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SAP Life Sciences – Overview



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SAP in Life Sciences Industries



7 of the 10 greenest pharmaceuticals, biotechnology and life sciences companies run SAP S/4HANA.



SAP customers in the pharmaceuticals, biotechnology, and life sciences industry generate a combined revenue of US\$1.1 trillion



The 10 largest companies in the pharmaceuticals, biotechnology, and life sciences industry are SAP customers



SAP customers produce 92% of the pharmaceuticals, biotechnology, and life sciences industry's total revenue



SAP S/4HANA customers in the pharmaceuticals, biotechnology, and life sciences industry generate a combined revenue of US\$840 billion



SAP Customers in Life Sciences

Pfizer **AMGEN** **teva**

AstraZeneca

Roche

NOVARTIS

Johnson & Johnson



Boehringer Ingelheim

FRESENIUS

Dr.Reddy's



SUN PHARMA

Boston Scientific

GSK

stryker

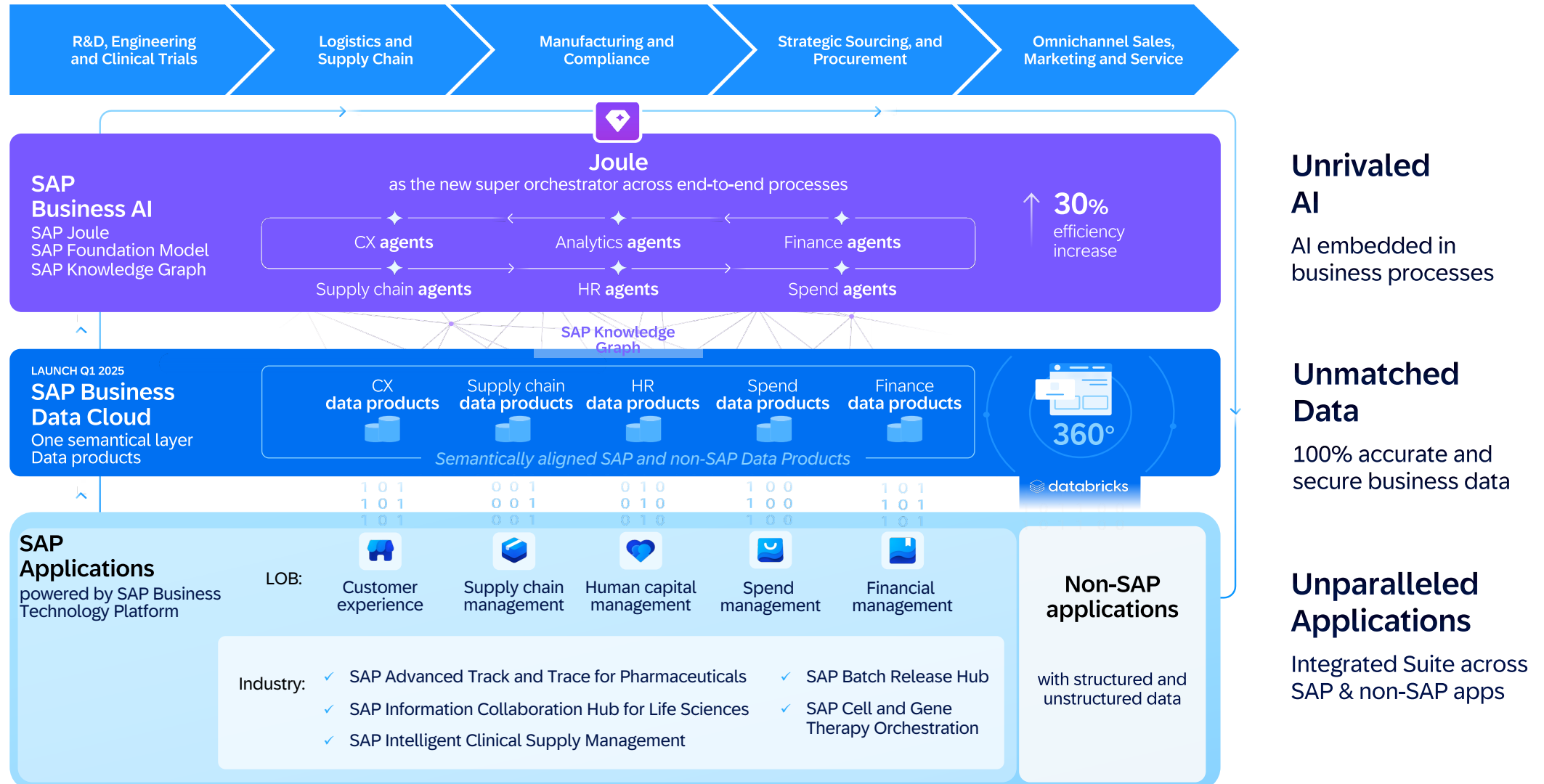
TERUMO

sanofi



SAP Business Suite for Life Sciences

SAP brings all components together, along the Value Chain, to lead the way into the next era of enterprise management

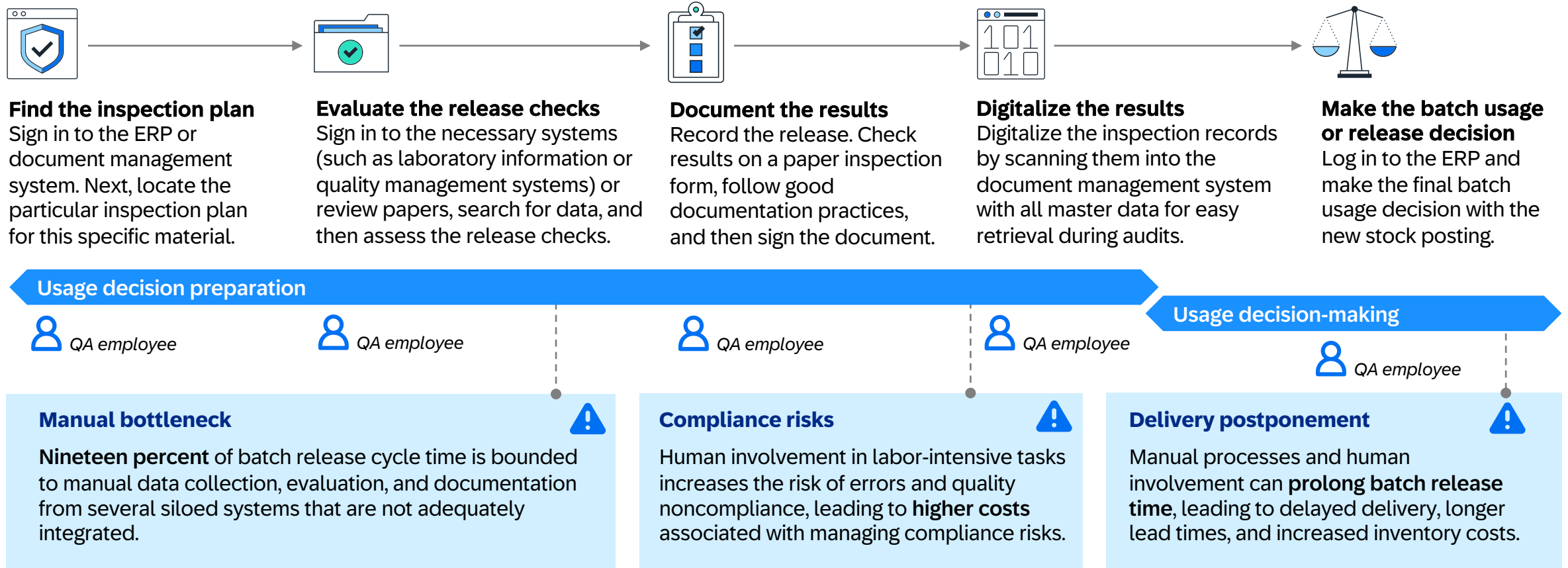


SAP Batch Release Hub



In the past: Process batch release management

As is (today)



Reimagined: Process batch release management with SAP Batch Release Hub for Life Sciences

To be (future)



Prepare the usage decision

Use SAP Batch Release Hub for Life Sciences to digitally manage batch release inspection plans and automatically evaluate, document, and digitalize the results of release checks.



Make the usage decision

Use automatic updates on release check statuses and clear process visibility to help the QA employee make quicker, better-informed, and more compliant batch release decisions.

Usage decision preparation



SAP Batch Release Hub
for Life Sciences

Usage decision-making



QA employee

Improved compliance



Reduced **risk of quality noncompliance** by standardizing and simplifying the batch release process, thereby reducing the risk of human error

Reduced cost



Reduced **compliance management costs** by automating and simplifying time-consuming and labor-intensive legacy batch release activities

Improved lead time



Reduced **order fulfillment lead time** by enabling faster batch release cycle time, thanks to automation and standardization
Reduced **days in inventory**, thanks to shorter batch release cycle times and order fulfillment lead times

Potential value

10%-20%

Reduced risk of quality noncompliance

5%-25%

Reduced inspection costs

1%-25%

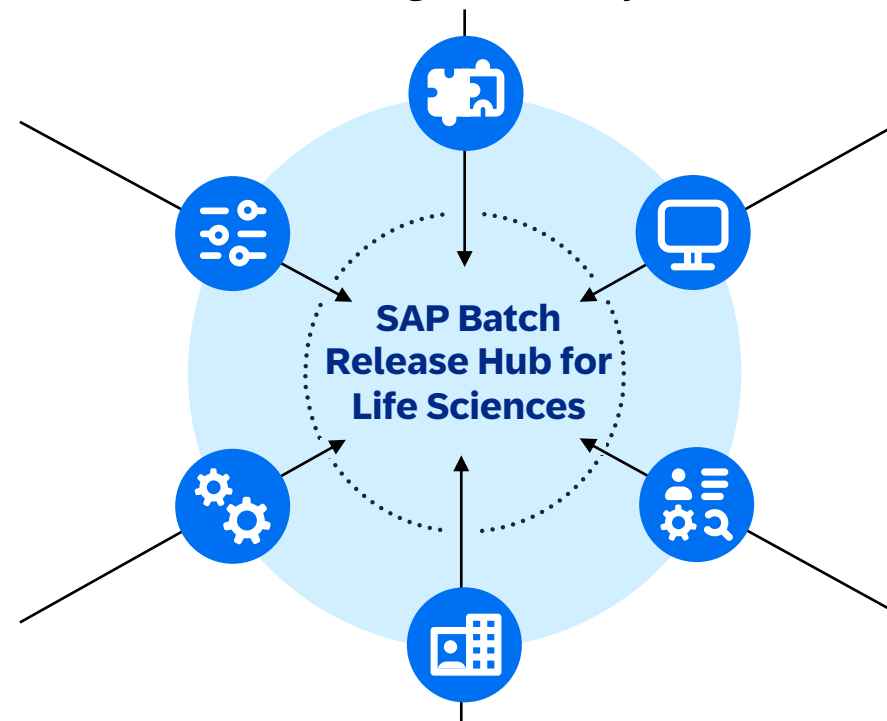
Reduced days in inventory

Key capabilities of SAP Batch Release Hub for Life Sciences

- **Flexibility and comprehensive configuration** to support batch release scenarios such as raw material, bulk, and finished product release
 - Predefined release checks with automatic evaluation as well as custom release checks to integrate manual checking activities

Automatic data evaluation of predefined release checks such as batch components, regulatory approvals, and batch record review

