Non conformance



#### **Optimized testing**

Flexible sampling plans +skip lot

Instrument calibration

New quality order triggers

Quality order integration to Trace Add-in



### **Digitized manufacturing**

Electronic Batch Record Production dispensing



### **Regulatory compliance**

Approved customer list

Customer specific COA

Electronic signature



#### **User productivity**

Quick test result entry

Quality management workspaces

## Features to enable in Feature Management

Feature name	Module
(Preview) Approved customer list	Accounts receivable
(Preview) Dispense management	Production control
(Preview) Electronic signature improvements	Organization administration
(Preview) Advanced quality management	Inventory and warehouse management

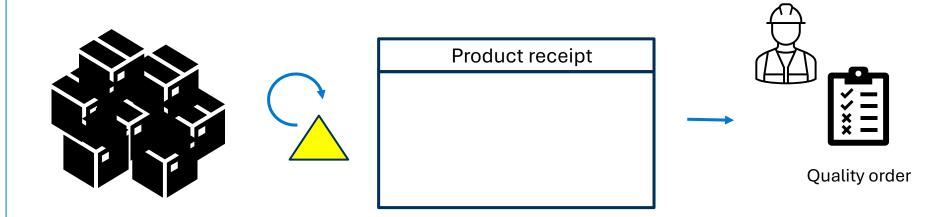
## Introducing – Flexible Sampling Plans

### What is it?

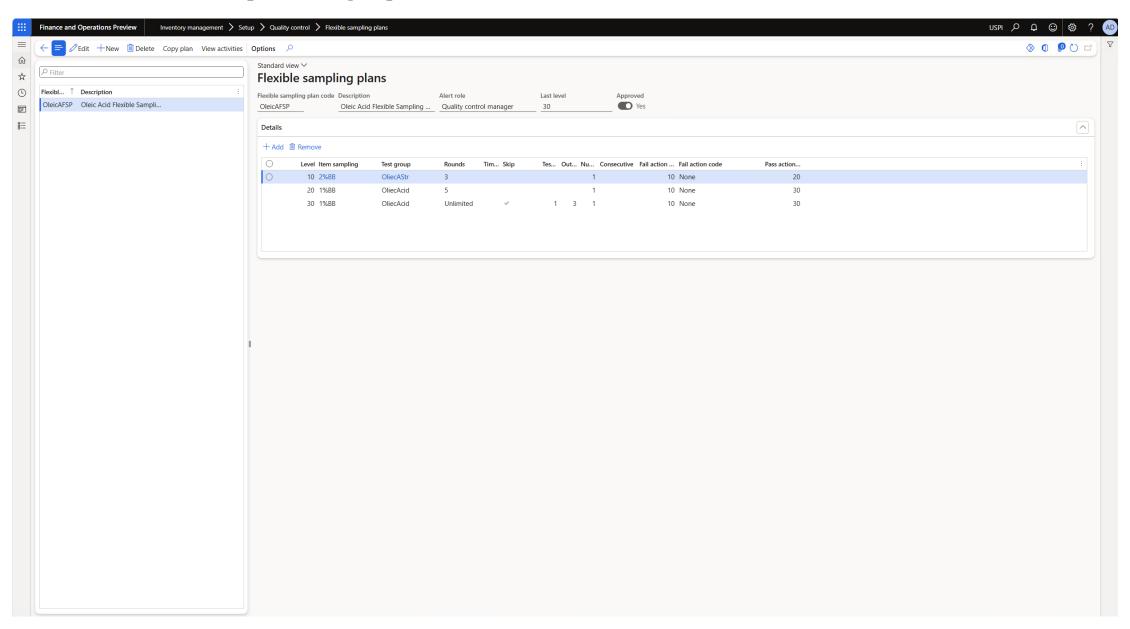
 A test plan where sample sizes and test groups adjust over time based on test outcomes.

### **Key benefits**

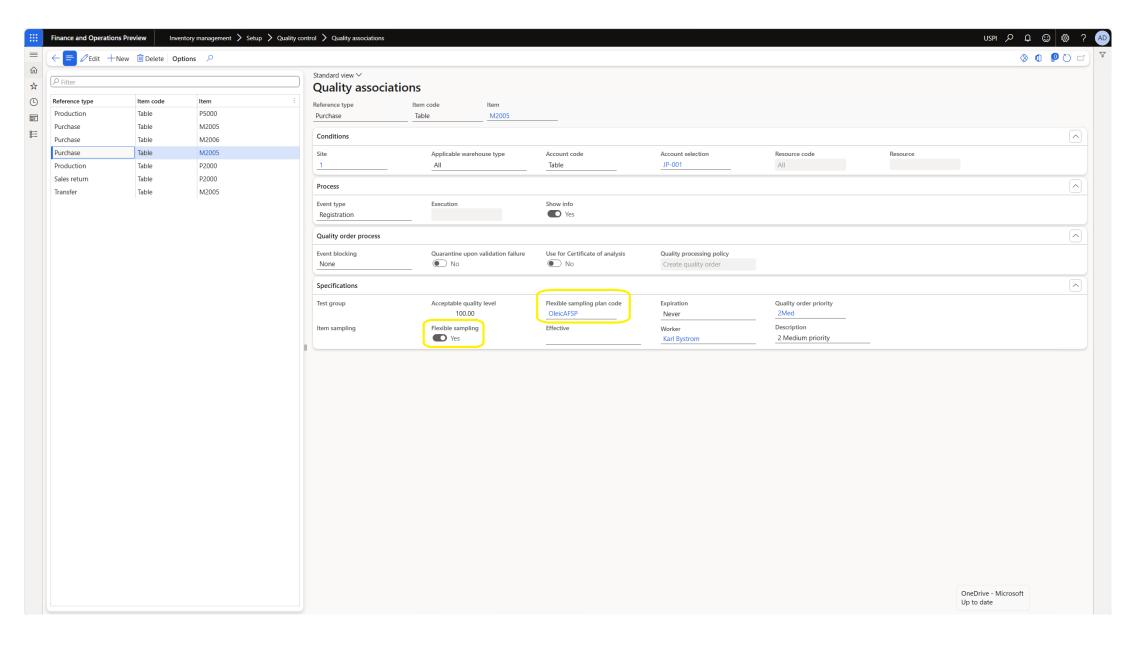
 Reduce cost and improve efficiency by optimizing resource use.



