



8TH ADVANCED GMP WORKSHOP 2023

Harnessing ERP for enhanced compliance

Session By

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TENTHPIN

Making the difference



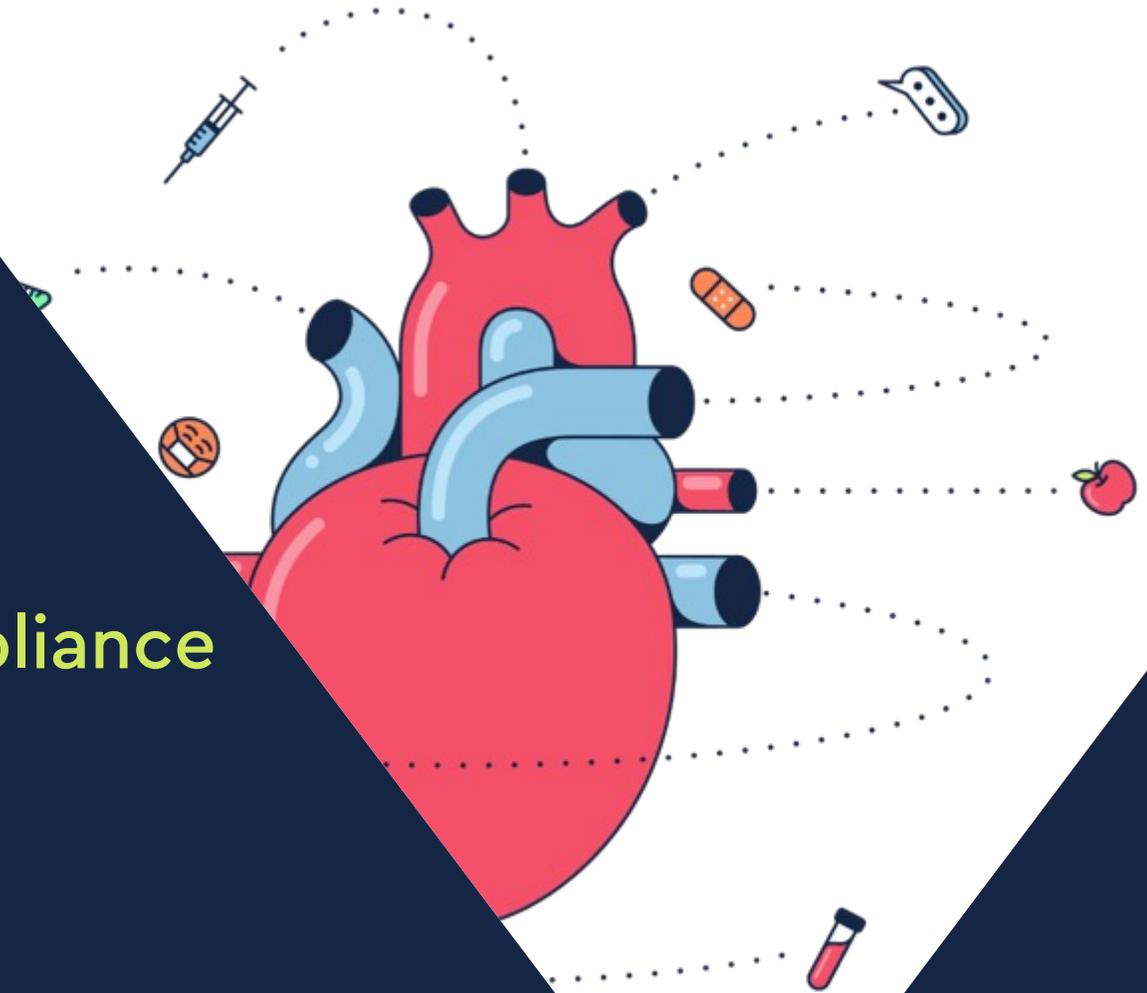
Harnessing ERP for enhanced compliance

IPA Conference

04 Oct 2023

Raghuram Janapareddy

Managing Director - India



ABOUT TENTHPIN

SAP Diamond Initiative names Tenthpin as

"Partner of the Year for Process & Life Sciences Industries 2023"

We are a global boutique consultancy company

100% focused on Life Sciences + Technology (SAP & Non-SAP)

Our truly global team makes the difference in any transformational change, by combining deep industry, process and technology expertise.

Key facts & figures

- Founded in 2017
- HQ in Basel, Switzerland
- Management owned and independent
- Own software company
Tenthpin Solutions
- **SAP's #1 Life Sciences Innovation Partner**