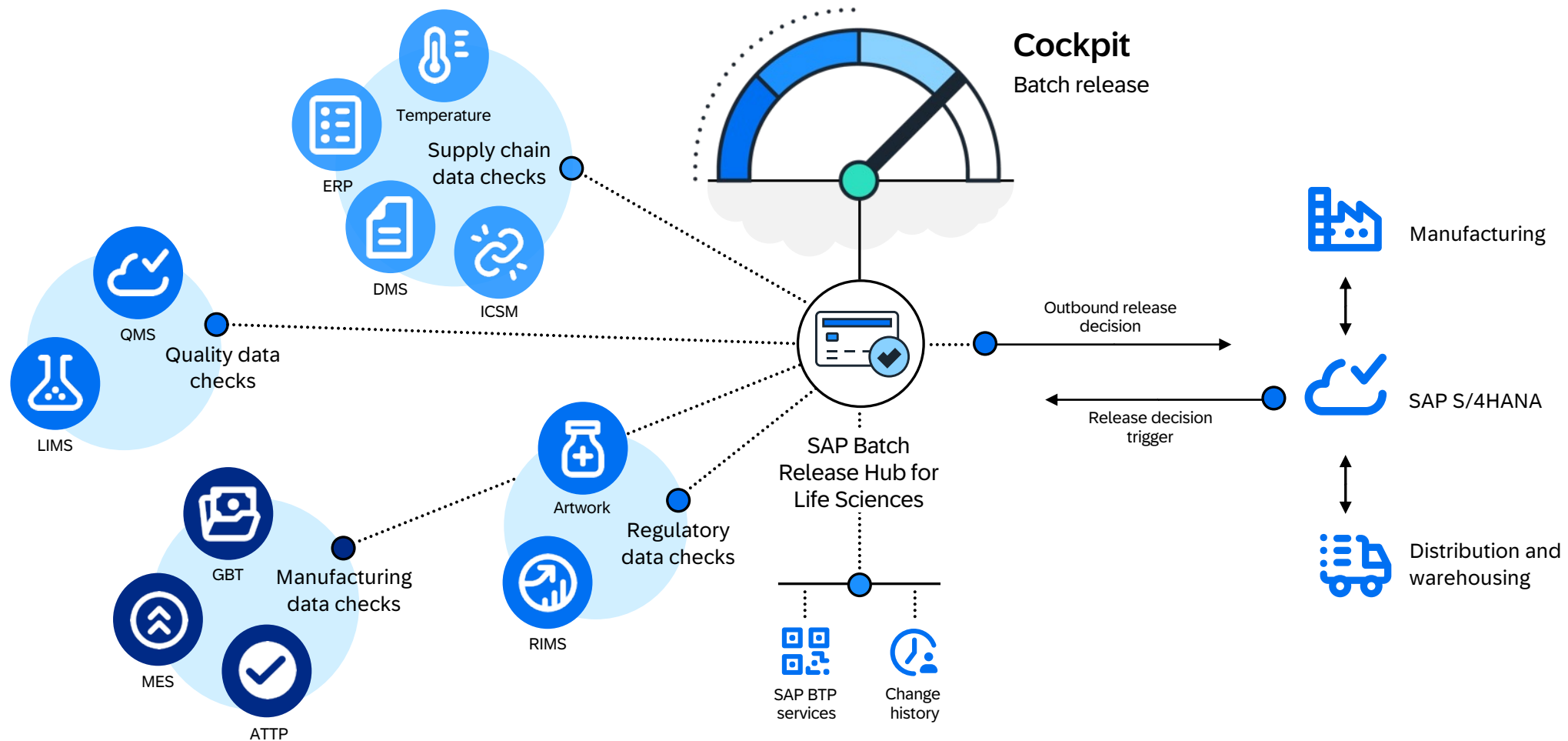
Tight integration with SAP and third-party software such as laboratory and system-manufacturing execution systems



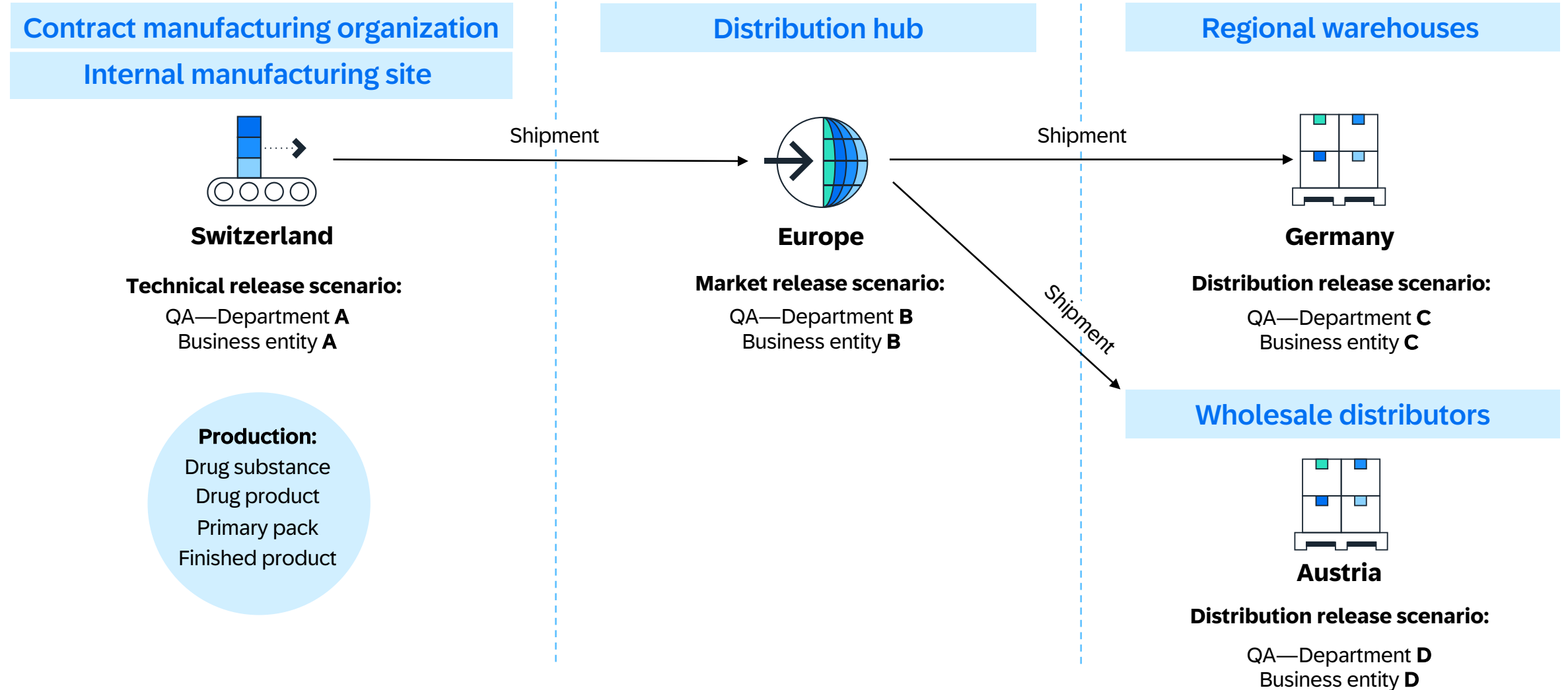
Management of stock posting to allow partial release scenarios in a regional warehouse or a distribution hub in a certain country

- **User-friendly interface** with role-based and individualized worklists
- In-app help functionality for faster knowledge sharing
- **GxP² (good practices) tools and services** including e-signature, provisioning of change log, and signature log for diverse user changes
- Freezing of data after release

Central platform for releasing batches, tightly integrated with the ERP backbone



Various organizational setup and user responsibility management

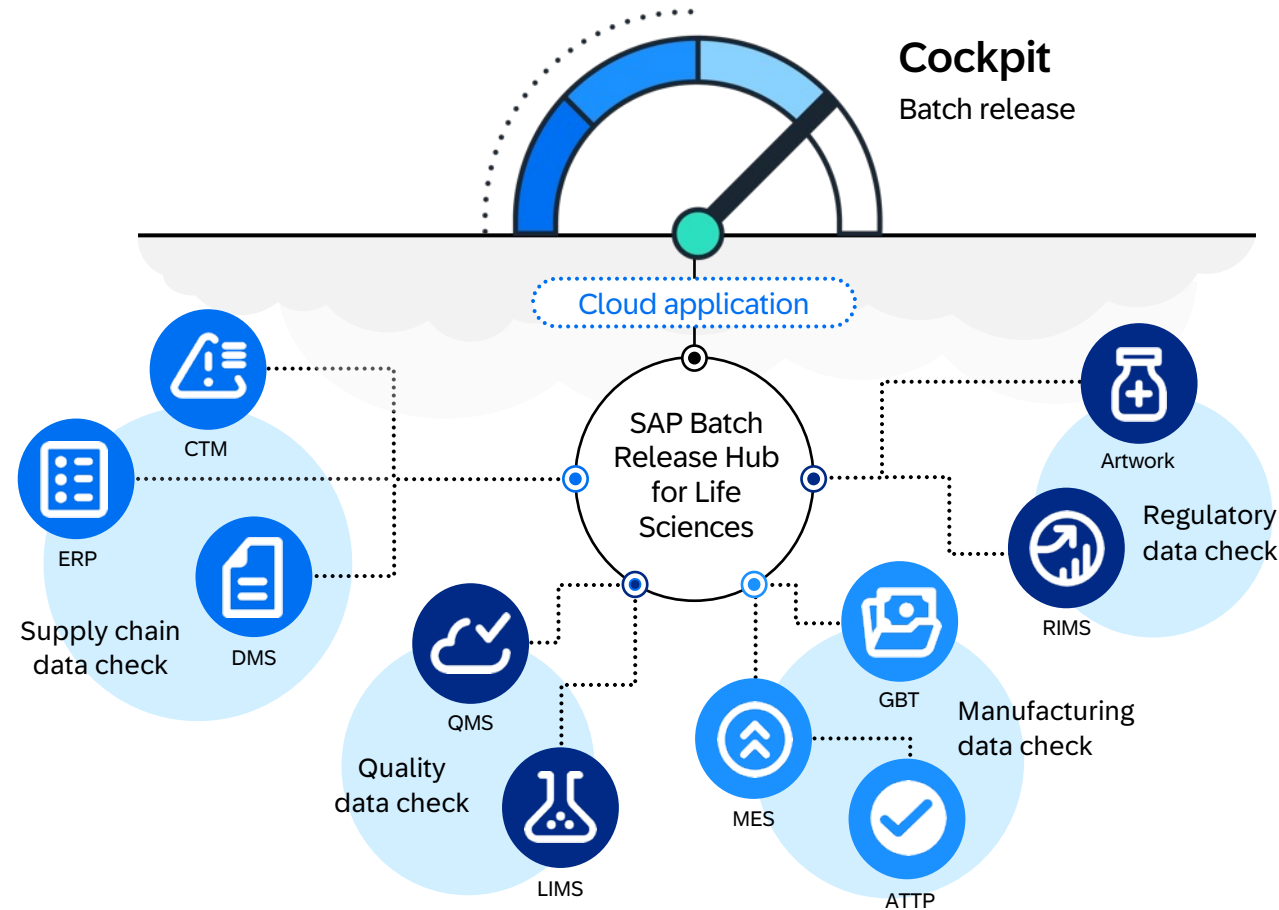


SAP Batch Release Hub for Life Sciences is a software-as-a-service (SaaS) cloud solution that enables faster and more accurate batch release decisions

Standard across
the organization

Faster batch release
cycle time

Intuitive training
for new hires



Elimination of
human errors

Improved user
experience

Scalability for smaller
batch sizes

ATTP: Advanced track and trace for pharmaceuticals
CTM: Clinical trial management
DMS: Document management system
ERP: Enterprise resource planning

GBT: Global batch traceability
QMS: Quality management system
RIMS: Regulatory information management system

Automated Batch Release

Release efficiency

- Higher release productivity with fully automated batch assessment without human intervention
- Full automation with **business rules** combined with **zero-time batch release**
- Configurable automated outcomes/release decision for release scenarios(2511)
- Release decision without e-signature

The screenshot shows the SAP Release Type configuration interface. The left sidebar contains a navigation menu with categories like 'Make General Settings', 'Configure Release Checks', 'Configure Release Decisions', 'Configure Countries/Regions', 'Configure Release Types', 'Determine Release Types', and 'Configure Quality Departments'. The main content area is titled 'Technical Release for Internal Production' and shows the 'Release Type Details' tab. It includes sections for 'General Data' (Release Type ID: TRI, Description: Technical Release for Internal Production, Status: Active), 'Administrative Data' (Created On: May 16, 2022, Changed On: Oct 18, 2024), and 'Assigned Release Checks (16)'. The 'Assigned Release Checks' section is a table with 16 rows, each containing a 'Release Check ID' and a 'Release Check Description'.