# Flexible sampling plans



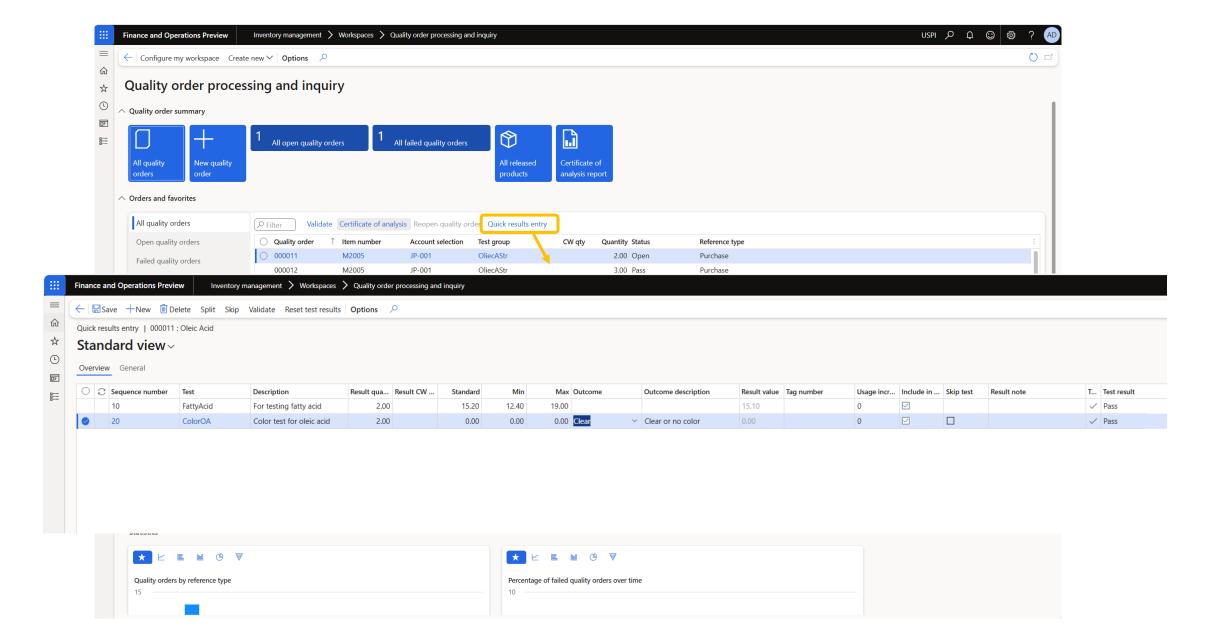
# Quality associations



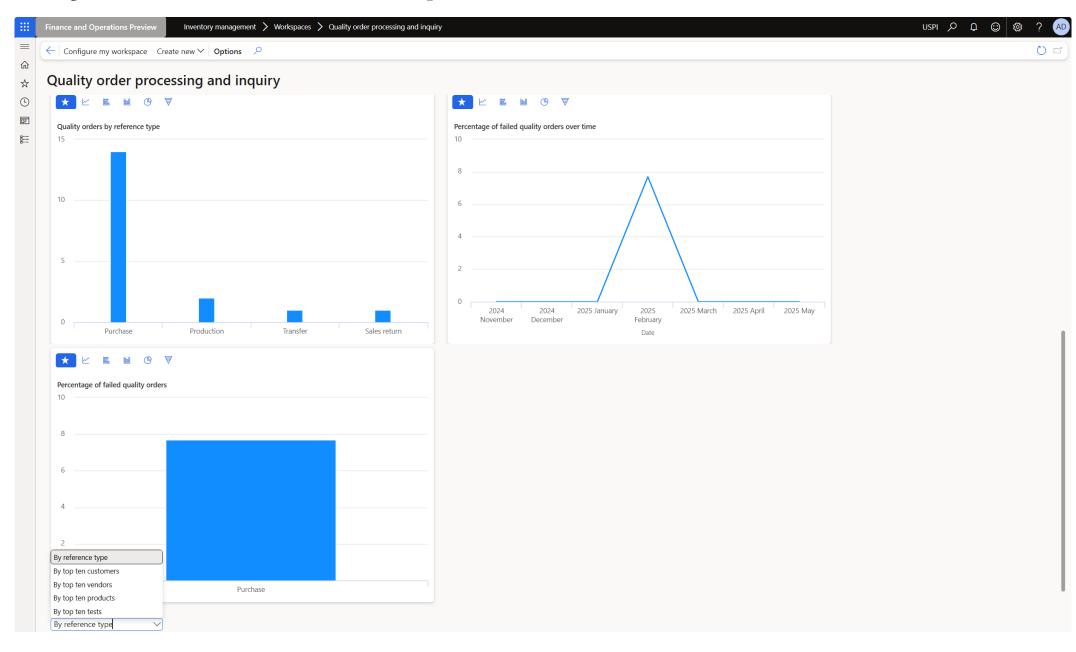
# Flexible sampling plan activities

	ing plan code Reference type	Item number	Account selection	First activity 12/8/2024										
RM1	Purchase   ↑ Created date and time	RM1 Level Test group	US-111 Ro Item sampling	frequency	Quality order	Status	Validated by	Validated date and time	Fail action Fail action code	Reason code	Pass action Reference	Modified by	Modified date and time	
	1 12/8/2024 8:43:36 PM	10 Str-TG-RM1	1 10%8PUQ		000031	Pass	Julia Funderburk	12/8/2024 9:06:34 PM	None		1st test round - No skip L. 2		12/8/2024 9:06:39 PM	
	2 12/8/2024 9:09:27 PM	10 Str-TG-RM1	2 10%8PUQ		000056	Pass	Julia Funderburk	12/8/2024 9:10:23 PM	None			Admin	12/8/2024 9:10:23 PM	
	3 12/8/2024 9:10:53 PM	10 Str-TG-RM1	3 10%8PUQ		000057	Pass	Julia Funderburk	12/8/2024 9:11:24 PM	None			Admin	12/8/2024 9:11:24 PM	
	4 12/8/2024 9:11:24 PM	10	0						None	System	20 Pass criteria met	Admin	12/8/2024 9:11:24 PM	
	5 12/8/2024 9:11:56 PM	20 Len-TG-RM1	1 2%8PUQ		000058	Pass	Julia Funderburk	12/8/2024 9:12:26 PM	None		1st test round - No skip L. 2	Admin	12/8/2024 9:12:26 PM	
	6 12/8/2024 9:13:00 PM	20 Len-TG-RM1	2 2%8PUQ		000059	Pass	Julia Funderburk	12/8/2024 9:13:23 PM	None			Admin	12/8/2024 9:13:23 PM	
	7 12/8/2024 9:13:59 PM	20 Len-TG-RM1	3 2%8PUQ		000060	Pass	Julia Funderburk	12/8/2024 9:14:16 PM	None			Admin	12/8/2024 9:14:17 PM	
	8 12/8/2024 9:14:17 PM	20	0						None	System	30 Pass criteria met	Admin	12/8/2024 9:14:17 PM	
	9 12/8/2024 9:14:57 PM	30 Len-TG-RM1	1 1%8PUQ	1 out of 3	000061	Pass	Julia Funderburk	12/8/2024 9:15:25 PM	None		1st test round - Skip lot s A	Admin	12/8/2024 9:15:25 PM	
	10 12/8/2024 9:16:03 PM	30 Len-TG-RM1	0 1%8PUQ			Skipped			None			Admin	12/8/2024 9:16:03 PM	
	11 12/8/2024 9:16:24 PM	30 Len-TG-RM1	0 1%8PUQ			Skipped			None			Admin	12/8/2024 9:16:24 PM	
	12 12/8/2024 9:16:52 PM	30 Len-TG-RM1	2 1%8PUQ	1 out of 3		Skipped			None		1st test round - Skip lot s A	Admin	12/8/2024 9:17:58 PM	
	13 12/8/2024 9:17:08 PM	30 Len-TG-RM1	0 1%8PUQ			Skipped			None			Admin	12/8/2024 9:17:08 PM	
	14 12/8/2024 9:17:24 PM	30 Len-TG-RM1	0 1%8PUQ		000062	Pass	Julia Funderburk	12/8/2024 9:17:58 PM	None			Admin	12/8/2024 9:17:58 PM	
	15 12/8/2024 9:18:23 PM	30 Len-TG-RM1	3 1%8PUQ	1 out of 3	000063	Pass	Julia Funderburk	12/8/2024 9:18:42 PM	None		1st test round - Skip lot s Z	Admin	12/8/2024 9:18:42 PM	
	16 12/8/2024 9:19:08 PM	30 Len-TG-RM1	0 1%8PUQ			Skipped			None			Admin	12/8/2024 9:19:08 PM	
	17 12/8/2024 9:19:23 PM	30 Len-TG-RM1	0 1%8PUQ			Skipped			None			Admin	12/8/2024 9:19:23 PM	
	18 12/8/2024 9:19:44 PM	30 Len-TG-RM1	0 1%8PUQ	1 out of 3	000064	Fail	Julia Funderburk	12/8/2024 9:20:28 PM	None		1st test round - Skip lot s	Admin	12/8/2024 9:20:28 PM	
	19 12/8/2024 9:20:28 PM	30	0						10 None	System	Quality order 000064 failu (	) Admin	12/8/2024 9:20:28 PM	
	20 12/8/2024 9:20:58 PM	10 Str-TG-RM1	1 10%8PUQ		000065	Pass	Julia Funderburk	12/8/2024 9:21:28 PM	None		1st test round - No skip L. 2	Admin	12/8/2024 9:21:28 PM	
	21 12/8/2024 9:21:58 PM	10 Str-TG-RM1	2 10%8PUQ		000066	Pass	Julia Funderburk	12/8/2024 9:22:21 PM	None			Admin	12/8/2024 9:22:21 PM	
	22 12/8/2024 9:22:50 PM	10 Str-TG-RM1	3 10%8PUQ		000067	Pass	Julia Funderburk	12/8/2024 9:23:09 PM	None			Admin	12/8/2024 9:23:09 PM	
	23 12/8/2024 9:23:09 PM	10	0						None	System	20 Pass criteria met	Admin	12/8/2024 9:23:09 PM	
	24 12/8/2024 9:23:40 PM	20 Len-TG-RM1	1 2%8PUQ		000068	Pass	Julia Funderburk	12/8/2024 9:24:02 PM	None		1st test round - No skip L 2	Admin	12/8/2024 9:24:03 PM	
	25 12/8/2024 9:24:48 PM	20	0						None	Good	30 €	Admin	12/8/2024 9:24:48 PM	
	26 12/10/2024 2:51:17 PM	30 Len-TG-RM1	0 1%8PUQ	1 out of 3		Skipped			None		1st test round - Skip lot s	Admin	12/10/2024 2:51:17 PM	
	27 12/10/2024 2:52:18 PM	30	0						None	Good	20 Back to 20 for testing	Admin	12/10/2024 2:52:18 PM	
	28 12/10/2024 2:58:32 PM	20 Len-TG-RM1	1 25/8PUQ		000106	Pass	Julia Funderburk	12/10/2024 3:22:06 PM	None			Admin	12/10/2024 3:22:08 PM	

## Quality order workspace



# Quality order workspace



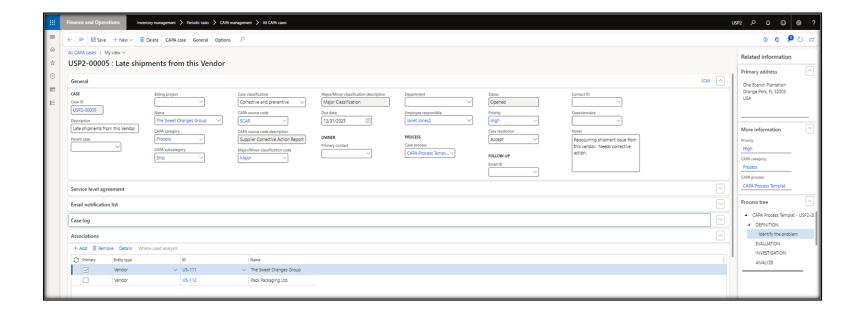
# Introducing - CAPA Management

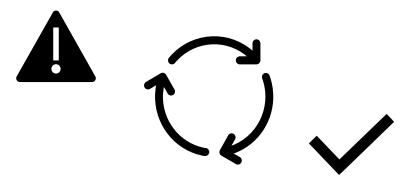
### What is it?