India Presence

- Bangalore
- Pune
- Hyderabad

+450
consultants

+5.000 years
experience in Life
Sciences

12 of Top 20
Life Sciences
companies are
our clients

We Deliver Digital Transformation in Life Sciences

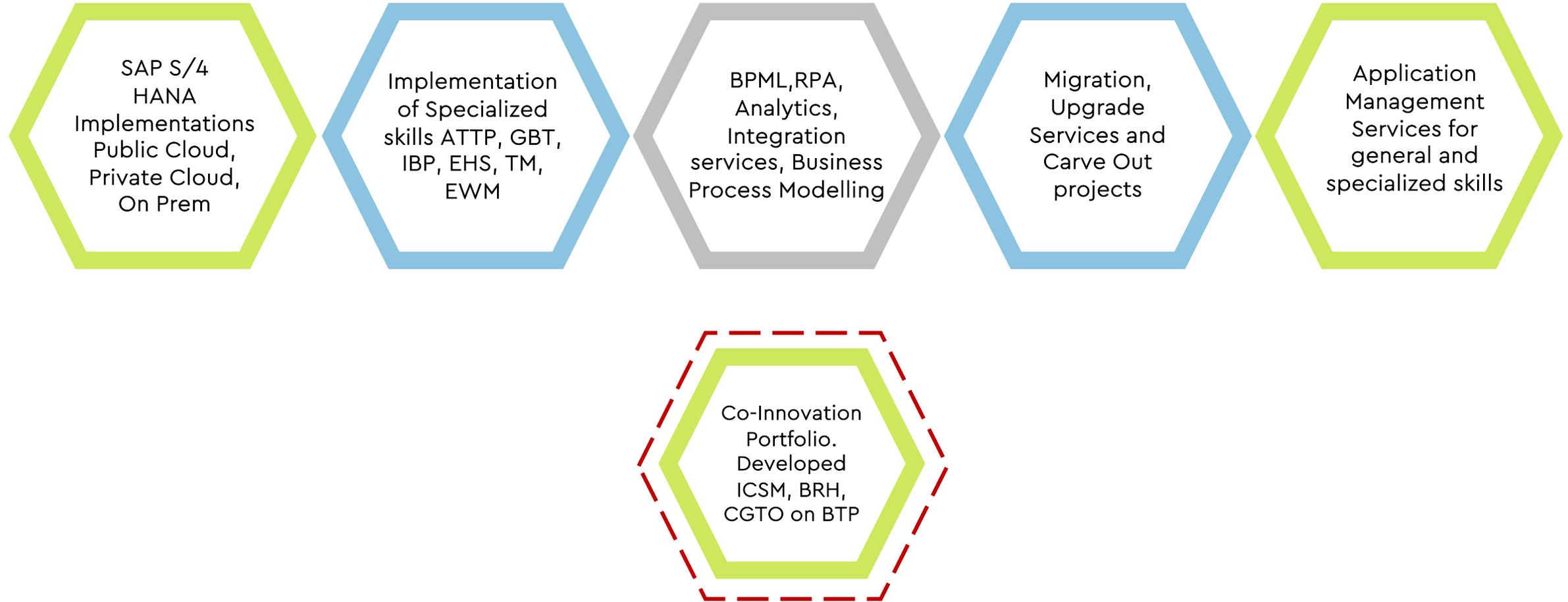
Our Service and Solution Portfolio at a Glance



SAP Transformations	<ul style="list-style-type: none"> SAP S/4HANA Transformations from Strategy to Implementation Life Sciences-Centric, Global Template Design and Deployment Design and Implementation of SAP Industry Cloud/BTP innovations Next Generation Application Management Services (AMS)
SAP Innovations	<ul style="list-style-type: none"> SAP Intelligent Clinical Supply Management (ICSM) SAP Cell & Gene Treatment Orchestration (CGTO) SAP Batch Release Hub (BRH)
Value Chain Optimization	<ul style="list-style-type: none"> Transformation to Data-Driven, Patient-Centric Value Chains Clinical & Commercial Operating Model Design and Implementation Digital Supply Chain Transformation Advisory Services Environmental, Social and Corporate Governance (ESG)
Digital, Data & Analytics	<ul style="list-style-type: none"> Digital Strategy Advisory & Digital Transformation Support Business Value Discovery Automation (RPA) and Artificial Intelligence (AI) Enterprise Data Management
Transformation Management	<ul style="list-style-type: none"> Post-Merger Integration and Divestment Management Program-/Project Management and Quality Assurance Organizational Change Management & Communications
Tenthpin Solutions	<ul style="list-style-type: none"> Co-Innovation and Co-Development with the Life Sciences industry Solution Design and Development of Future Core Capabilities Upvance Biotech Suite for Cell Therapies, Molecules and Gene Therapies Tenthpin Quality Management Evolved (T/QME)

TENTHPIN works from End-to-End

Business Transformation to Digital Transformation



Our Clients. A Selection.

We exclusively advise the Life Sciences industry, spanning from Pharma & Biotech, Consumer Health, Animal Health, to Medical Technology. Both small and large enterprises rely on Tentpin.



Changing Regulatory Environment

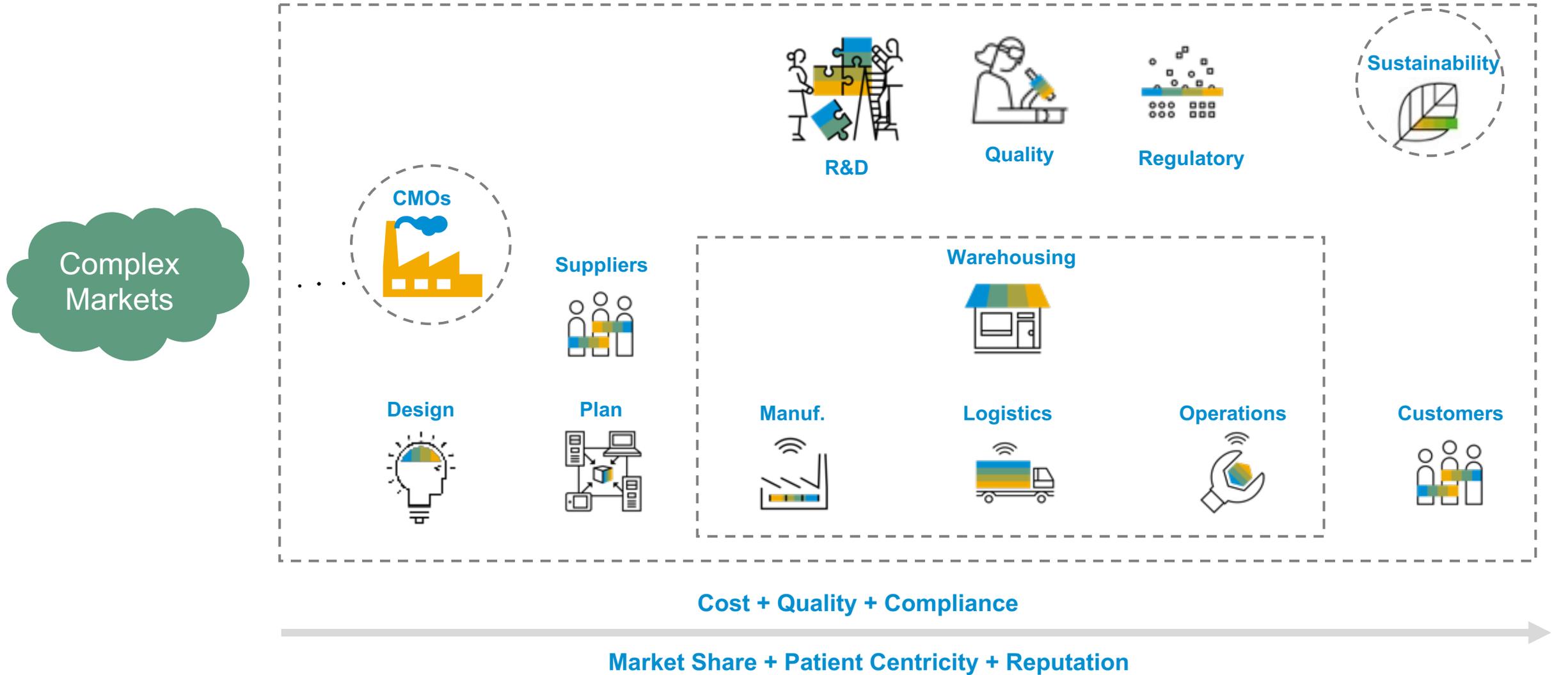
Status Quo in Life Sciences is being disrupted