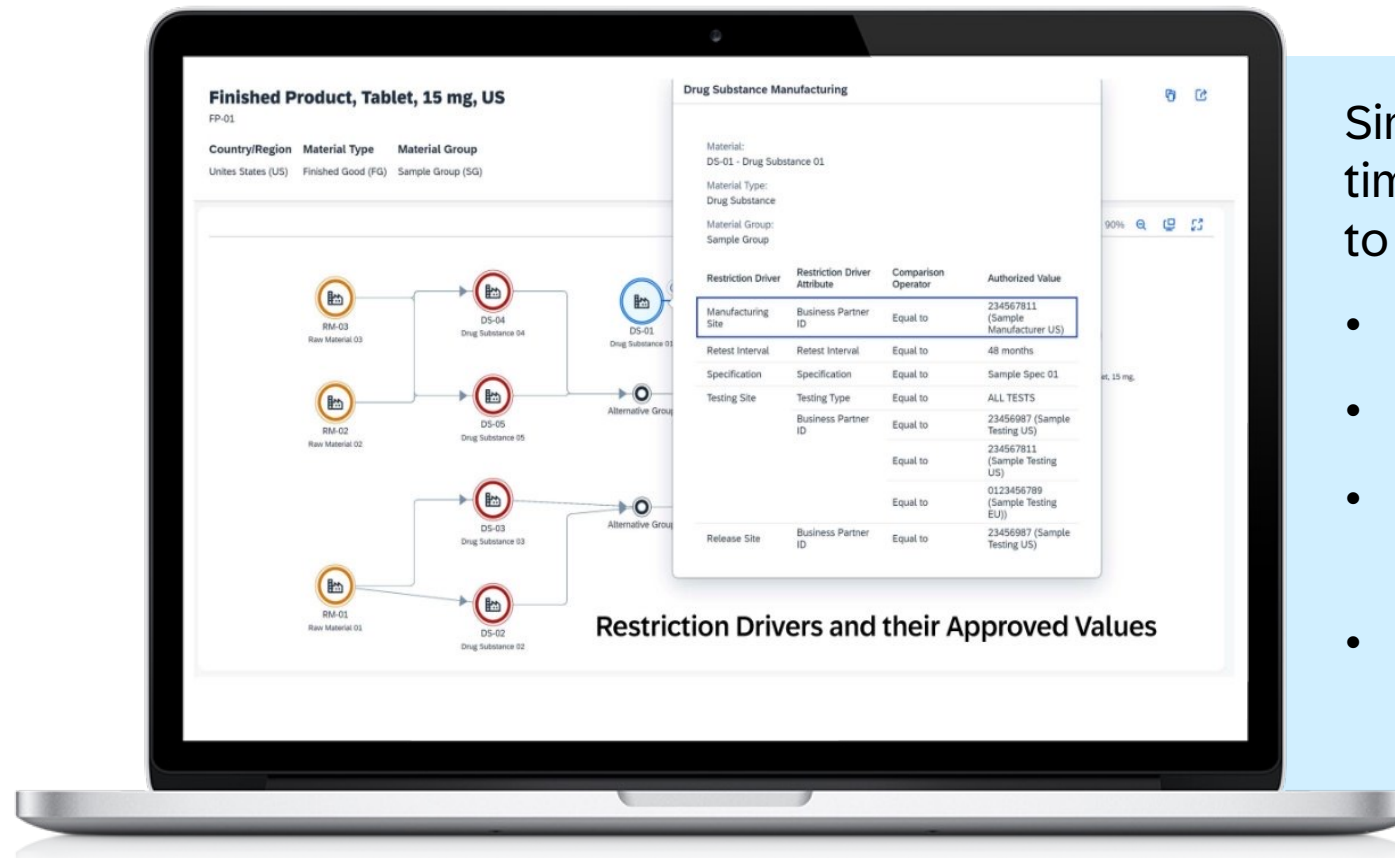
| Release Check ID | Release Check Description |
|------------------|--------------------------------|
| Custom_AI | Custom Release Check for AI |
| APQR | APQR Check |
| SER | Serialization Data Check |
| ART | Artwork and Safety Label Check |
| MQPRCL | Manual QP Checklist |
| REGULATORY | Regulatory Data Check |
| JCC | Jurisdictional Control Check |
| GEA | Genealogy Check |
| COMPC | Component Check |



Jurisdiction controls and supply chain maps launch

Commitment to innovation and solving real industry challenge

Co-innovating with Gilead Sciences Inc. to develop new product capabilities that include jurisdiction controls and supply chain maps



Since June 2024, customers can save more time releasing batches and can bring them to market faster.

- Authorized Supply Chain Map
- Jurisdiction Control/Market Suitability
- Manage CMO Batches for Jurisdiction Control
- Re-evaluation of JC post release decision based on change in actual or reference data

SAP Batch Release Hub for Life Sciences

AI-assisted custom release checks

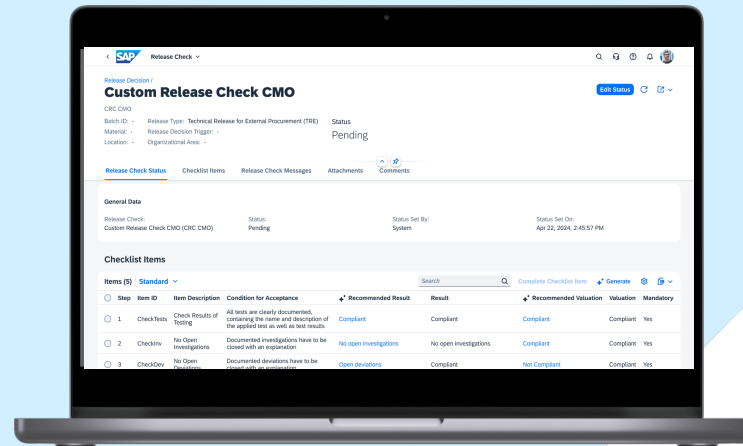
Planned (Q4/24)

Challenge Solution Benefits



Melanie
Qualified Person

“As a qualified person, I want to accelerate batch releases and improve time to market for our products while continuously ensuring highest compliance.”



SAP Business AI technology in SAP Batch Release Hub for Life Sciences uses generative AI to analyze the documents attached to custom release checks of a batch and proposes results for the release check items.

The solution empowers Melanie to save a significant amount of time by focusing on reviewing the recommendations provided while keeping the role of the final decision-maker. This accelerates the batch release process while empowering Melanie to ensure compliance and quality.

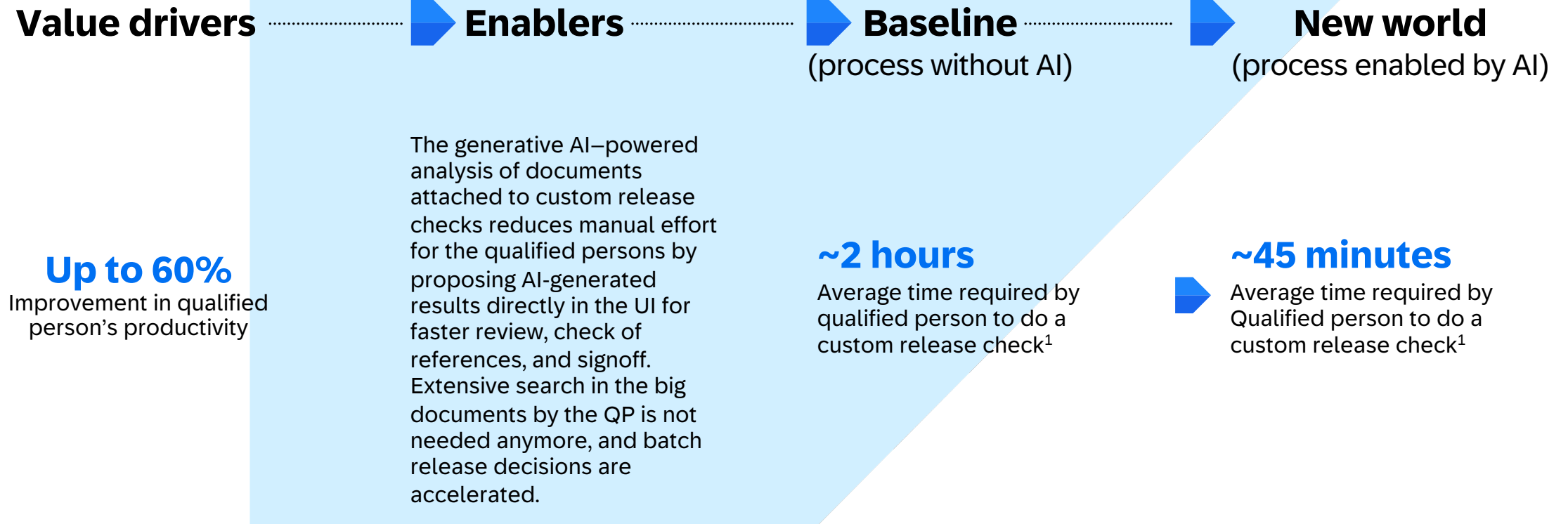
Up to 60%
improvement in qualified person's productivity

Increased
compliance

Improved
user experience

SAP Batch Release Hub for Life Sciences

AI-assisted custom release checks



¹ Source: SAP expert estimation based on customer feedback

SAP Intelligent Clinical Supply Management



SAP Intelligent Clinical Supply Management (ICSM)

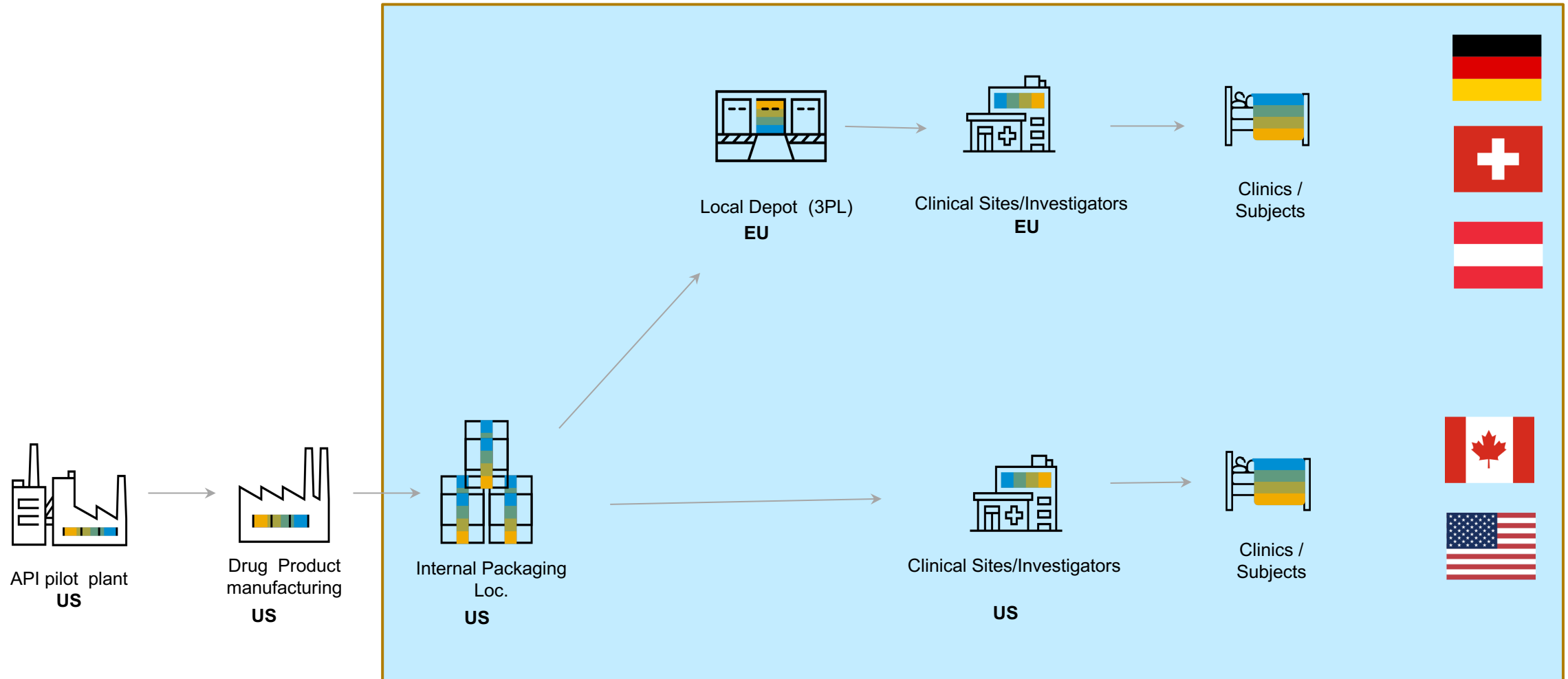
Vision

Reimagine Clinical Supplies Operations & Define an Industry Standard Solution

- Harmonize clinical and commercial SCM processes and systems□
- Bring in new innovations to reduce cycle times and inventory levels□ while adapting faster to changing trial and patient needs