CAPA (Corrective and Preventive Actions), is a systematic approach used to identify, investigate, and resolve non-conformances in products and processes.

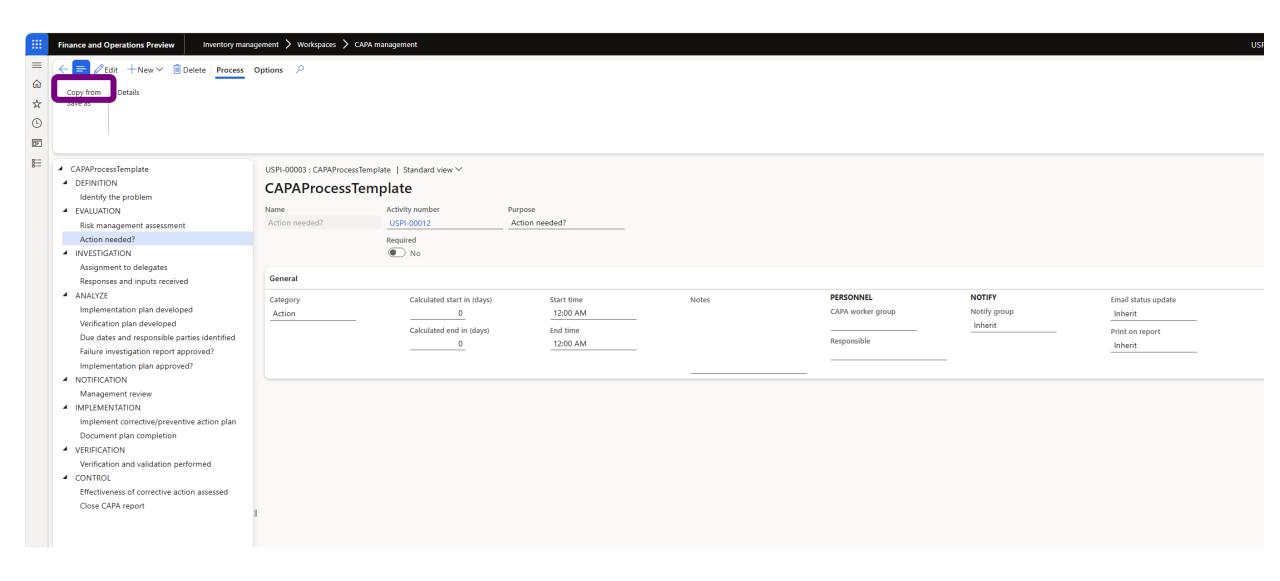
### **Key benefits**

Improves product quality, ensures regulatory compliance, reduces costs from defects, and fosters continuous improvement.

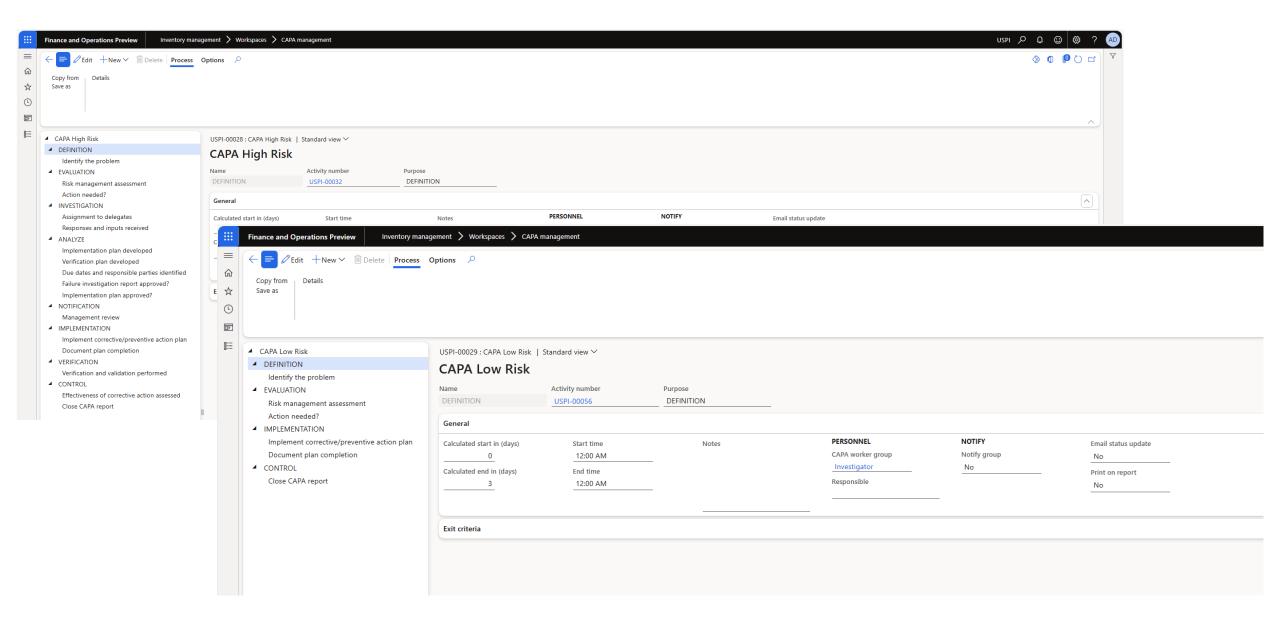




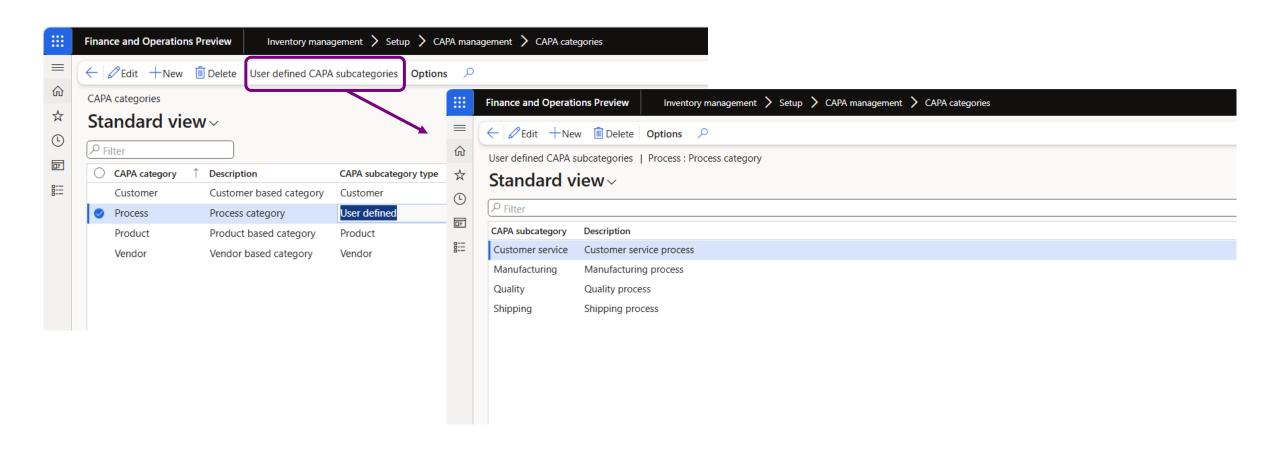
### CAPA Process template



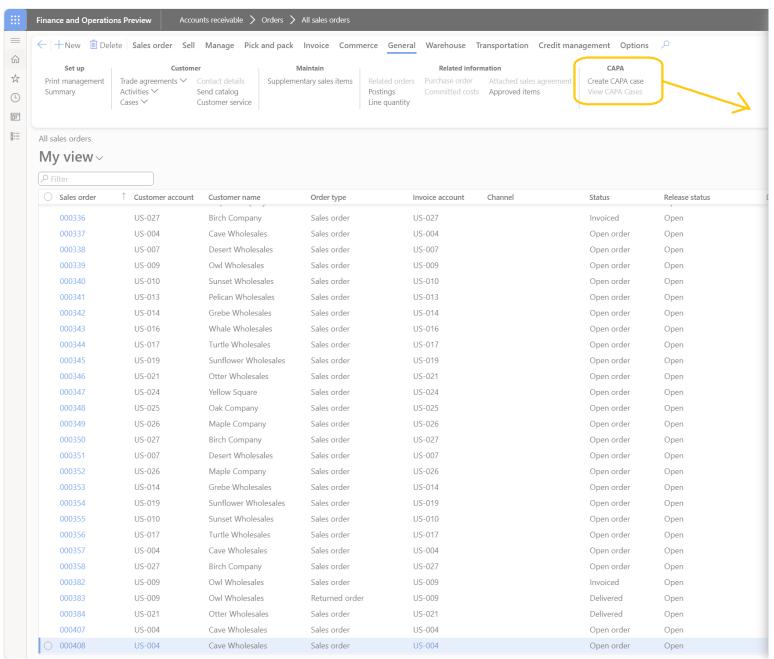
### Flexible definition of process flows