Indian Context



 **New Challenges require ...
...new Core Capabilities**

The Supply Chain is becoming more networked



Supply Chains are now networked Value Chains

1



Complex
Global Supply
Chains

Changing Landscape

Agile, Resilient Value Chains: Swift decision-making and adaptability with end-to-end, data-driven transparency.

Collaborative Integration: Improved collaboration and seamless integration with external value networks.

Enhanced Value Chain Transparency: Managed risk, environmental and societal implications for a resilient future.

The Regulatory Impact

- Failure-safe value chain compliance across the network
- Interoperability across value chain

Technology Solutions

- Integrated Business Planning capabilities
- Comprehensive Quality Management system
- GS1 & GXP Standards compliant systems



Agile R&D Capability is key for Future Success

2



Shrinking
R&D
Timelines

Changing Landscape

Optimized Clinical Supplies Management: Cost effective management of clinical supplies.

Shrinking Clinical Trial durations: Adapting to changing dynamics in clinical trials management, reduction of cycle times.

Staying ahead of Competition: Early completion of trials, patient retention, personalized treatment options, effective management of clinical trial process.

The Regulatory Impact

- GS1 Standards adoption for seamless data interpretation across the supply chain
- Transparent and clear/complete data submissions complying to regulatory formats

Technology Solutions

- Intelligent Clinical Supplies Management
- Clinical Trials Management Solutions (IRT/EDC/Medical Coding)
- Cell & Gene Therapy Orchestration



Everchanging Price Regulations

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Price
Regulations
impacting
profitability

Changing Landscape

Price Regulations/Controls: Price fixation by governments impacting the profitability

Dynamic Supply Chain Planning: Price controls impacting the entire supply chain planning for better resources.

Staying ahead of Competition: Early completion of trials, patient retention, personalized treatment options, effective management of clinical trial process.

The Regulatory Impact

- Quick adoption of Regulatory Pricing
- Market communications
- Recalibration of the entire supply-chain for cost optimization

Technology Solutions

- Integrated Business Planning
- Sales channel adjustment for Pricing



Traceability Across the Supply Chain

4



Drug
Traceability is
impending

Changing Landscape

Spurious Drug Market Impact : Loss of business and credibility

Quick Product Re-calls: Tracing the batches across the supply-chain

Complying to local country regulations: almost every country coming out with the traceability and serialization regulations

The Regulatory Impact

- Lost of Business if not compliant
- Penetration in newer markets impeded

Technology Solutions

- Track & Trace Solutions
- Batch Release Management



Compliance to GXP Documentation

5



Stringent
Documentation
Requirements

Changing Landscape

Batch Traceability: Ability to reproduce the batch genealogy documentation

ALCOA Requirements: Attributable, Legible, Contemporaneous, Original & Accurate Documentation. + Complete, Consistent, Enduring and Available. + Traceable

The Regulatory Impact

- Potential temporary stoppage of Manufacturing lines
- Not able to ship already manufactured goods
- Loss of Business + High pile of Inventory

Technology Solutions

- Track & Trace Solutions
- Batch Release Management
- GxP compliant software
- Interoperability of Solutions through a single platform



Making right decisions around ERP

Best of the Breed

Each one a different Brand

Advantages

- Cost effective sometimes
- Need based Features

Dis-Advantages

- Multiple Vendors
- Multiple Technologies to handle
- Integration issues
- Could lead to silos
- Upgrade compatibility



Integrated

Advantages

- Single Vendor
- Better Integration
- Single Technology
- Continuous Feature Upgrades
- Multiple Partner Products

Dis-Advantages

- Initial high investment
- Some features may still be missing



It is always important to make right decisions around
your ERP solutions.

Harness it
Strain it
Squeeze it

First of all, USE it

Organizations should consider solutions and technical platforms that offers
interoperability and minimal integration requirements

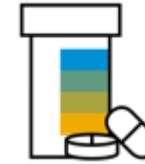
The Solutions should be GxP compliant and should support the
QMS and SOPs defined by the Company

Harnessing your ERP

Major Assumption

Many or All of Indian Pharma Alliance Members are using SAP S/4 HANA as ERP

Develop to Consume for Pharmaceutical Industry



DEVELOP & CLINICAL TRIAL

Recipe Development & PLM

Gather patient feedback to leverage experience data
 Develop recipe formula & generate BOM
 Product Lifecycle Costing
 Handover to MFG
 Collaborate with internal and external parties
 Develop patient label data
 Product Compliance

Enterprise Product Development

Extended capabilities around drug development & collaboration for the LS industry.

Clinical Supply Management

Address specific blinding and randomization needs for clinical trials to facilitate demand forecasting, manufacturing, packaging, labeling, and shipments of clinical trial materials.

PLAN & COLLABORATE

Planning

Plan Demand
 Plan Supply
 Master Schedule for Production & Procurement
 Schedule Production
 Segmentation

Supplier Network

- Ariba SCC
- Supply Chain Control Tower
- 3PL and CMO collaboration

PRODUCE & SERIALIZE

Weigh & Dispense

- Worker Guidance on scale system
- Specific recipes down to every phase

Mixing and Filling

- Batch production with automatic reporting
- Machine Integrated in MES processes
- Process parameter checking, adjusting and recording
- Inline Quality Inspection integrated with S/4HANA

Pharma Serialization

Provide advanced serial number management including randomization. Integrate with ERP master data, Warehouse operations, 3PL and CMO partners and shop floor serialization solutions.