SAP Intelligent Clinical Supply Management | Scope Overview

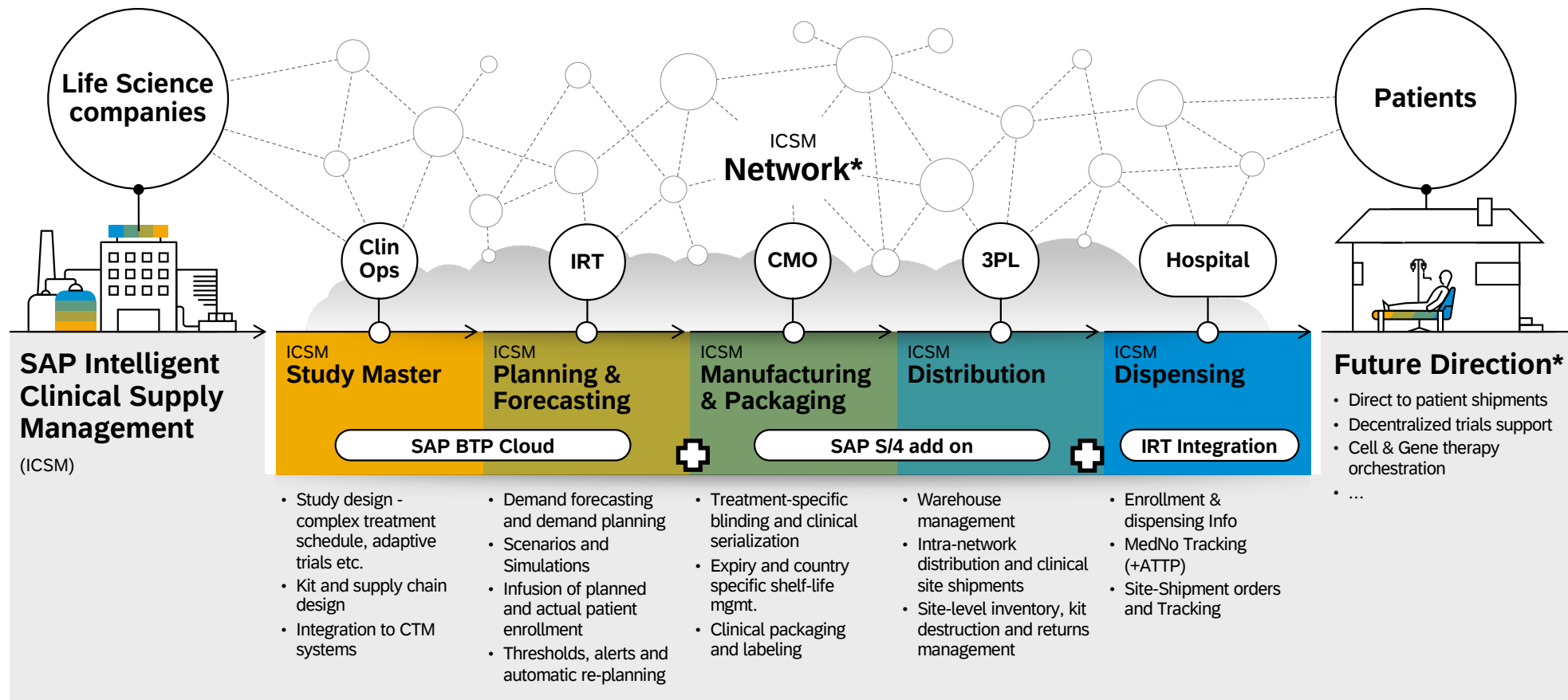
Clinical Trial Supply Chain



SAP Intelligent Clinical Supply Management I Solution Map

End to end clinical supplies planning, operations and integration into clinical supply ecosystem

ICSM is a frontrunner for **the Industry Cloud for Life Sciences** providing end to end process operations and visibility to plan, source, manufacture, distribute and reconcile supplies for clinical R&D. This is a mandatory step to prove that new medications can **improve patients' lives**. With the S/4 standard extensions, the solution also addresses the specific blinding and randomization needs for clinical trials to facilitate manufacturing, packaging, labeling, and shipments of clinical supplies. Please see Video here.



SAP Digital Manufacturing



Complex legacy MES are powerful - but costly, rigid, and not suited for all plants. SAP Digital Manufacturing is a modern alternative worth exploring.

Challenges of complex legacy MES

- Costly to implement & maintain
- Lengthy projects
- Rigid & inflexible
- Hard to scale
- Hard to innovate
- Outdated technology stack
- Not suited for all plants
- ...

Benefits of a modern, light-weight MES

- **Out-of-the-box features**
- **Scalable & future-proof platform**
- **Tightly integrated**
- **Cost-Efficient**

Seamlessly integrate your top floor to the shop floor

ISA-95 Model

Level 4

Enterprise
Business Processes

ERP

SAP S/4HANA or ECC

Level 3

Manufacturing Operations
Management

MES

SAP Digital Manufacturing

Level 0-2

Monitoring &
Process Control

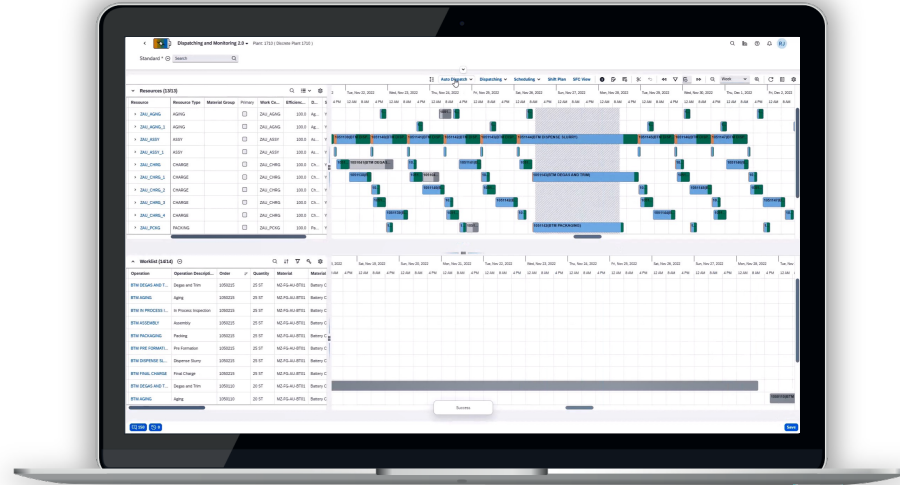
Shop
Floor



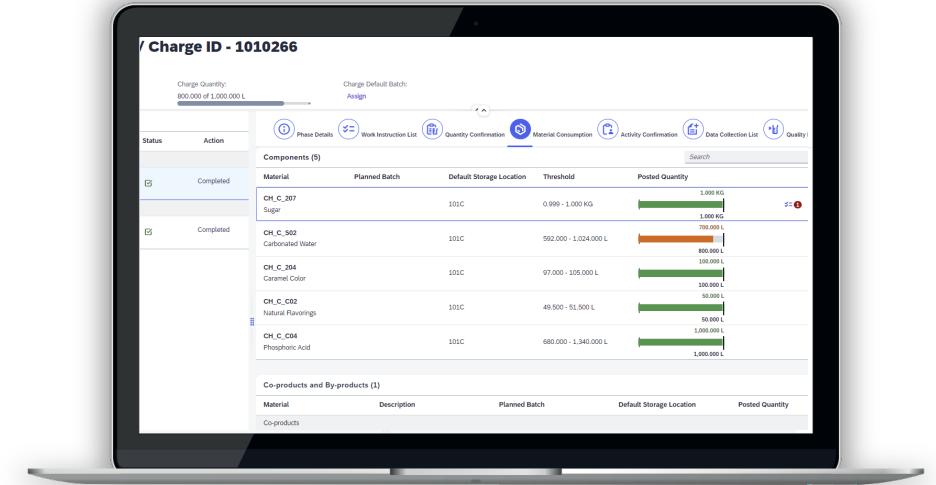
Check-In

- » SAP DM is **future-proof, cloud-based** MES
- » You can immediately use well integrated **standard capabilities**
- » And configure, analyze & extend **beyond standard**
- » **Scalable**, from select use cases up to global roll-out across plants

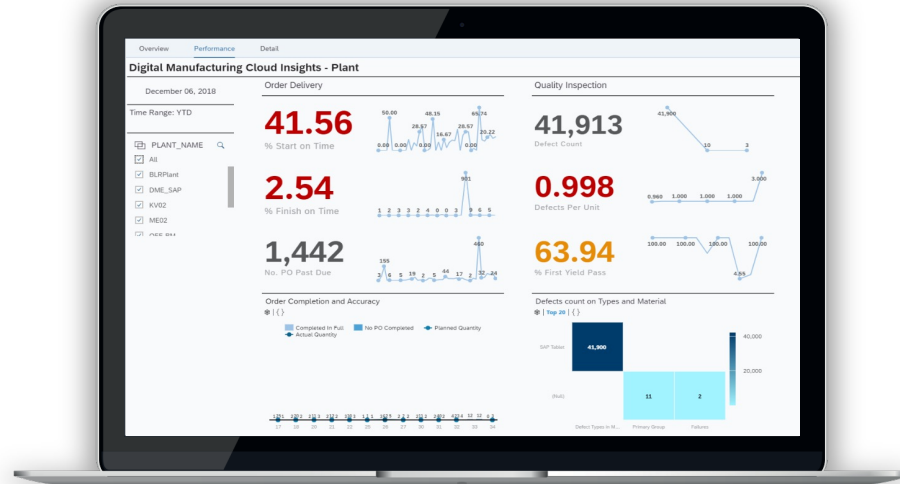
SAP Digital Manufacturing is a **single application** supporting a multitude of use cases inside your plants – going beyond known PI-Sheet capabilities



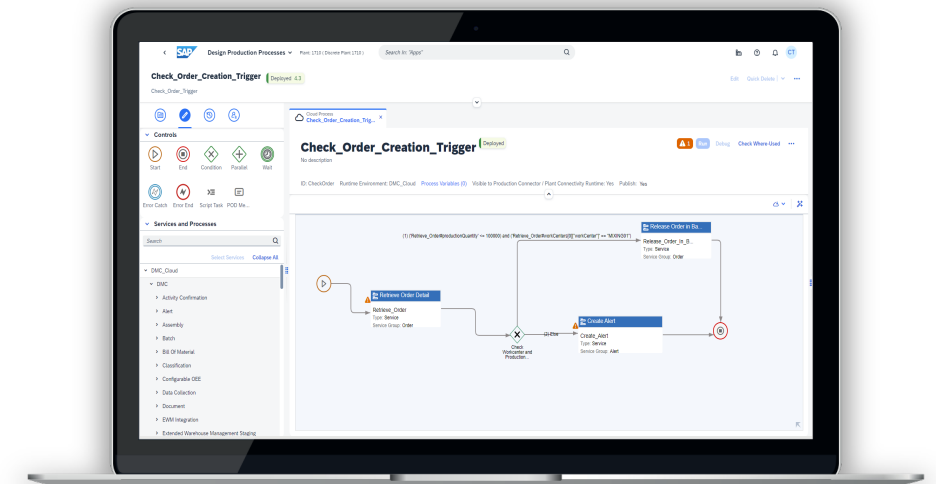
Resource Orchestration



Execution

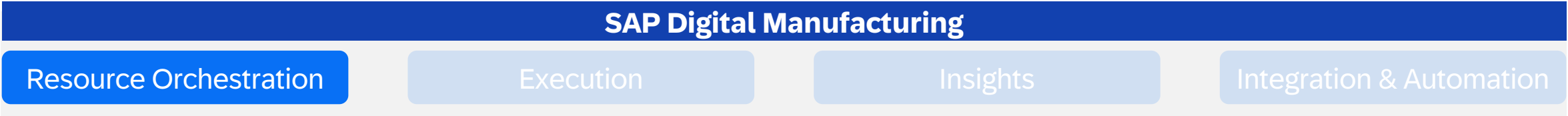


Insights



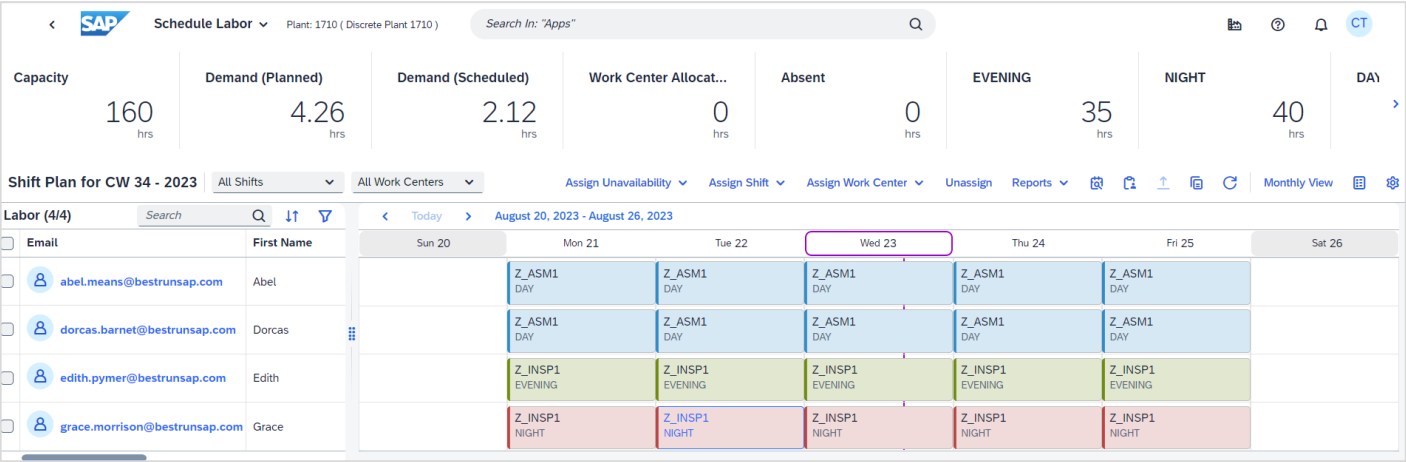
Integration & Automation

We can help you achieve your manufacturing goals across various processes.