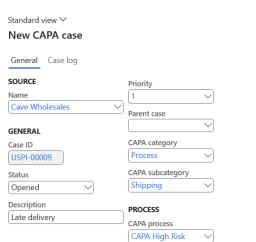


## Categories and sub-categories



### Create CAPA case

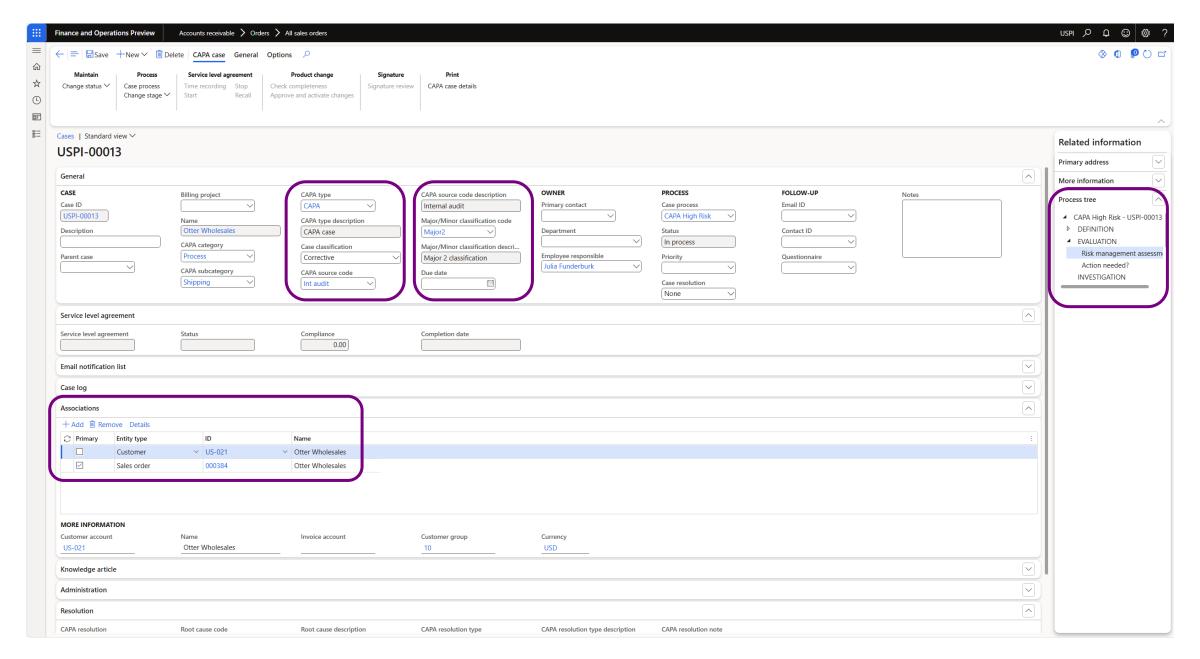




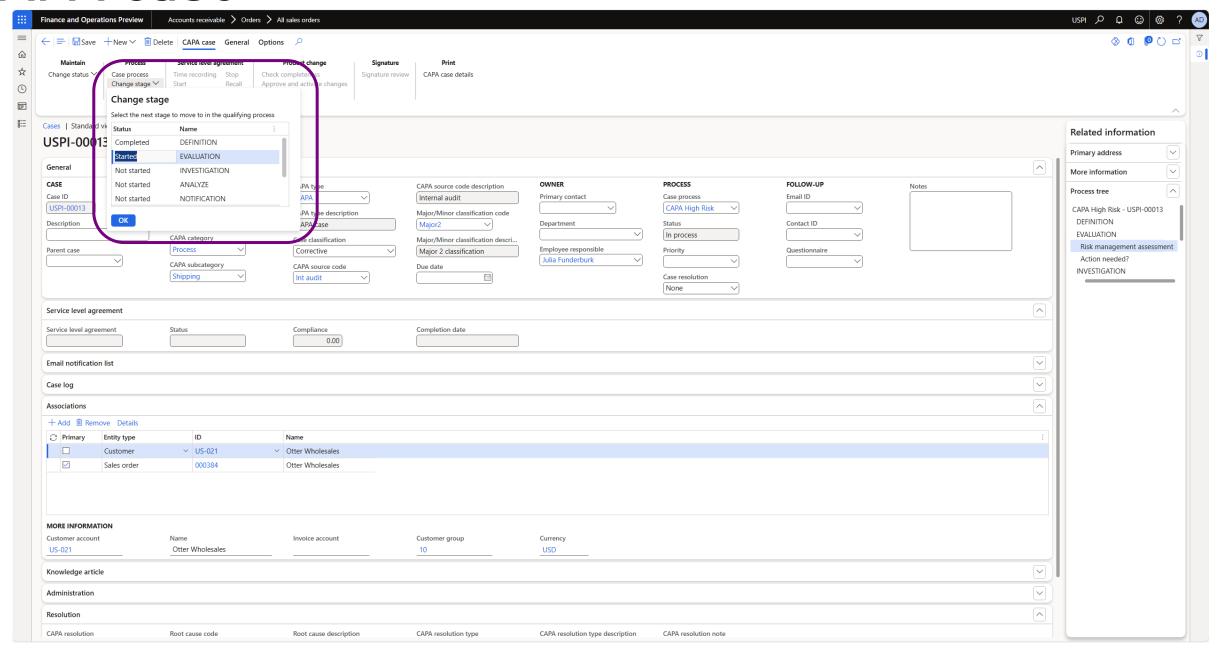
?

Cancel

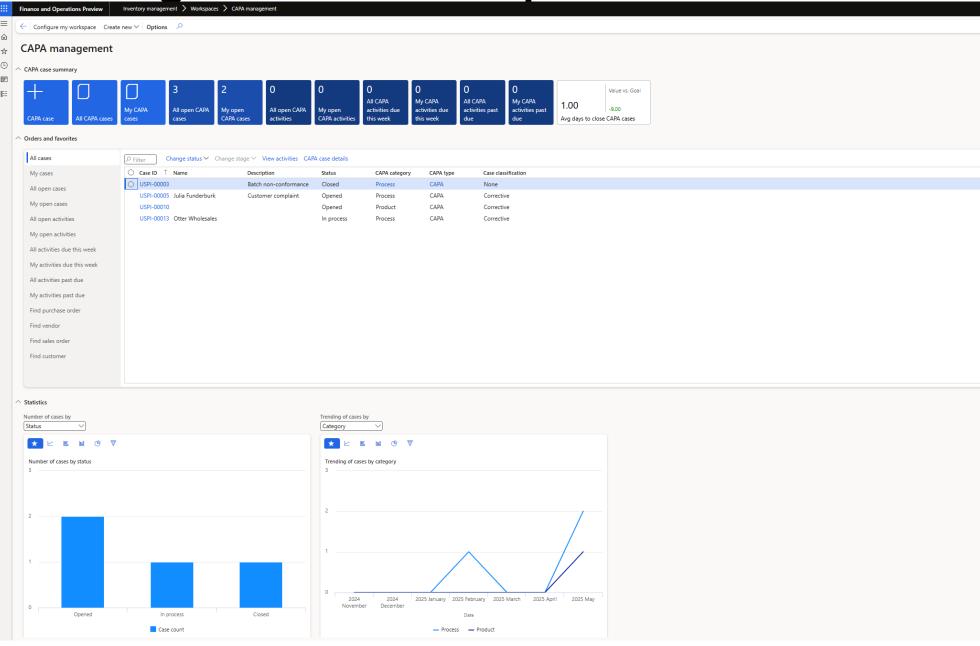
### CAPA case



### CAPA case



# CAPA management workspace



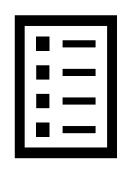
## Introducing – Electronic Batch Record (EBR)

### What is it?

 Digital document that records the production details of a produced batch.

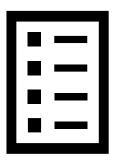
### **Key benefits**

- It ensures compliance with 21 CFR Part 11 regulations
- Makes internal audits more efficient (eliminate paperwork, data consolidation etc.).