CHECK & RELEASE

Batch Traceability

- Traceability of batches in multistep production with drilldown

Batch Release Management

Quality Assurance with an overview of relevant datapoints in an all-in-one hub to enable batch release processes to be compliant and more efficient.

DELIVER & REPORT

Outbound Logistics

- Integrated Warehouse management and transport planning
- Efficiently collaborate with carriers for tendering
- Global Batch Traceability, long Supply Chain (up and down stream)
- Track CO₂ emissions along the supply chain

Reporting for Serialization Data

Exchange of serialization traceability data with Business Partners. Connection with regional and local government reporting databases incl. readily formatted compliant reporting messages and connectivity handling.

Logistics Network

- Material traceability from raw material to finished goods
- 3PL Collaboration

CONSUME & TREAT

Service

- Service orders under S/4HANA Service contract agreement
- Dispatching work orders via SAP Field Service Management
- Integrated with TeamViewer Frontline on mobile devices

Intelligent Asset Maintenance

- Digital Twin of the asset
- Maintenance notification generated by real asset status
- Work order creation in S/4HANA base on integrated notification
- Work order execution on mobile App

Cell & Gene Therapy

Facilitate and manage cell & gene therapy operations by ensuring chain-of-identity and chain-of-custody.

ERP is at the Core - But there is more

Intelligent, sustainable enterprise



Industry-specific end-to-end processes

Business process transformation

Intelligent Suite

Industry Cloud

Customer Experience

HR

ERP

Spend Management

Finance

SAP Apps

Partner Apps

Business network

Industry cloud

Experience management

Planning

Business Technology Platform

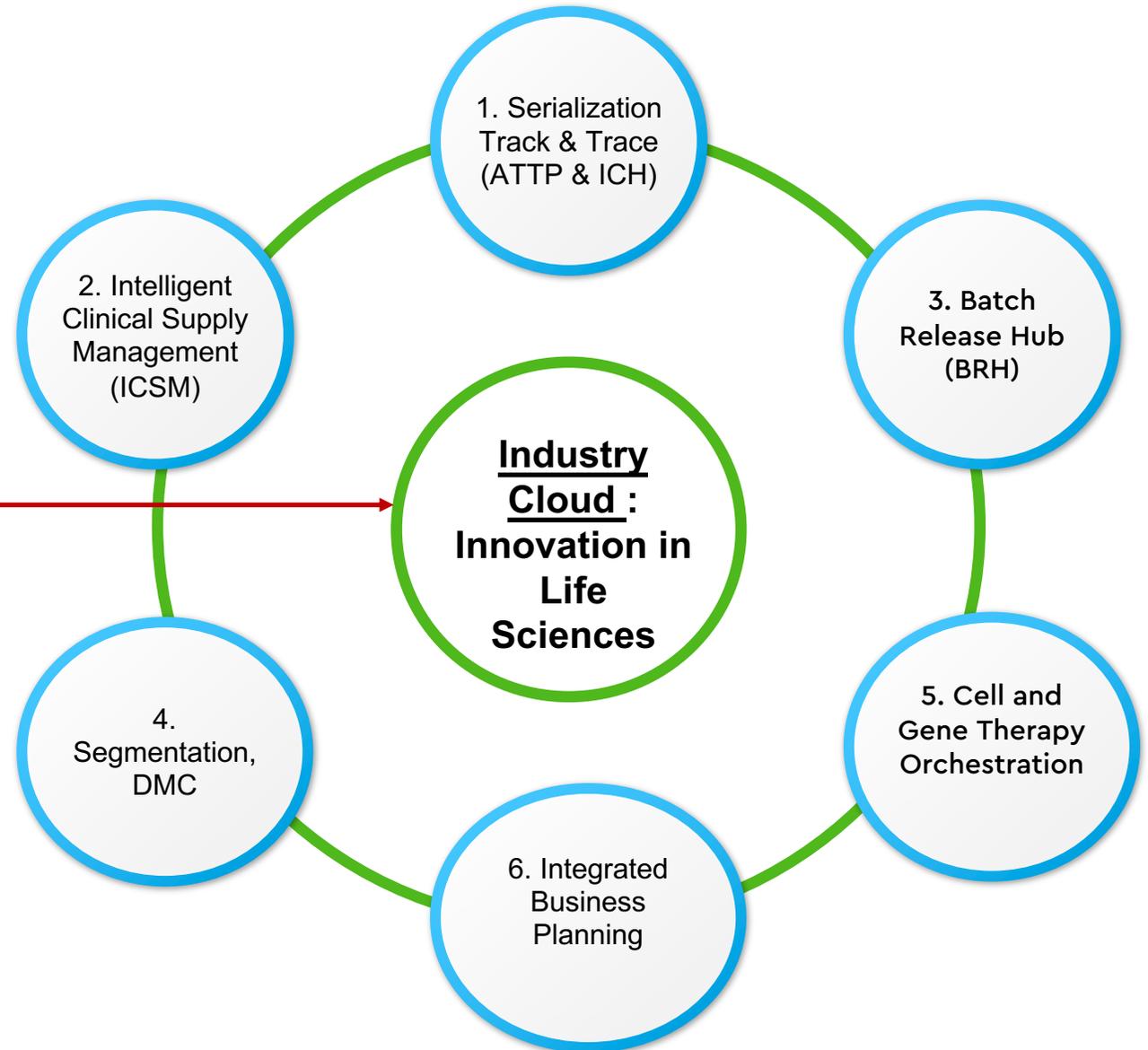
App dev

Automation

Integration

Data and analytics

AI



Some of the Key Areas where ERP is least explored



Quality Management

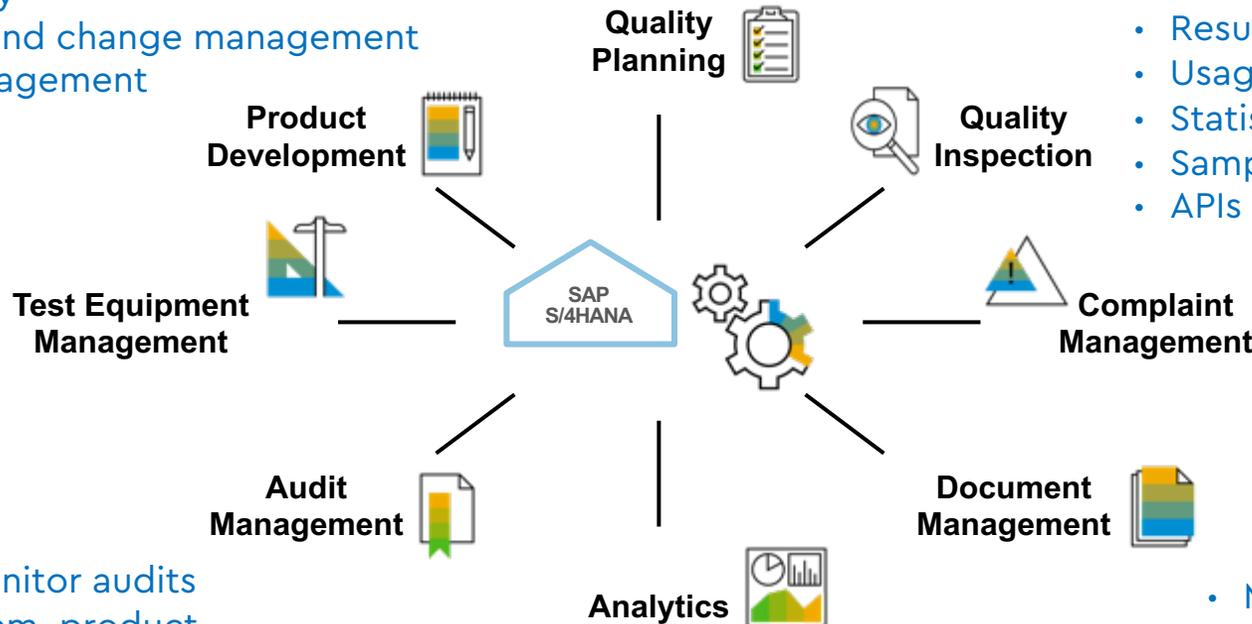
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Quality Management in SAP S/4 HANA



- Closed loop inspection planning incl. FMEA (Failure Mode and Effects Analysis) and control plan
- Stability study