Benefits

- » React to unforeseen events and **maximize capacity utilization on the shop floor**
- » **Streamline workforce planning** in line with demand
- » Visualize constraints like labor, tooling and scheduling alerts to **ensure efficient execution**



SAP

Manage Skill Matrix

Plant: D100 (Discrete Plant)

Search In: "Apps"

We can help you achieve your manufacturing goals across various processes.

SAP Digital Manufacturing

Resource Orchestration

Execution

Insights

Integration & Automation

Benefits

- » Paperless production and worker guidance ensuring **full traceability** incl. **Electr. Signature**
- » Transparent and efficient process execution including **Non-Conformances, Review by Exception and SAP QM integration**
- » Powerful **machine integration** and **flexible automation**

Order POD with Review by Exception - Plant: 1010 (Process Ind...)

Order ID - 2000520

Batch: 0000000621 Phase: 2000520-000000-0011 - Add Premix Material: CH_C_001 Material Description: Paint Purple Planned Date: May 8, 2025 - May 9, 2025 Work Instructions: Goods Receipt Quantity: 0 of 1,000,000 L

Phases (3)

| Phase ID | Status | Action |
|---------------------|----------|----------|
| 0010 - Paint Mixing | | |
| 0011 Add Premix | Complete | Complete |
| 0012 Mixing Phase | Start | Start |
| 0013 Cleaning Phase | Start | Start |

Review by Exception

| Nonconformance Code | Date / Time | Phase | Status |
|---------------------|-------------------------|---------------------|----------|
| 0010_DEF-TOL | May 8, 2025, 1:23:08 AM | 2000520-000000-0011 | Approved |

Nonconformance Activity Log

- Signed by ISAC.MICA 5/8/25 at 1:23 AM Status: Approved
- Signed by ISAC.MICA 5/8/25 at 1:23 AM Status: Reviewed
- Processed by ISAC.MICA 5/8/25 at 1:23 AM Status: Closed
- Logged by ISAC.MICA 5/8/25 at 1:23 AM Nonconformance Code: 0010_DEF-TOL SFC: 10101661 Phase: 2000520-000000-0011

Mixing POD - Plant: 1010 (Process Industry Plant 1010)

Order ID - 1049305 / Charge ID - 101034

Batch: 0000000328 Phase: 0011 - Mixing Phase Material: CH_C_002 Planned Date: Sep 29, 2022 - Sep 30, 2022 Charge Quantity: 0 of 1,000,000,000 L Charge Default Batch: Assign

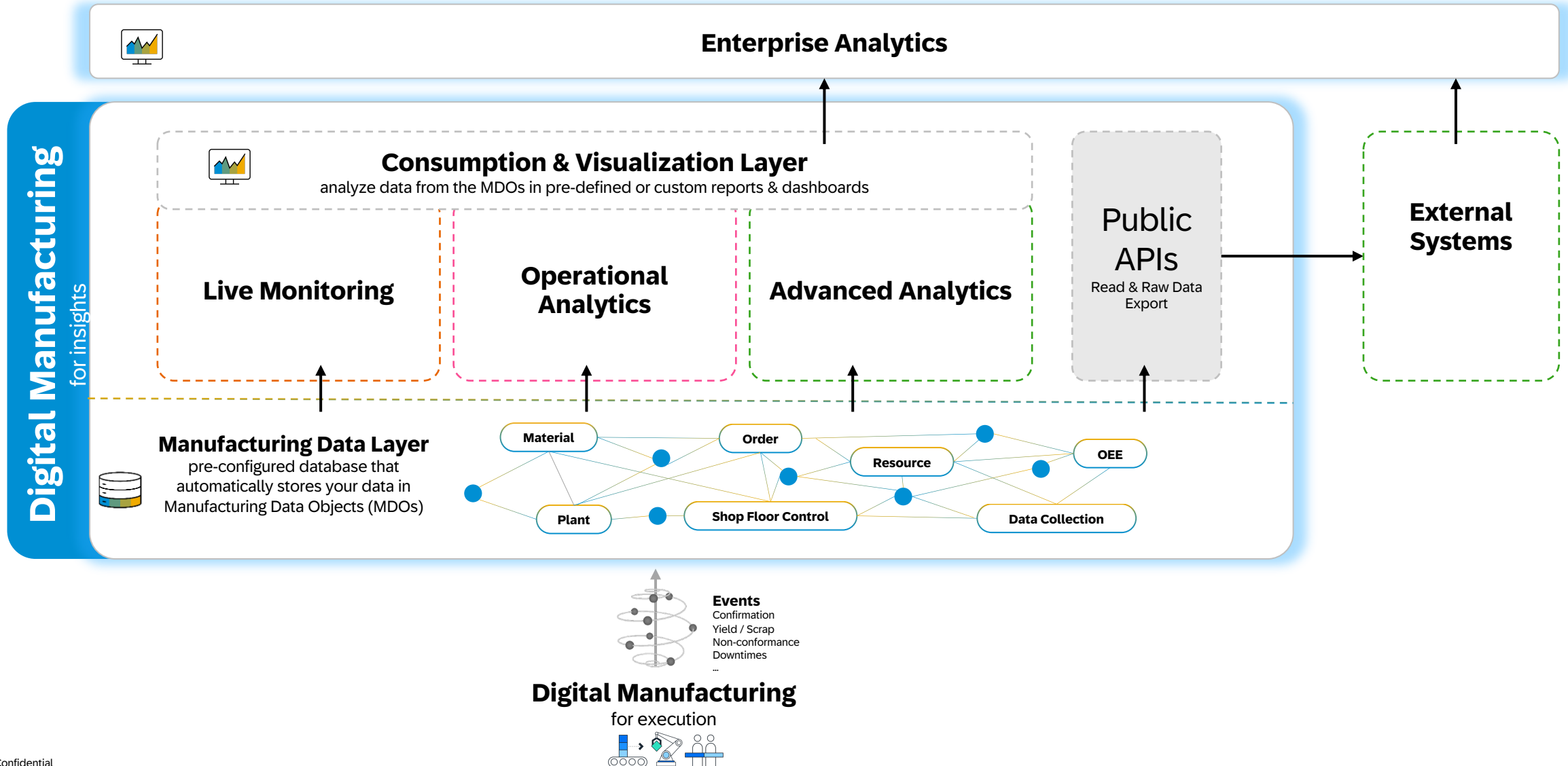
Phases (2)

| Phase ID | Status | Action |
|------------------------|----------|----------|
| 0010 - Beverage Mixing | | |
| 0011 Mixing Phase | Complete | Complete |
| 0020 - Bottling Phase | | |
| 0021 Bottling Phase | Start | Start |

Quality Inspection Characteristic List

| Inspection Characteristic | Recording Method | Inspection Results | Summarized Valuation | Results Origin | Inspected | Sample Size |
|---------------------------|------------------------------------|-----------------------|----------------------|----------------|-----------|-------------|
| CO2 | Single Value Recording / Mandatory | 67 G Limit: 0 - 130 G | Valuation in range | Manual | 1 | 1 |
| Temperature | Single Value Recording / Mandatory | Limit: 0 - 100 °C | | Manual | 0 | 1 |
| Water Purity | Single Value Recording / Mandatory | Limit: 90 - 100 % | | Manual | 0 | 1 |
| Brix | Single Value Recording / Mandatory | Limit: 0 - 120 EA | | Manual | 0 | 1 |

The future-proof analytics architecture automatically collects and stores data from shop floor events, which you can then visualize and analyze inside or outside of SAP DM.



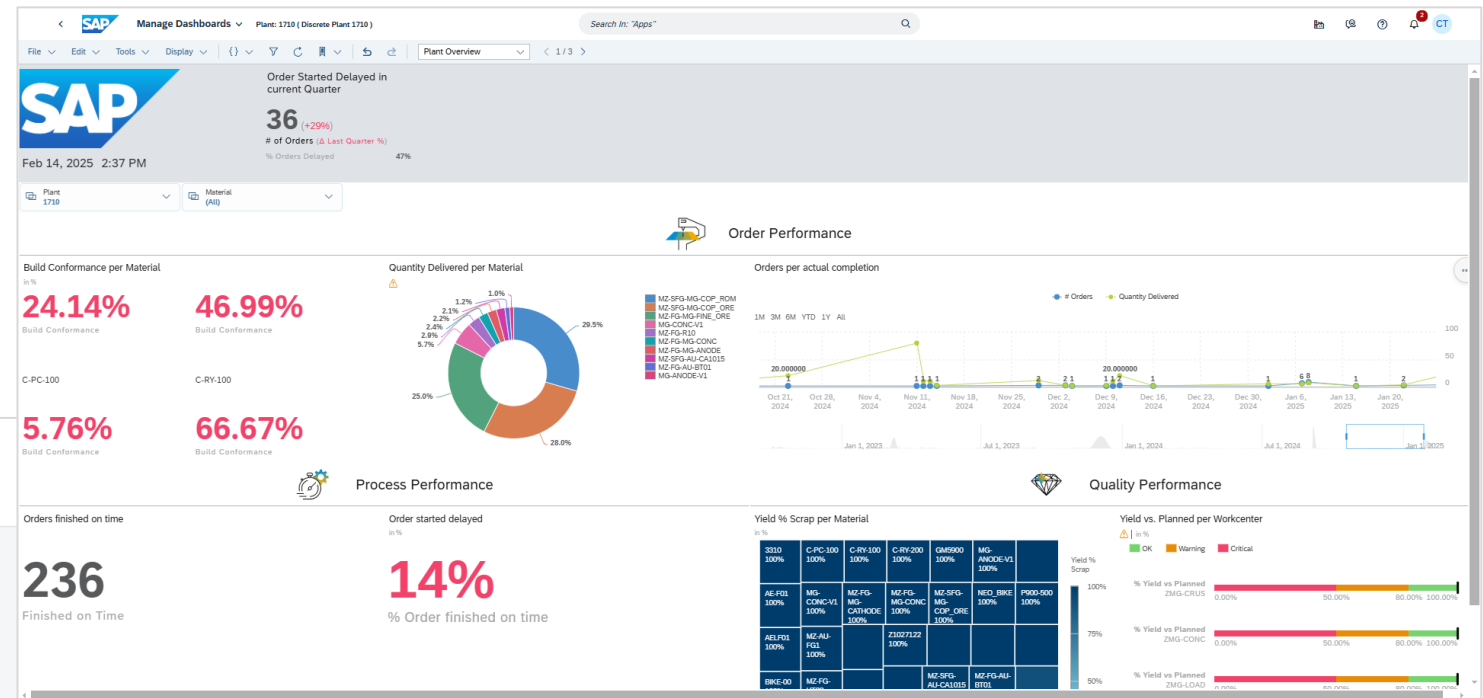
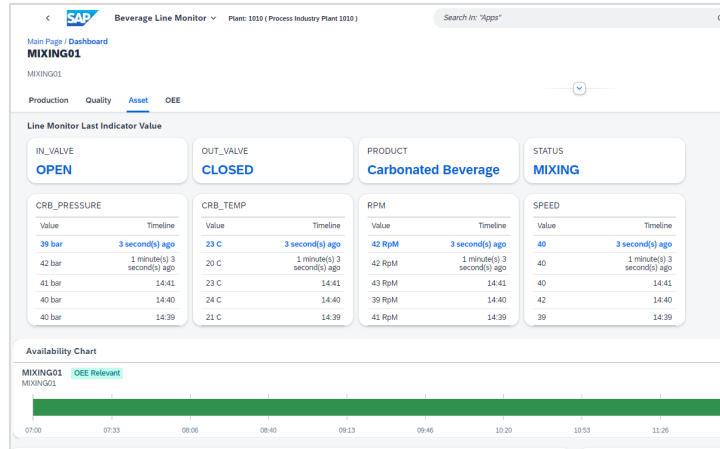
We can help you achieve your manufacturing goals across various processes.