### **MMR – Master Manufacturing Record**

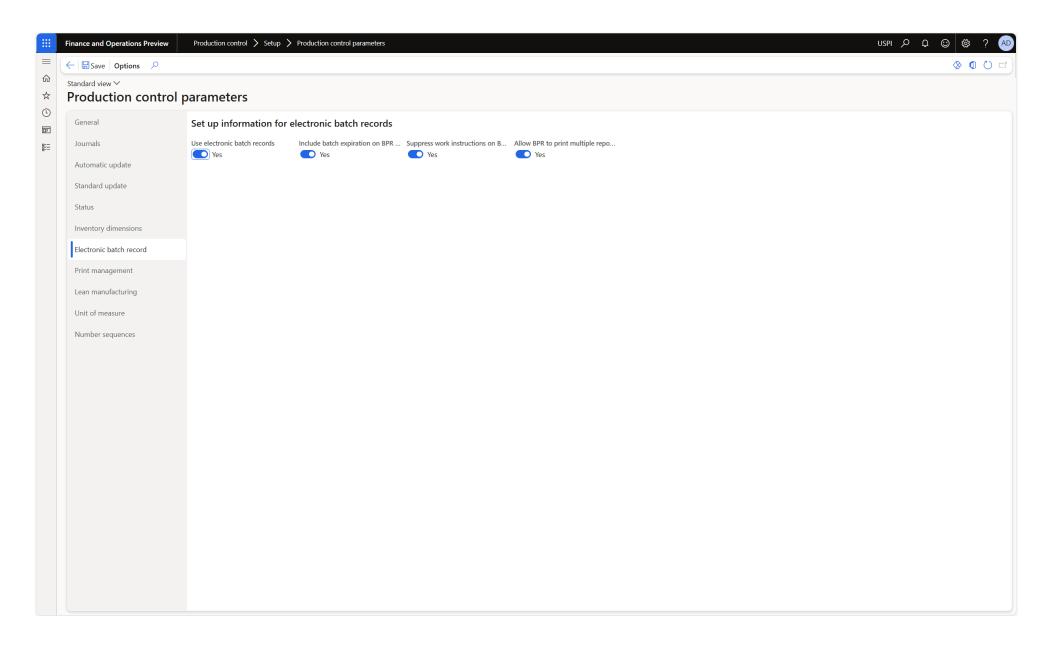
- Manufactured item (BOM, Formula, or Planning Item)
- BOM/Formula versions
- Route versions
- Quality associations
- Inventory batch attributes

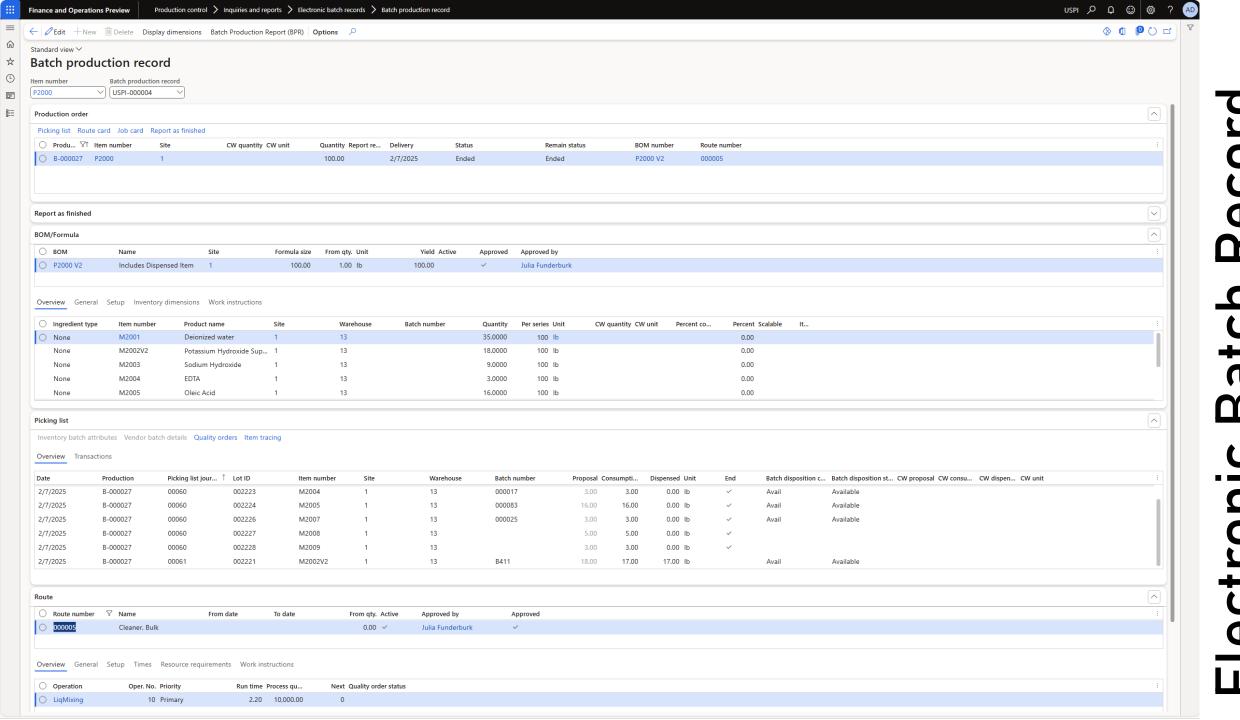


### **BPR – Batch Production Record (Inquiry and Report)**

- Manufactured item (BOM, Formula, or Planning Item)
- BOM/Formula versions on order
- Route versions on order
- Route and job card on order
- Quality orders for ingredients and finished goods.
- Inventory batch attribute values for ingredients and finished goods

### **Electronic Batch Record**





### Introducing – Test Instrument Calibration

### What is it?

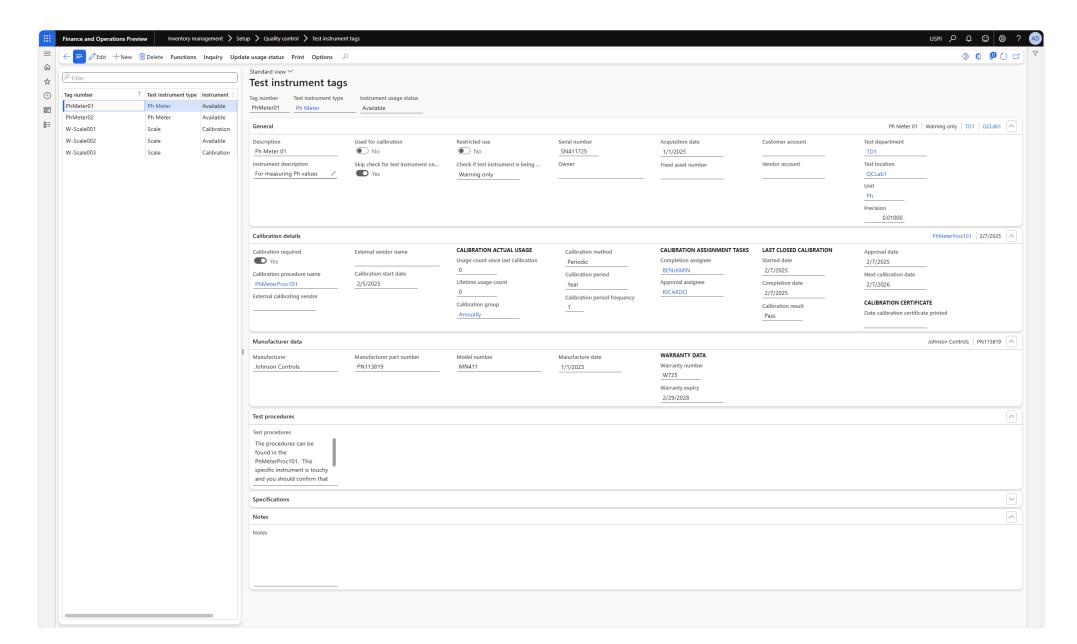
Tool to manage calibration of test instruments on a planned or ad-hoc basis.

### **Key benefits**

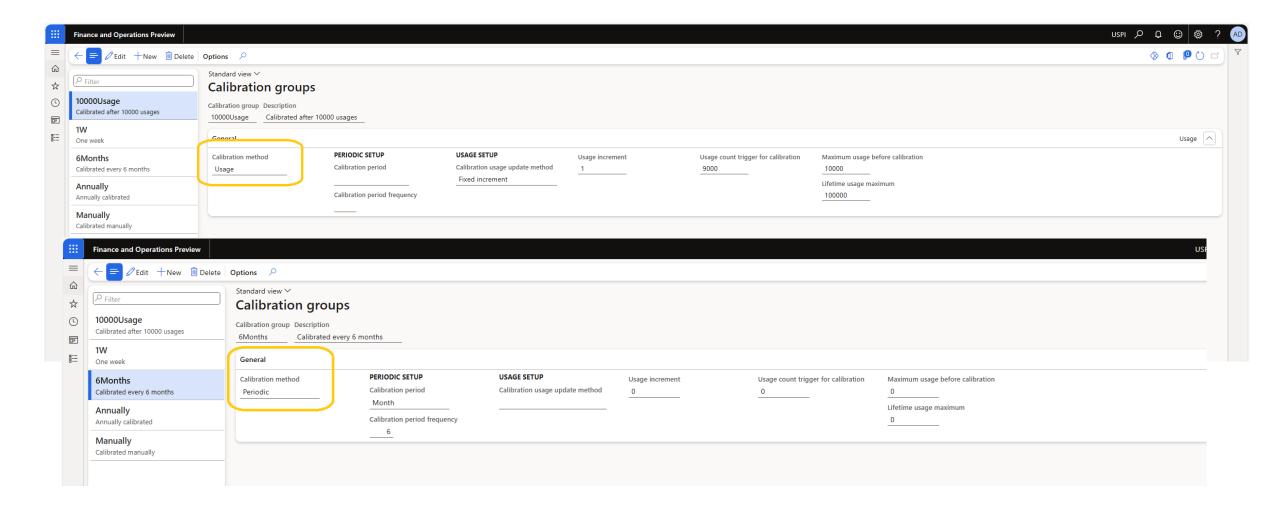
Ensures precision, accuracy, safety, and valid data, preventing false-positive and false-negative quality control tests.