- Master data and change management
- Supplier management

- Inspection plans e.g. for goods receipt
- Inspection planning within routings and master recipes for production
- Planning of procurement control
- Planning of delivery control
- Dynamic modification of inspection scope

- Plan and perform calibration inspections for test equipment



- Automatic creation of inspection lots
- Results and defect recording
- Usage decision and release of stock
- Statistical process control (SPC)
- Sample management
- APIs for integration of complex measuring systems

- Manage supplier, customer, and internal complaints
- Capture quality costs
- Record defects

- Plan, perform, and monitor audits such as supplier, system, product, and process audits

- Evaluate data from quality inspections, quality notifications, and audits

- Manage quality relevant documents by using SAP S/4HANA Document Management (DMS)



Quality Management in SAP S/4 HANA

Significant benefits for pharmaceutical company in various ways.

- Sample management (sample tracking ,scheduling)
- Workflow management
- Remote access to lab data
- Lab equipment management.
- Integration with Hand-held devices.
- Statistical process control
- Inventory management
- Quality costs management
- Quality planning (APQP, FMEA, PLP, inspection plan),
- Quality control (inspection order results recording)
- Supply Relationship Management
- Vendor release



TENTHPIN Quality Management Evolved

T/QME advances your SAP QM for life science quality assurance and control

Trends and Challenges



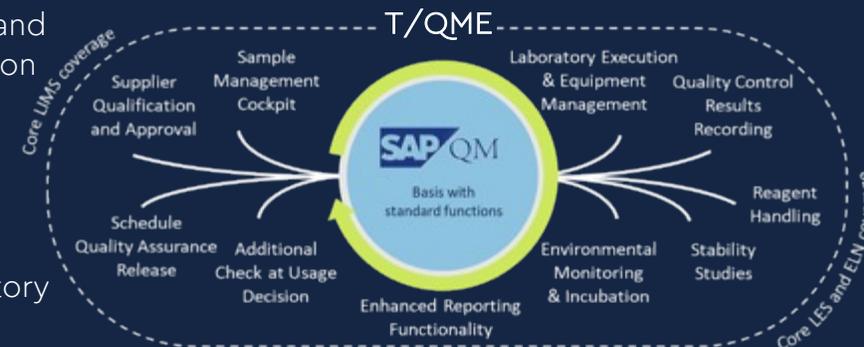
Life science companies are constantly faced with increasing legal and regulatory requirements, as well as growing customer expectations, especially with regards to quality assurance and control.



Even though SAP QM provides a large number of functions and processes, life sciences companies require more than the standard solution. Industry specific demands will not be covered by SAP QM.

TENTHPIN Quality Management Evolved

- T/QME is a pre-validated and configurable add on solution which will enrich existing SAP QM processes.
- It covers LIMS (Laboratory Information Management Systems) and LES (Laboratory Execution System) capabilities.