SAP Digital Manufacturing

Insights

Benefits

- » Full transparency into **standard and custom KPI** based on **real-time manufacturing data**
- » **Real-time visibility** and performance monitoring across regions, plants, work centers and machines
- » **Easy configuration** of dashboards with **powerful visualizations** to harmonize across plants



We can help you achieve your manufacturing goals across various processes.

SAP Digital Manufacturing

Resource Orchestration

Execution

Insights

Integration & Automation

Benefits

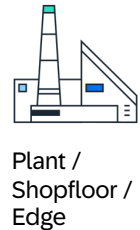
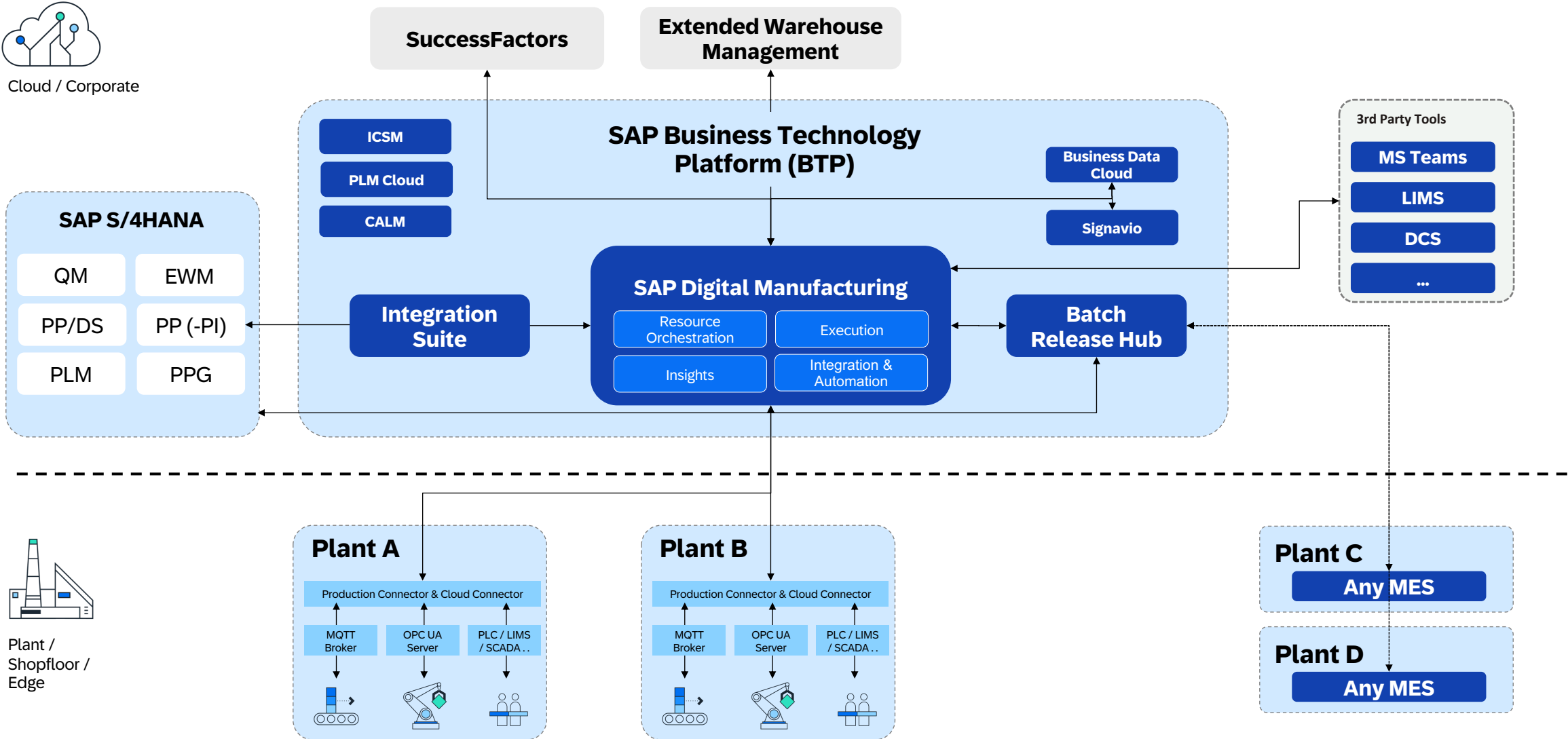
- » Empower users through **Low-Code / No-Code tools** to easily configure the solution
- » **Reduce integration efforts** through out-of-the-box integrations with key solutions
- » **Realize innovative automation scenarios** on the shop floor leveraging future-proof protocols

The screenshot displays the SAP Digital Manufacturing interface. On the left, a workflow diagram titled 'Check_Order_Creation_Trigger' is visible, showing a sequence of steps including 'Check Order', 'Release Order', and 'Create Alert'. Below the diagram is a 'Services and Processes' list. In the center, a 'Toolbox' contains various UI elements like 'Bezeichner', 'Bild', 'Drucktaste', 'Eingabe', 'Expanderbarer Text', 'HTML', 'IFrame', 'Link', 'Menüdrucktaste', 'Symbol', 'Text', 'Text für Datum/Uhrzeit', 'Textbereich', and 'H3 Titel'. On the right, the 'DetailsPage' for 'EBR 1234' is shown. It includes a 'General Information' section with 'Order Details', 'Material Details', and 'Dates'. Below this is a table of 'SFCs (2)' with columns for SFC, Planned Quantity, Actual Quantity, Scrap Quantity, Delivered Quantity, and Status. The table contains two rows of data. To the right of the details page is an 'Activity Log' showing a timeline of events with user avatars and timestamps. On the far right, a 'Properties' panel lists various settings like 'Background Design', 'Layout Type', and 'Behavior'.

| SFC | Planned Quantity | Actual Quantity | Scrap Quantity | Delivered Quantity | Status |
|------------|------------------|-----------------|----------------|--------------------|--------|
| 0000040673 | 100 L | 99 L | 1 L | 99 L | Active |
| 0000040678 | 101 L | 95 L | 1 L | 93 L | Done |

SAP Reference Architecture for Life Sciences

Application Architecture Overview Diagram | MES Centric



SAP Integrated Business Planning



SAP IBP: Best-in-Class Life Sciences Supply Chain Planning Capabilities

Characteristics -Based Planning

- ✓ Supply and demand matching based on characteristics
- ✓ Regulatory / Compliance Planning
- ✓ Country of Origin / Embargo
- ✓ CBP with Shelf-Life Planning

Shelf-Life Planning and Management

- ✓ FEFO (First Expire, First Out) approach
- ✓ Minimum Remaining Shelf Life (MRSL) requirements matching for customer demands
- ✓ Gating Factor Generation - "Projected Stock – Shelf Life" alerts

New Product Introduction (NPI) Planning

- ✓ Complex product launches with regulatory approval timelines and market introduction strategies
- ✓ Curve Based Forecasting
- ✓ Dummy / Placeholder Planning

Integrated CMO Management

- ✓ Seamless Third-Party Manufacturing Integration
- ✓ Real-Time Visibility Across Manufacturing Network
- ✓ Collaborative Planning with External Partners
- ✓ Regulatory Compliance Coordination

Vaccine Planning Capabilities

- ✓ End-to-End Vaccine Supply Chain Orchestration
- ✓ Planning and Allocation by Characteristics
- ✓ Priority-Based Allocation for Constrained Supply

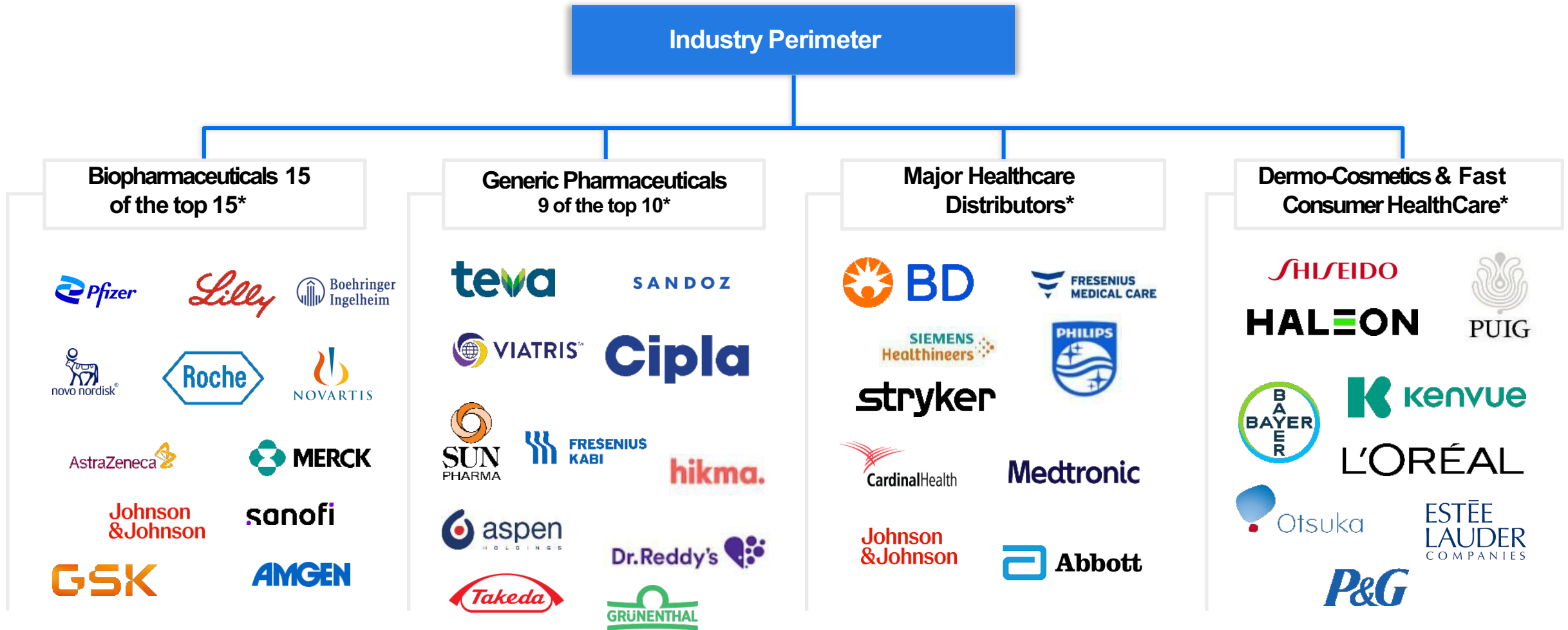
Clinical Supply Planning

- ✓ Seamless Clinical Demand Integration
- ✓ Multi-Level Supply Planning
- ✓ Optimization of shared inventory by pooling supply needs across clinical and commercial products to reduce waste
- ✓ Real-Time Replanning when ICSM pushes updated clinical demand forecasts,

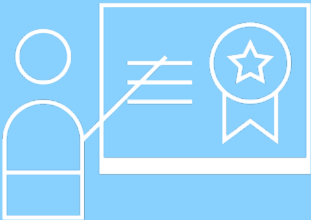



Collaboration and Integration

- ✓ Microsoft Teams Integration : Task Synchronization, Direct Teams Channel Notifications
- ✓ Real Time Integration with ICSM + SAP S/4HANA
- ✓ CMO Integration

SAP is a trusted partner supporting major companies in Life Sciences, Cosmetics, and Consumer Healthcare



Key Constructs and Values drivers for Life Sciences Industry

| | | | |
|--|--|---|---|
| <div></div> <div><h3>Outcome based Planning</h3></div> <div><ul style="list-style-type: none">✓ Drive targeted outcomes by proactively steering Supply plans to fulfil the outlined objectives (Markets, Channels, Brands)</div> <div><div></div><div>.....</div></div> | <div></div> <div><h3>Scalable and Performant Model</h3></div> <div><ul style="list-style-type: none">✓ Products with version details infused as characteristics (Ibuprofen → Dosage form, Potency..)✓ Leverage CBP attributes as Planning Levers (Market, Regulatory Qualification, category, country of origin...)</div> <div><div></div><div>.....</div></div> | <div></div> <div><h3>Fully integrated Planning and execution</h3></div> <div><ul style="list-style-type: none">✓ End to end - Real time integration with S4 HANA with Demand Supply Segmentation and Batch Classification✓ Support for Non SAP systems with APIs</div> <div><div></div><div>.....</div></div> | <div></div> <div><h3>Industry specific Uses cases</h3></div> <div><ul style="list-style-type: none">✓ Regulatory / Compliance adherence – Commercial and Clinical supply chains✓ Supplier or Inhouse Production version selection based on demand attributes✓ Shelf Life and Safety stock planning✓ Finished Products, Bulk, Ingredients planning with characteristics propagation</div> <div><div></div><div>.....</div></div> |
|--|--|---|---|

Why Characteristics-Based Planning ?