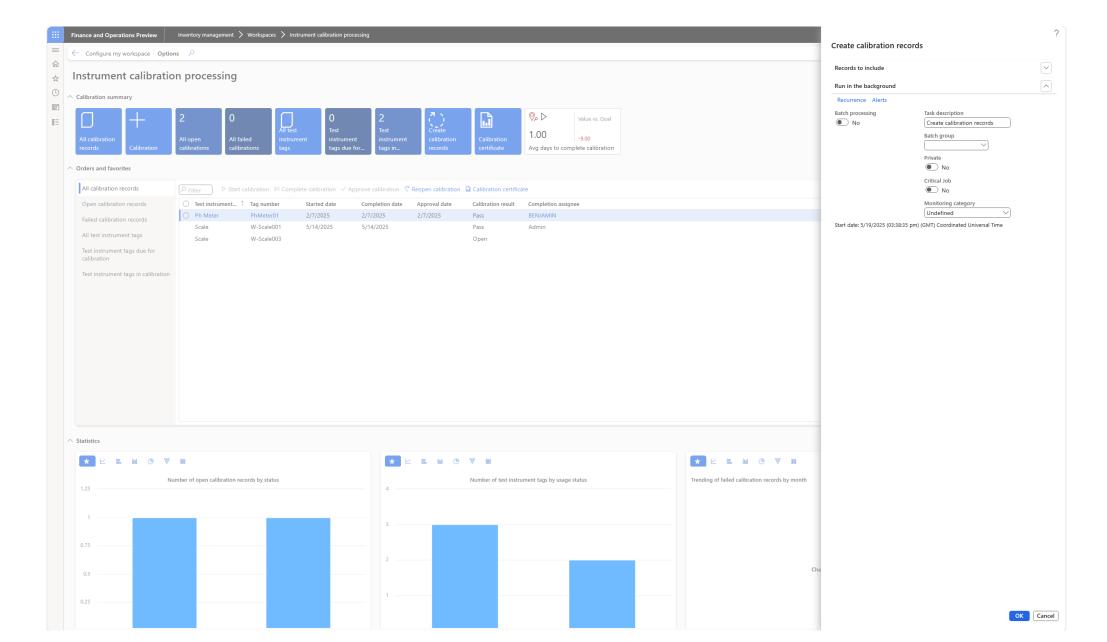
# Test Instrument Tag



# Calibration group



# Instrument calibration workspace



# Introducing - Production Dispensing

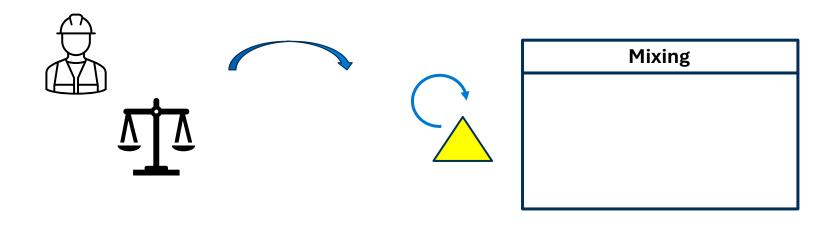
Dispensing

### What is it?

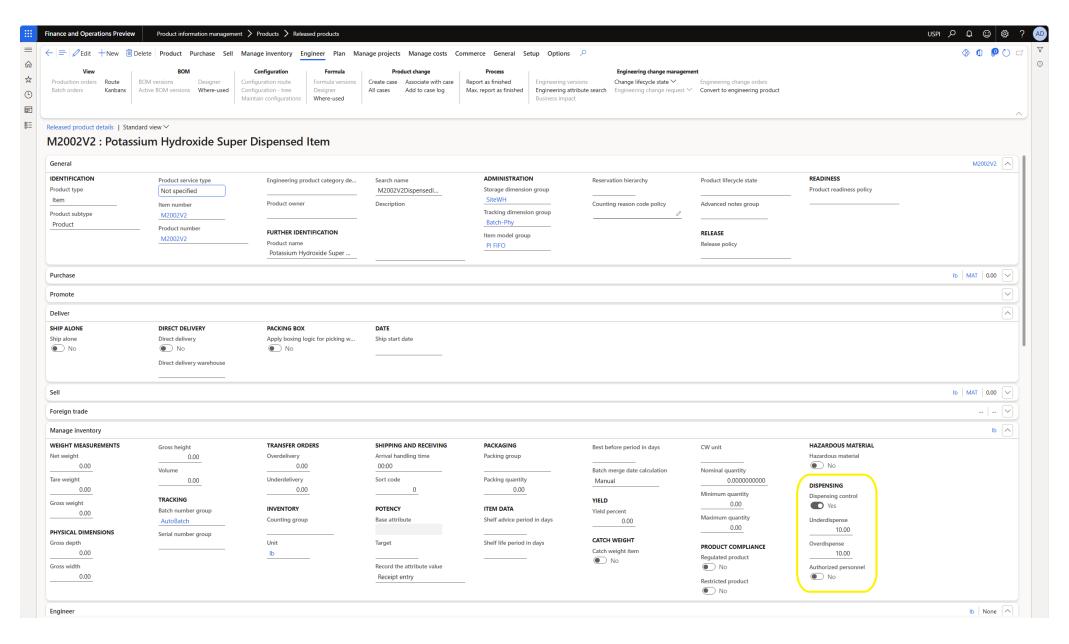
 Controlled process for allocating of hazardous or sensitive materials in production processes.

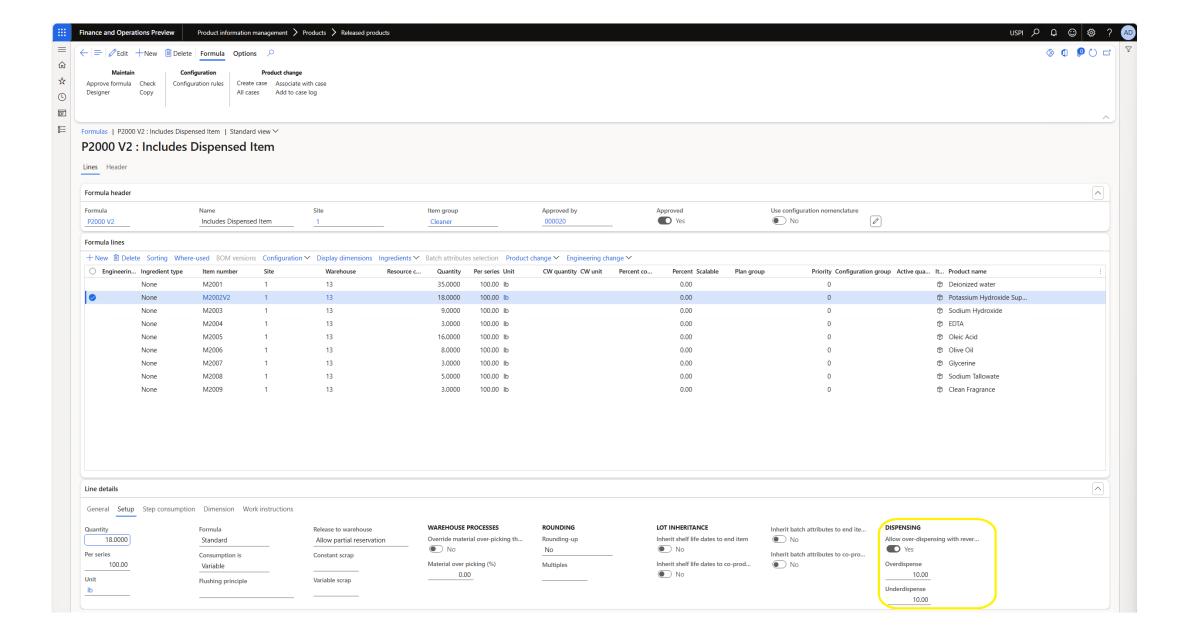
### **Key benefits**

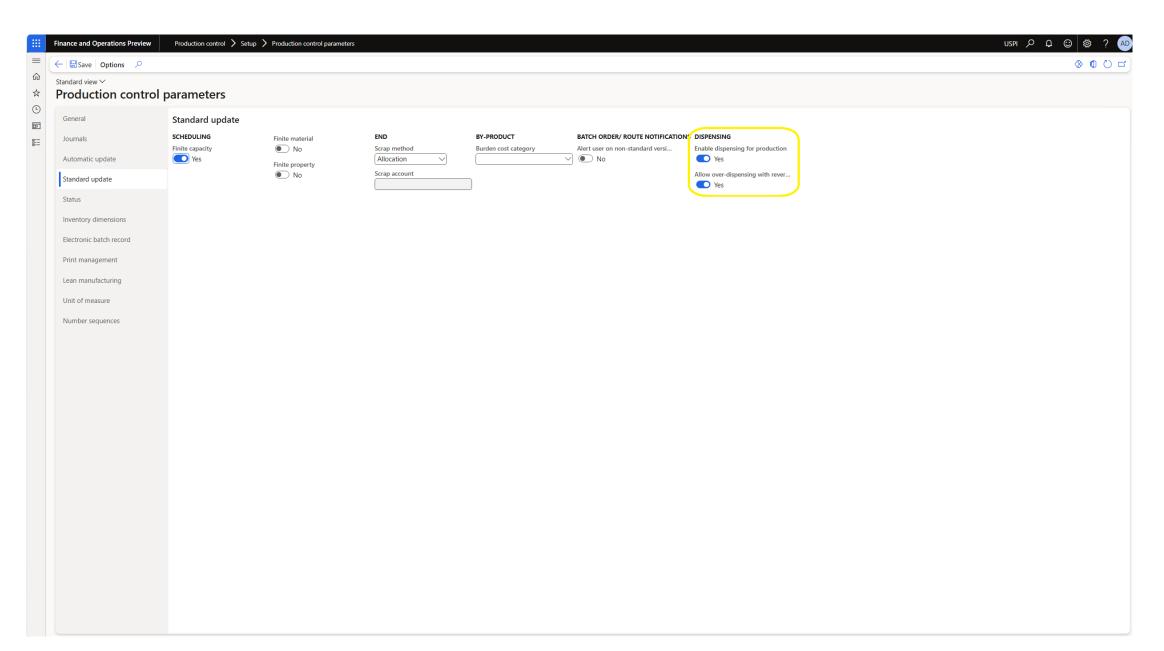
- Minimizes contamination risks.
- Preserves material integrity.
- Ensures the safety of both the product and personnel.