Innovation Partners

Technology Partner



Technology innovator and platform provider

Industry Knowledge

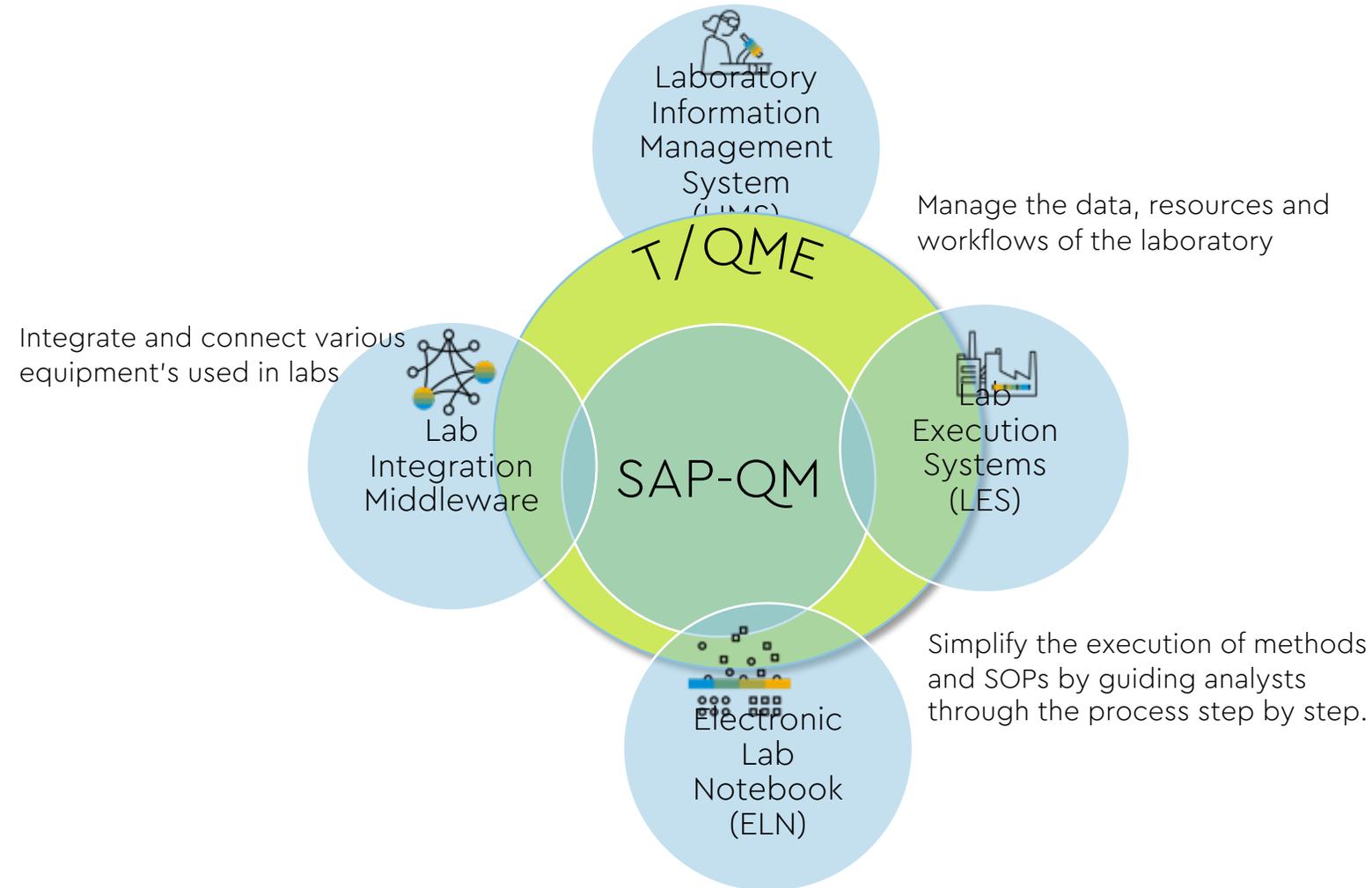
Leveraging industry expertise  Offering co-innovation partnership

T/QME is market driven, focusing on industry specific requirements

Key Benefits and Value Added

- T/QME integrates seamless into the SAP S/4 HANA platform and is therefore fully embedded in the SAP S/4 processes, creating a one-stop-shop for life science quality management.
- T/QME operates with the existing S/4 master data, avoiding data redundancy, and does not require any interfaces that increase cost and complexity of your system landscape.
- T/QME allows to leverage existing inhouse knowledge for maintenance and support by consistently utilizing the latest SAP technology such as custom Fiori.
- T/QME enables the effective execution of quality control through automating back-end processes (from sample creation to recording results) with an enhanced user interface,

Tenthpin Quality Management Evolved (T/QME)



What Tenthpin will offer with T/QME:

- Configurable add-on to SAP S/4 HANA covering the specific requirements of the industry.
- All developments are developed and performed in a dedicated namespace and will be deployed and configured in the client SAP S/4 HANA system.
- Tenthpin provides maintenance and support as well as regular releases to deliver new functionalities.

Batch Management



Batch Release Management

Challenges

Delayed Batch Release : Data collection from multiple systems takes time

High inventory carrying cost : Stock is available. But could not be released on time.