My company produces the same product but with different variations (Potency, Dosage forms, studies)?

How can I have more granular but flexible levers in planning to steer the supply plan?

Are your supply chains planned the same way — whether they need to be efficient or responsive — even when the business demands different strategies?

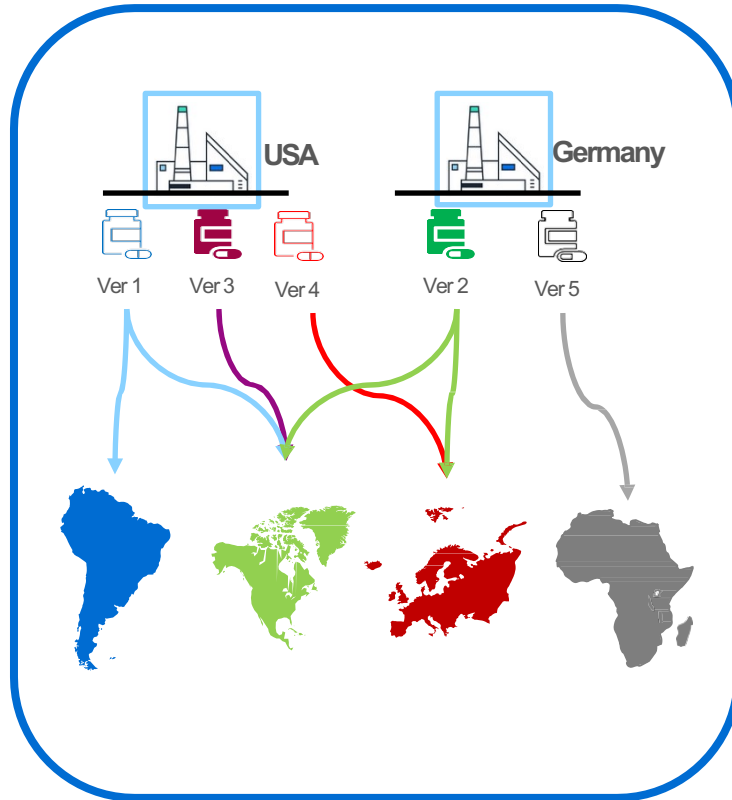
How can I ensure that I match the right qualified batch, potency, or specification to the right demand Market automatically?

Can planning already take care that the *right product version* goes to the *right Market Demand* without firefighting ?

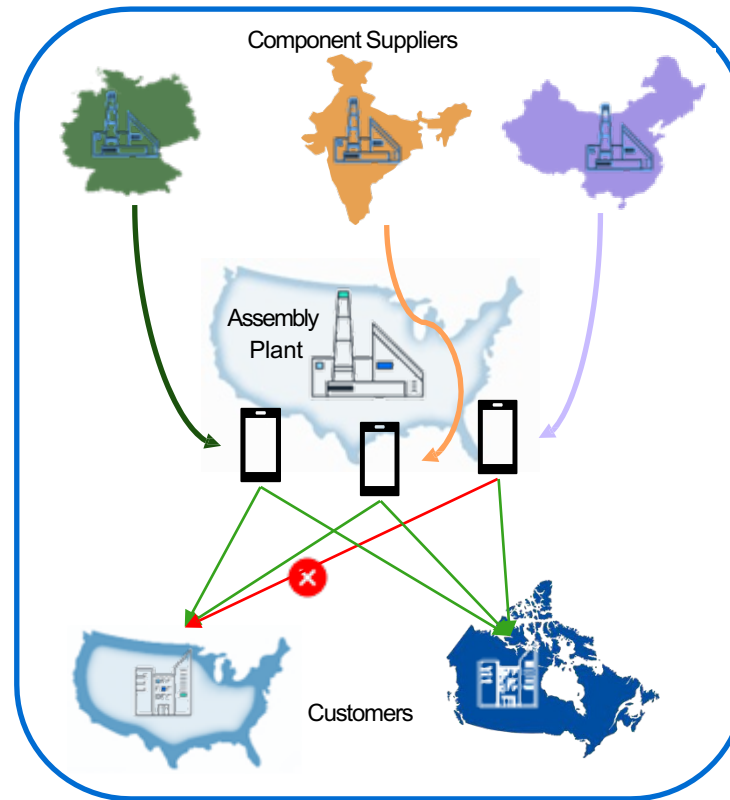
Can I avoid creating each and every variant in IBP – avoid data proliferation?

Key Use-Cases

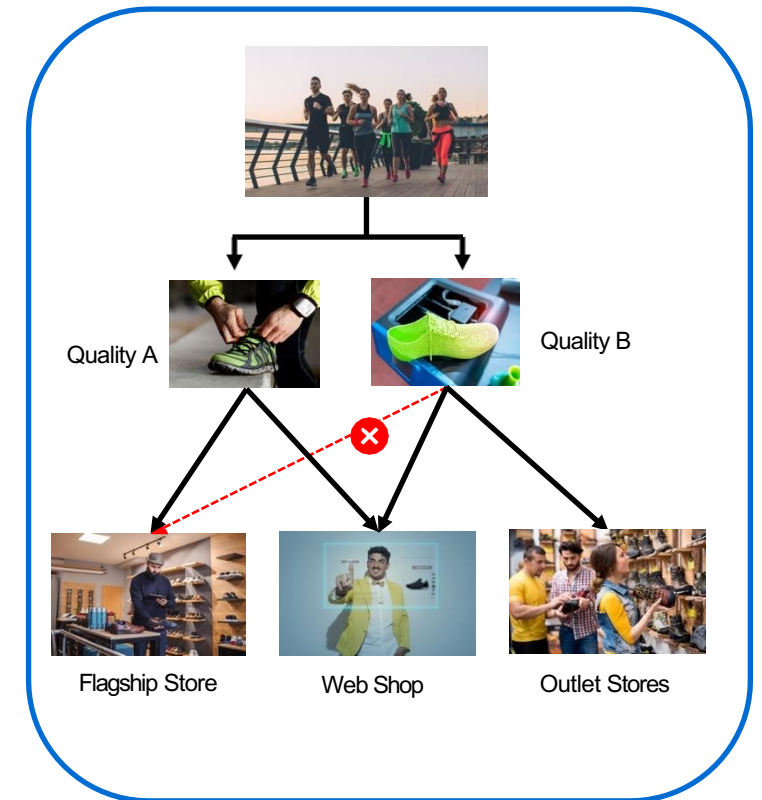
Regulatory / Compliance Planning*



Country of Origin / Embargo



Supply and demand matching based on characteristics*



Supply Chain Segmentation – define and drive policies and objectives per Segment

Use Case **Steering the Supply Plan with Supply Chain Segmentation Levers**

Industry: **All**

A company uses two supply chain segments — **Efficiency** (lowest cost, stable flows) and **Responsiveness/Agile** (fast response, volatile demand).

These Segments allow the business to balance cost and service trade-offs, unlocking both efficiency and agility in one supply chain. Below are some examples.

| Lever | SC Segment: Efficiency | SC Segment: Responsiveness | Business Outcome |
|------------------------------|--|--------------------------------------|---|
| Lot Sizing | Large economical batches | Small, frequent lots | Cost vs. agility |
| Lead Times & Frequency | Accept longer lead times, stable cycles | Shorter lead times, frequent replans | Lower cost vs. faster reaction |
| Inventory Policy | Lean safety stocks | Higher buffers | Working capital vs. service |
| Max Lateness & Max Earliness | Efficient Max early production with limits | No or min Lateness | Balance on-time delivery delivery with lean inventory |

With CBP in SAP IBP, you can proactively steer supply decisions for segmented supply chains based on their policies / strategies and measure their performance.

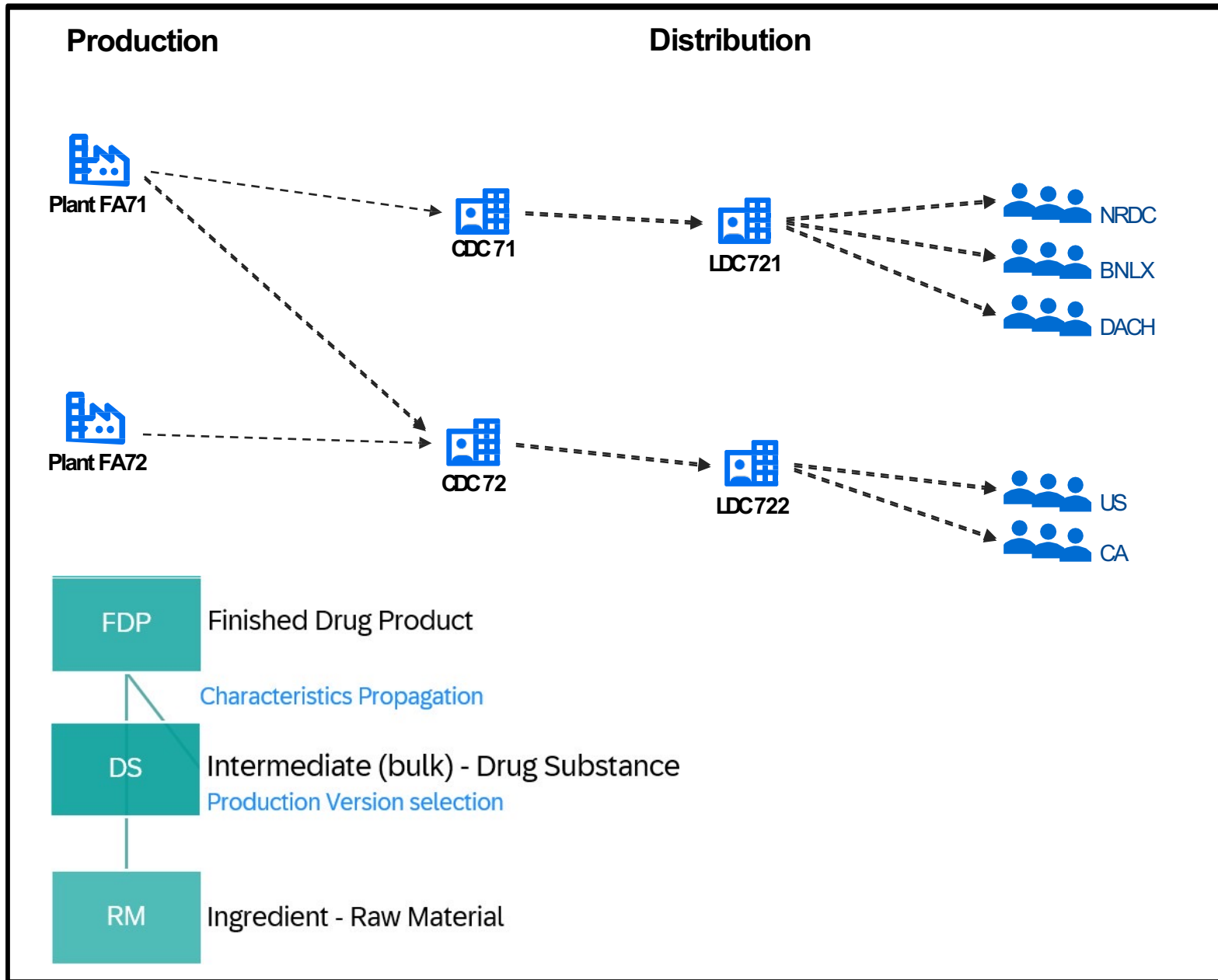
Industry: **Life Sciences**

A pharma manufacturer produces finished drugs from bulk drug substances, where potency and regulatory approvals dictate which production versions are allowed for target markets.