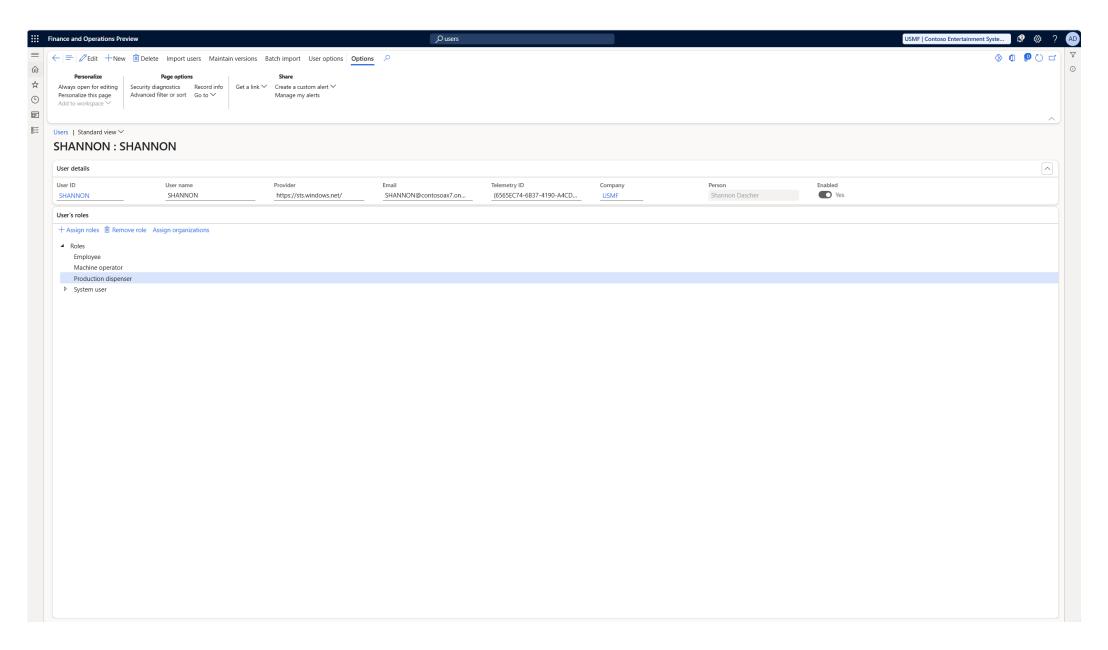


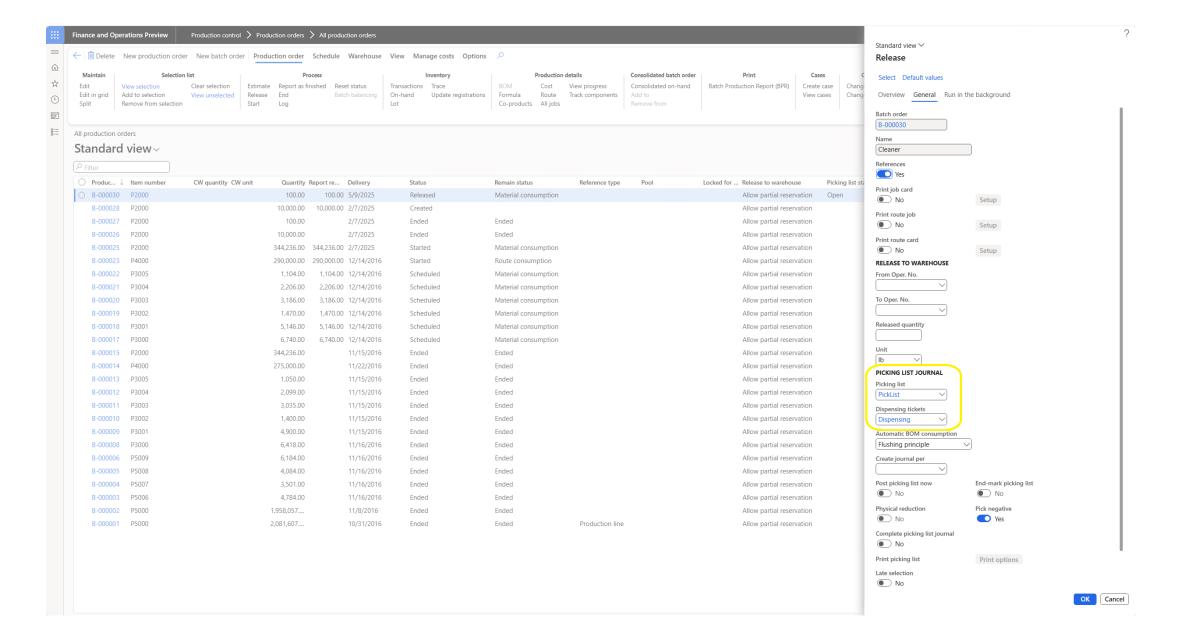
Consumption

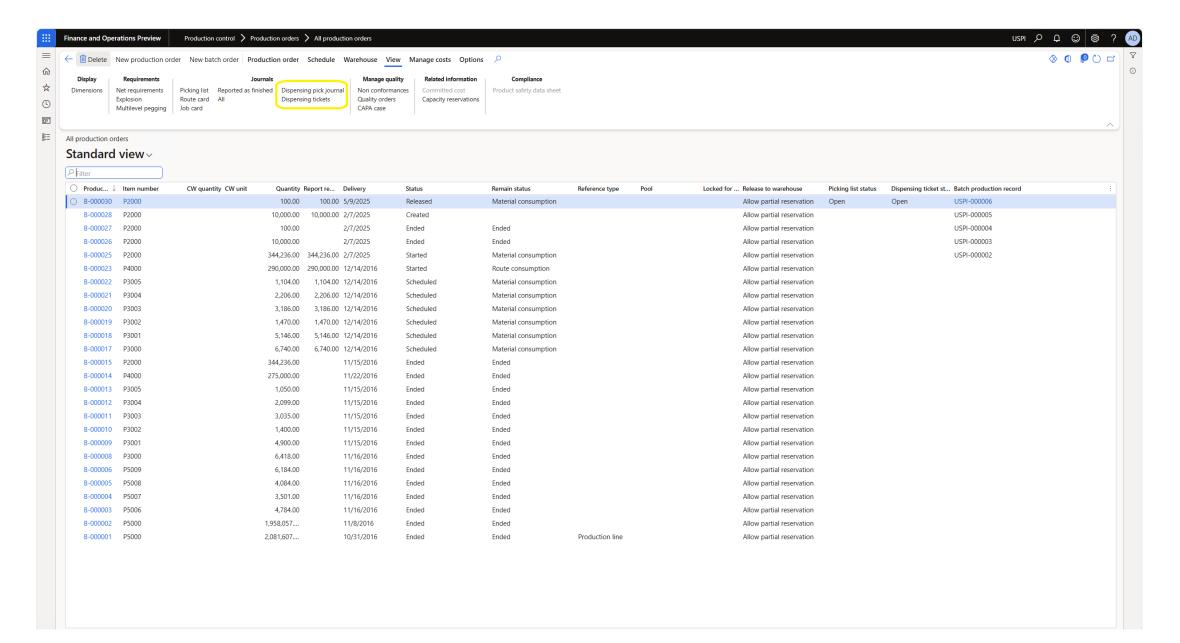


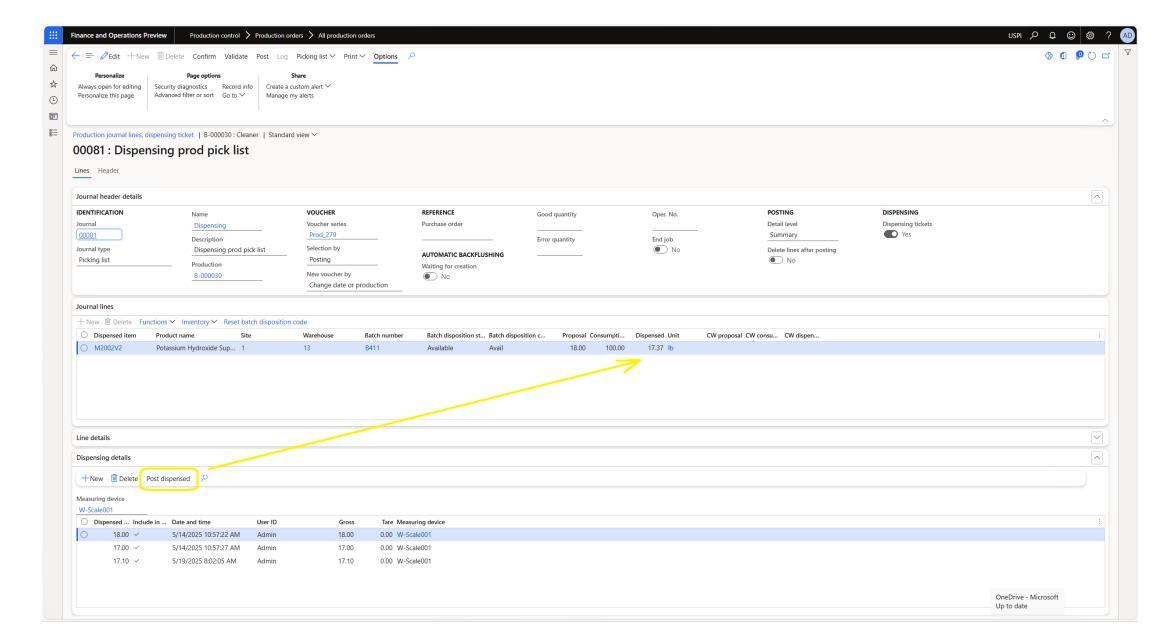


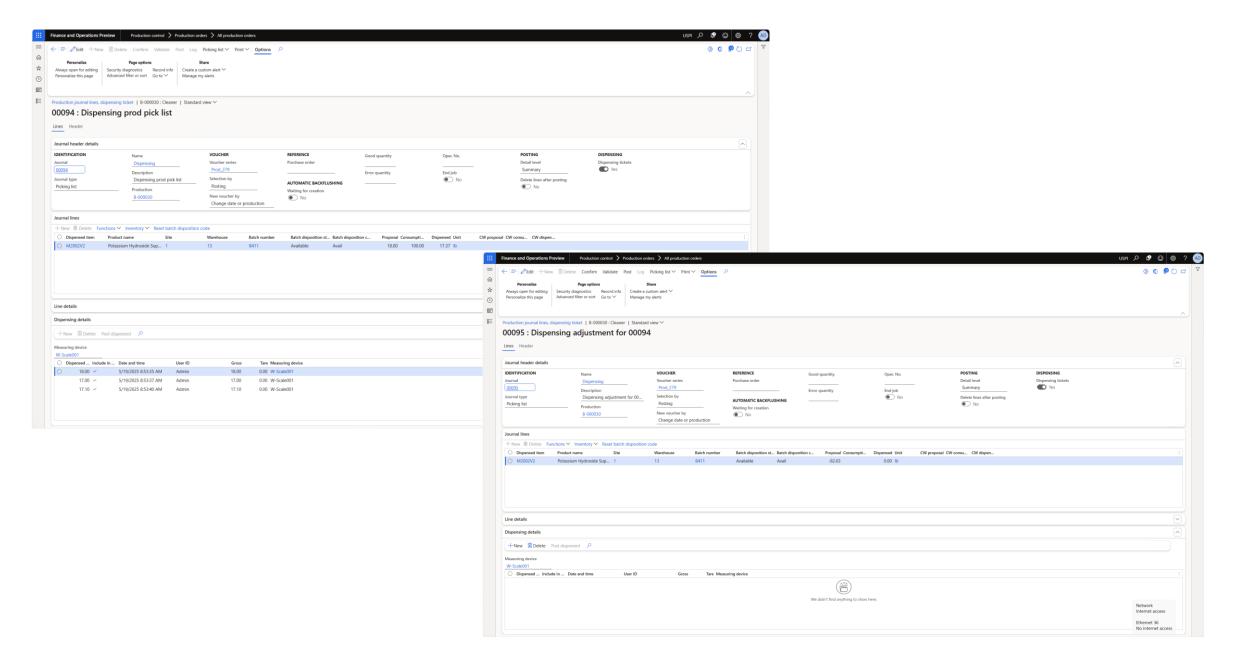












### What's next?

### **Acceptance Sampling**

#### What is it?

 A statistical quality method used to determine the maximum number of defective units acceptable within a particular sample size from a production batch.

#### **Benefits**

 Helps save time and cost by checking a sample instead of every item, while still ensuring product quality.

Public preview: 10.0.45

### **Sample Management**

#### What is it?

- Systematic handling, tracking, and control of samples on continuous production flows.
- Allows for identifying, registering, labeling, tracking, testing, and disposing of samples without inventory tracking.