Long preparation time for Audits : Human errors for data compilation

Delayed Sales fulfilment : Potential loss of business to competition

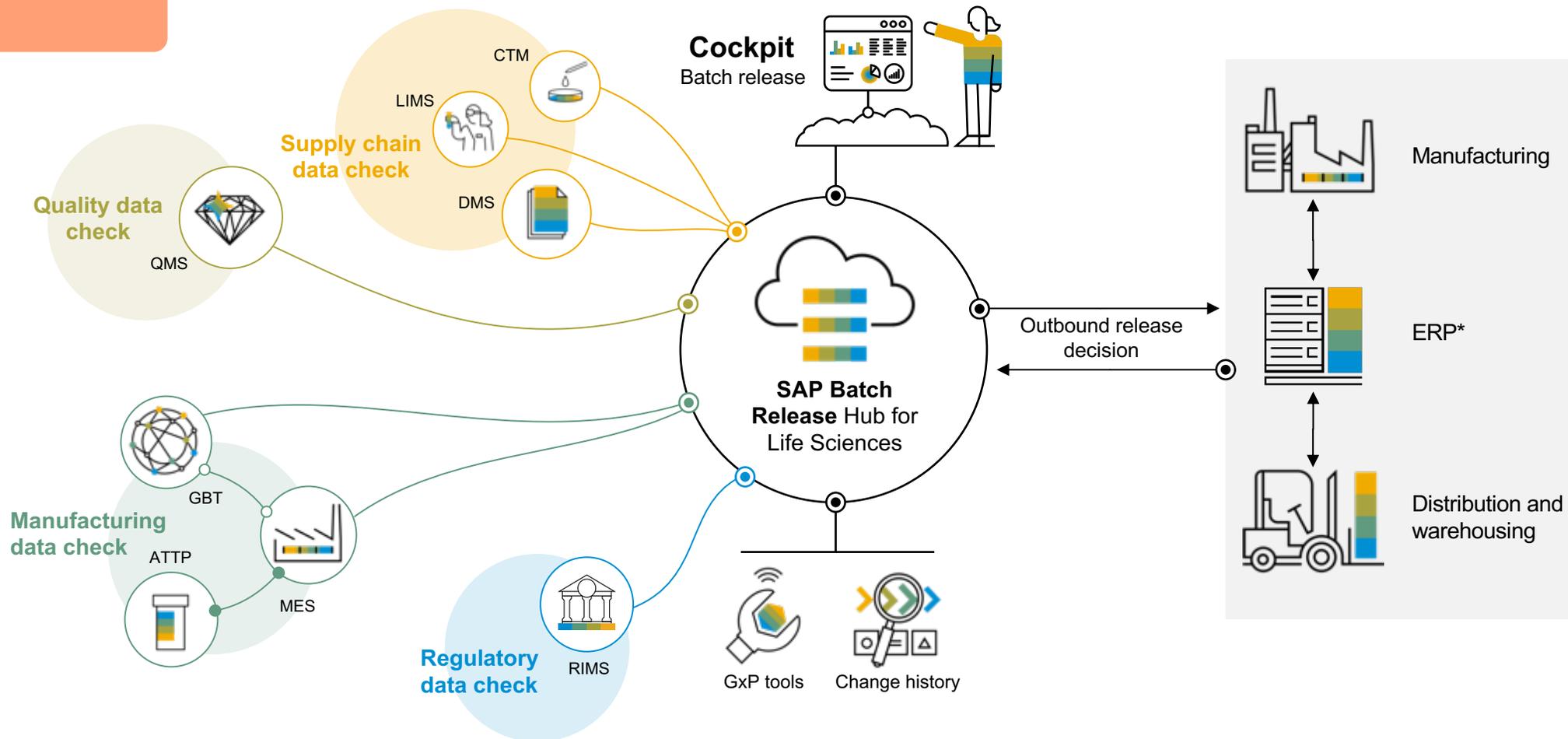
Product recalls - Loss of reputation : Long lead-times to trace batch genealogy

Over worked Quality Teams : Less Productivity and decisions prone to human errors

Technology Solution : Batch Release Hub for Life sciences

- **Optimize** and **accelerate** the batch release processes
- Increase compliance by **reducing manual effort** and the risk of human errors
- Reduce risk of product recall and protect brand reputation.
- Provide **reproducible reports** for **compliance auditors** to access release tracking history
- Enable a **harmonized overview** of relevant data from distributed systems
- Address standards and requirements for the pharmaceutical industry (GxP)
- Solution is easy to configure, easy to train and adopt changes
- Covers all release scenarios. E.g. **Technical, Market** and **Distribution release**.

Architecture overview



CTM: Clinical trial management
 LIMS: Laboratory information management system
 DMS: Document management system

QMS: Quality management system
 MES: Manufacturing execution system
 GBT: Global batch traceability

ATTP: Advanced track and trace for pharmaceuticals
 RIMS: Regulatory information management system
 ERP: Enterprise Resource Planning

*For SAP ERP and third-party ERP, SAP's open API framework together with SAP-managed or customer-managed integration options should be used subject to integration assessment.

Serialization and Track & Trace



Serialization Track and Trace

Challenges

Counterfeiting : Counter the large-scale counterfeiting/falsification of medicinal drugs

Local country regulations: Follow Strict Guidelines from various local country regulators to improve patient safety

Comply serialization Directives : Compliance to serialization directives is a MUST to retain the license to sell in regulated target markets.

Exchange Serialized Data : Serialization data exchange within complex supply chain

Technology Solution : Advanced Track and Trace for Pharmaceuticals

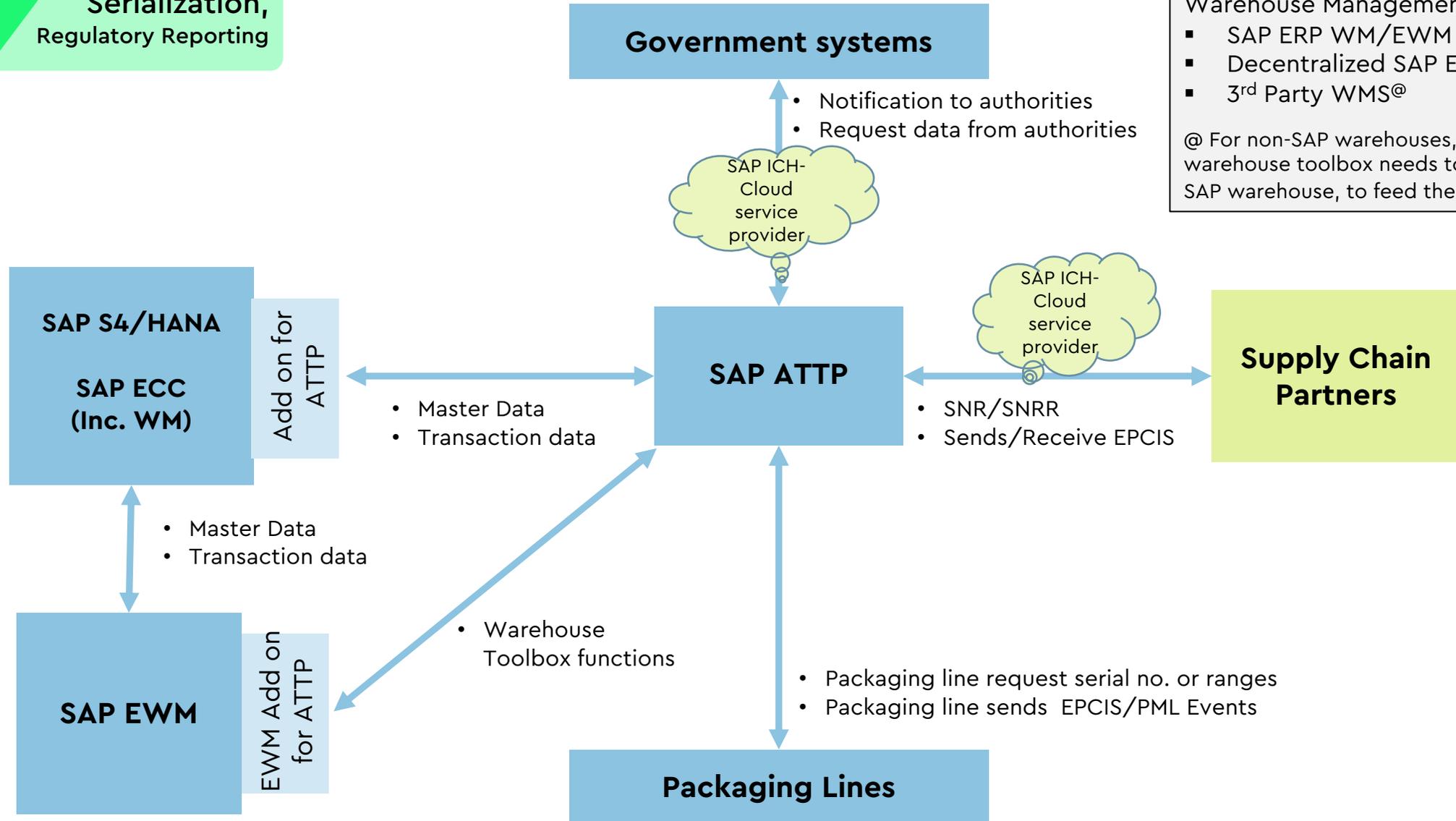
- **Corporate serialization repository & serial number management** solution with regulatory reporting interfaces and content supporting compliance to international legislation to fight falsified medicines.
- **Integration** with existing ERP and warehouse processing, packaging lines, and supply chain partners such as 3PLs and Contract Manufacturers (CMOs).
- An **Information Collaboration Hub (ICH)** for the services to connect different regulatory reporting systems around the world, collaborate with business partners to share and report regulatory information