CBP ensures allocation of approved **batches** and selection of **approved production**

locations, product versions for fulfilling demands approved for various Markets/Countries

Use case example supply chain



Example Rules:

- The FDP can be sold to customers in DACH, BNLX, US, CA
- The FDP and the DS100 can be manufactured either in plant FA71 or FA72
 - Plant 71 & 72 is approved by US and Canada
 - Plant 71 is approved only by DACH/ BNLX.
 - DS version 001 is approved by BNLX
 - DS version 002 is approved by DACH

End to End – out of the box Real Time integration across S4, IBP and ePPDS

Stock / Requirements Pegging

Show Overview Tree

Selection Criteria / Material Master Overview

Material: PDL_DP10 Ibuprofen
MRP Area: FA71 MRP Type: X0 Material Type: FERT Base Unit: EA
Plant: FA71

A - Free Available Stock Σ - Stock/Requirement Overview I - Additional Information

| MRP Status | Short Description | MRP elemnt | N | E | Req Storage Location | Delivery Date | MRP elemnt | Stock No. | E | Master Order | Stock Storage Location | Req.Segmnt | Stock Segment | Plan Date | Reqmts |
|------------|----------------------|------------|---|---|----------------------|---------------|------------|------------|---|--------------|------------------------|------------|---------------|------------|--------|
| A | Free Available Stock | | | | | 19.12.2025 | PldOrd | 0100000150 | | | 0001 | | | 19.12.2025 | |
| | | | | | | | PldOrd | 0100000151 | | | 0001 | | EU01EUUSSP1 | 19.12.2025 | |
| Subtotal | | | | | | | | | | | | | | | |

S4 Demand Supply Segmentation

Product: Ibuprofen (PDL_DP10), Location: Plant Glasgow (FA71)

Stock Projection Information

Items (3) Element View Daily View Filter by CBP Attribute Values Create Change Convert to Simulate Sales Order Start Planning Run Period

| Requested or Planned Date | Receipt or Requirement ID | Type of Receipt or Requirement | Source or Destination Location | Receipt or Requirement Quantity | Projected Stock (Pegging-Based) | CBP Attribute Values |
|---------------------------|---------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|----------------------|
| | Stock | Stock | | 0.000 | 0.000 | Stock |
| 19.12.2025 | 100000150 | Planned Order | | 10,000.000 | 10,000 | |
| 19.12.2025 | 100000151 | Planned Order | | 10,000.000 | 20,000 | |

LSMARKET = EU

LSPOTENCY = 01

LSQUALIFICATION = EUUS

LSSPECIFICATION = SP1

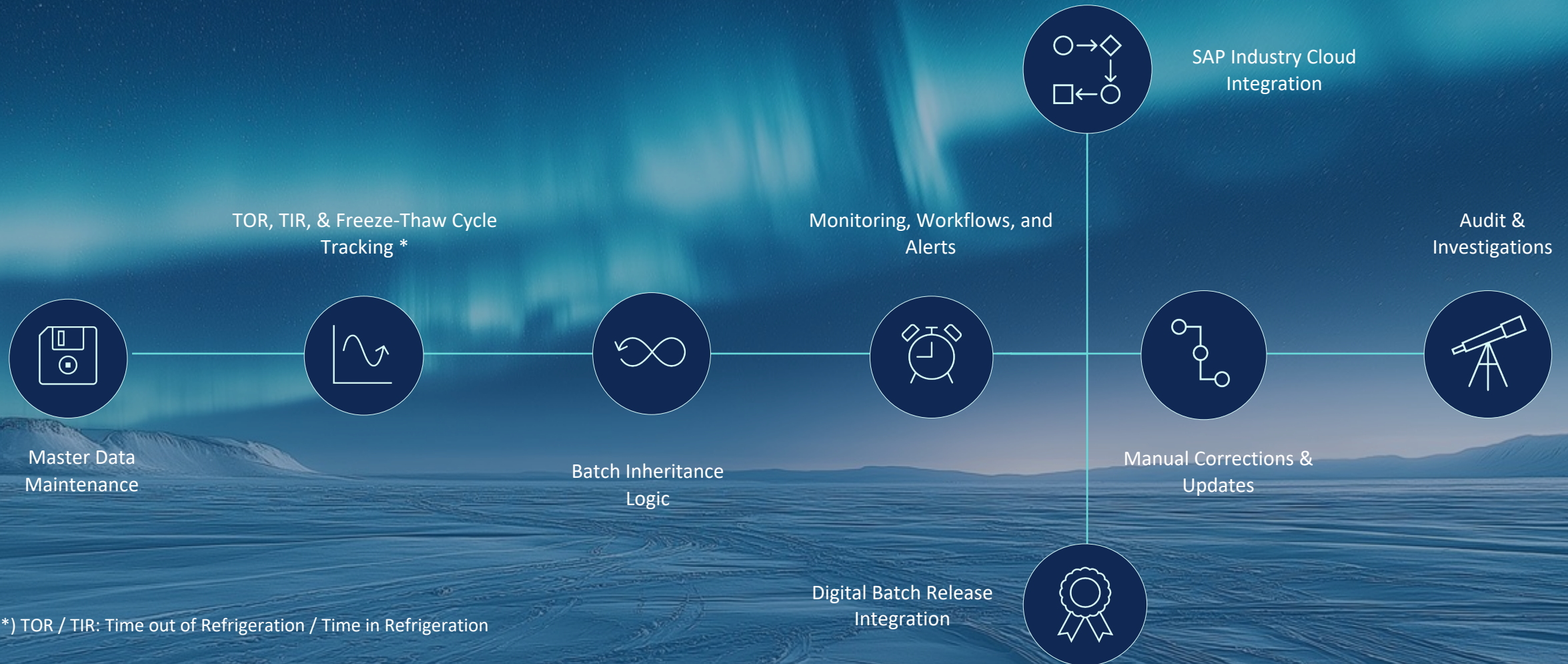
3 More

SAP IBP with CBP

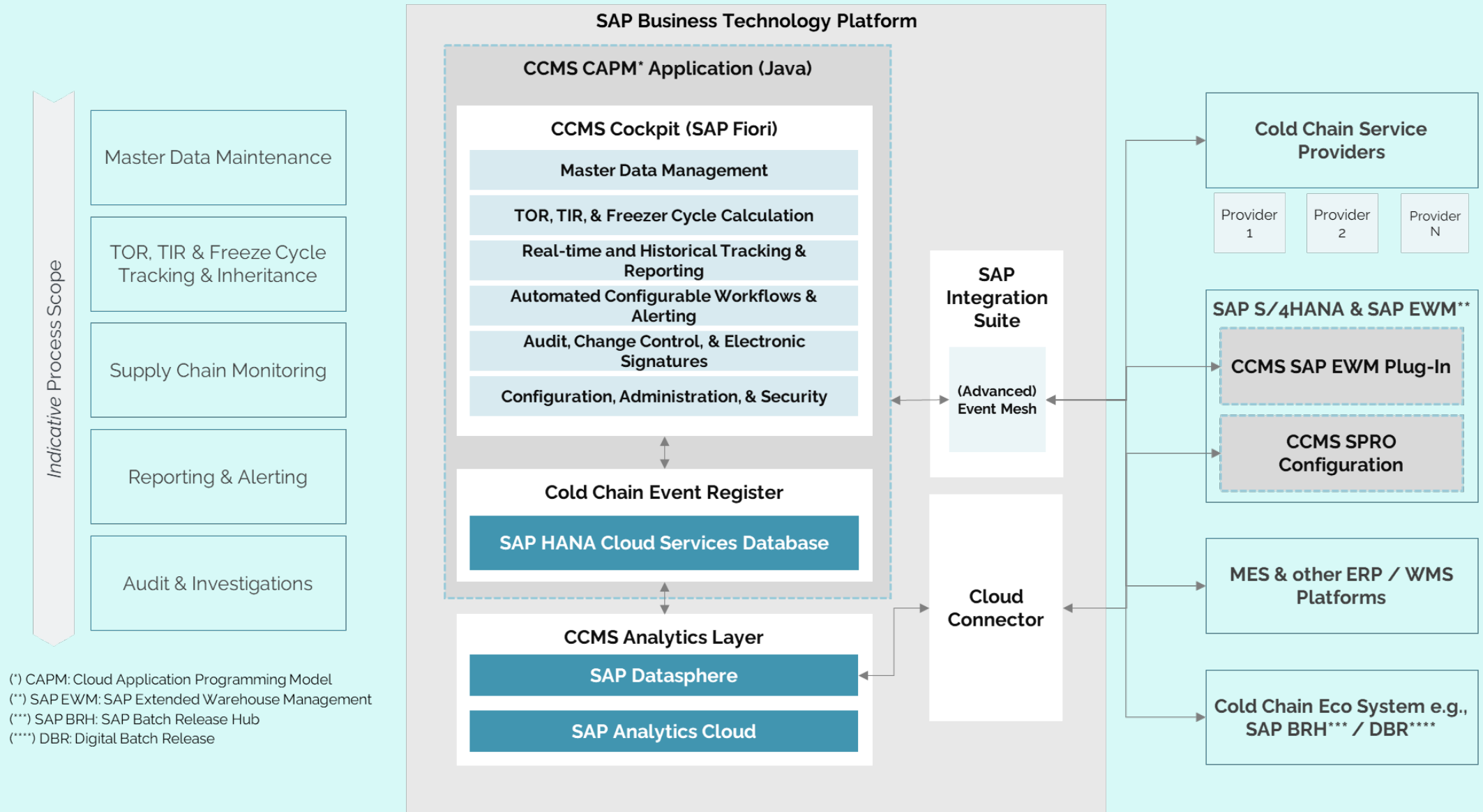
Cold Chain Management Solution (Partner)



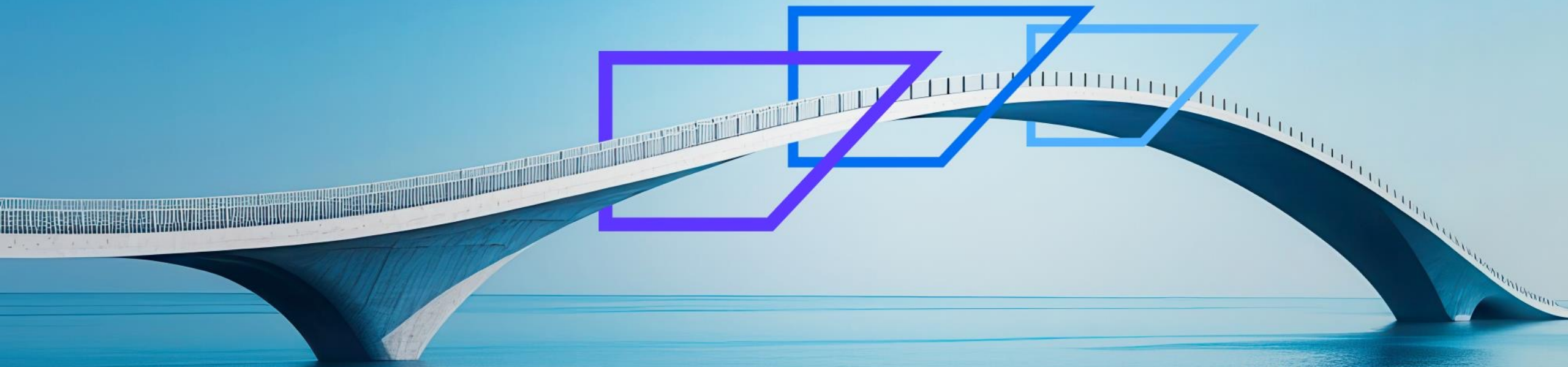
Cold Chain Management Solution (CCMS)



Fusion CCMS High-Level Solution Architecture



Thank you.



SAP Bring out your best.