#### **Benefits**

 Helps catch defects early, reduce waste, ensure quality, save costs, and keep the process running smoothly.

Public preview: 10.0.46

### Resources

- Advanced quality management overview (preview) Supply Chain Management |
   Dynamics 365 | Microsoft Learn
- Microsoft Dynamics 365 Release Plans
- <u>Subscribe Tech Talks</u>
- Enhance quality compliance with Dynamics 365 SCM
- Viva Engage / Yammer: Manufacturing
- Acceptance sampling

# Thank you

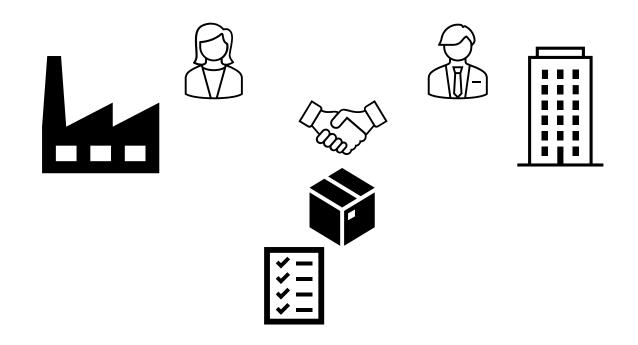
### Introducing - Approved Customer List

### What is it?

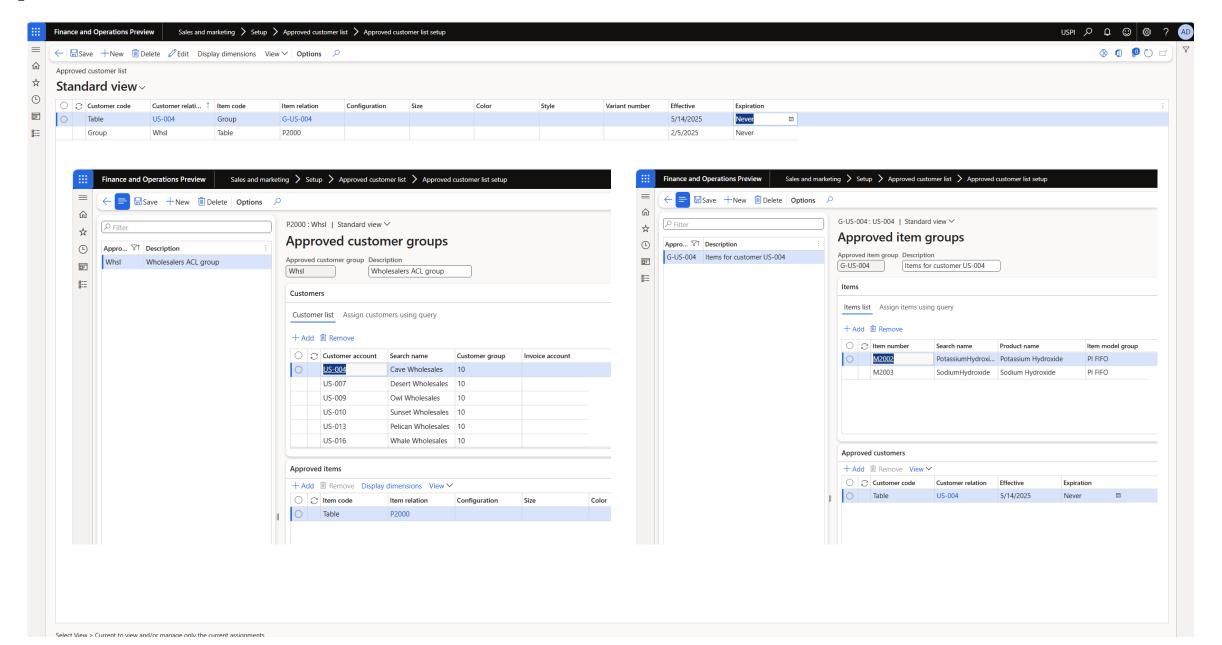
A framework that manages rules to determine which products can be sold, quoted, or contracted to specific customer accounts.

### **Key benefits**

- Ensure compliance.
- Improve sales accuracy.
- Prevents offering the wrong products to the wrong customers.



## Approved Customer List



### Approved Customer List