3



Traceability,
Serialization,
Regulatory Reporting

Serialization Track and Trace



SAP ATTP offers open integration tools to any Warehouse Management solution:

- SAP ERP WM/EWM (Warehouse Toolbox)
- Decentralized SAP EWM (Warehouse Toolbox)
- 3rd Party WMS[@]

@ For non-SAP warehouses, a functionality like the warehouse toolbox needs to be developed within the non-SAP warehouse, to feed the interfaces

3



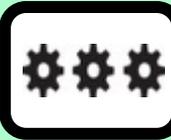
Traceability,
Serialization,
Regulatory Reporting

Serialization Track and Trace



Compliant Reporting

- Interfaces and predefined country version content for regulatory reporting
- Country versions available: Argentina, China, USA, European Union, India, South Korea, Turkey, Russia, Brazil (more planned)
- Generic rules framework as a trigger



Efficient integration with SAP ERP and S/4HANA

- Integration of trade items, locations and business partners
- Integration of batches
- Integration of documents, including outbound delivery, purchase order, inbound delivery, ...



Efficient business process integration

- Integrate with ERP transactions, warehouse management systems, and packaging lines
- Warehouse integration toolkit for integration to ERP Logistics Execution System WMS
- Warehouse integration toolkit for integration with SAP EWM



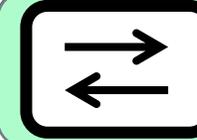
Global Serialization repository

- Generic EPCIS foundation
- Capture EPCIS or PML events
- View master data, object data, event data and serial number management within one central cockpit view
- Supports GS1 standards: core elements of EPCIS 1.2, core business vocabulary,...



Manage Global Number Pools

- Comprehensive serial number management solution
- Manage ranges or individual serial numbers
- Built-in serial number randomizer
- Request, retrieve and distribute crypto codes from order management stations



Track & Trace

- Serialized trade items, lots, events, business transaction documents
- Display object hierarchies (aggregation)
- Government and business partner reporting messages
- Authentication of objects

Supply Chain Calibration through Integrated Business Planning

Calibrating the Supply Chain

Challenges

Uncertain supply of Critical Material: Long lead time of API, Bulks etc. Supplier dependency.

Demand Volatility for goods and services: Manage constant change in demand across geographies. Capture forecast for new products and forecast accuracy.

Constraint capacity in manufacturing & Logistics : Transportation and internal factory/CMO disruptions

Inventory Oversteering : Multiple departments planning in isolation intensifying the bullwhip

Human Risk of balancing labour shortages and health safety of employees : Mid to long term view of manpower for overall demand

Technology Solution - Integrated Business Planning for supply chain

Sales & Operations planning - Create optimum business plan for mid to long term horizon by Demand/Supply balancing with Financial alignment/commitment

Demand Planning - Automate the (statistical) forecasting process, sense & react faster to short term demand changes with pattern recognition-based algorithms

Response and Supply - Tactical (rough cut) as well as operational supply planning, Constrained cost-based optimization and distribution planning.

Inventory Management - Maximize the efficiency of inventory and working capital, Improve customer service levels

Cross-application Integration - Connect every process within your supply chain and across your business for faster planning cycles

Intelligent Clinical Supply Management - ICSM

Intelligent Clinical Supply Management - ICSM

Challenges

Clinical Trials : Increase in number of clinical trials, Smaller and shorter trials, complex trial designs

User Experience : Sites and Patients seeking better user experience

Drug Development : Increased speed of Drug Development

Interaction with third party systems : Tighter interaction is needed

Tracking and multiple stakeholders/technology : Need for end-to-end tracking and visibility, manage multiple stakeholders and technology providers

Technology Solution – Intelligent Clinical Supply Management

- Enables blinding and randomization for clinical trials
- Infuses clinical trial parameters as well as enrollment rates into the supply and demand planning processes
- Supports new types of clinical trials and medicine
- Provides full visibility into global supply status, enabling a supplier network for stakeholders in the clinical trials process
- Proactively avoids shortages or waste when enrollment is faster or slower than expected

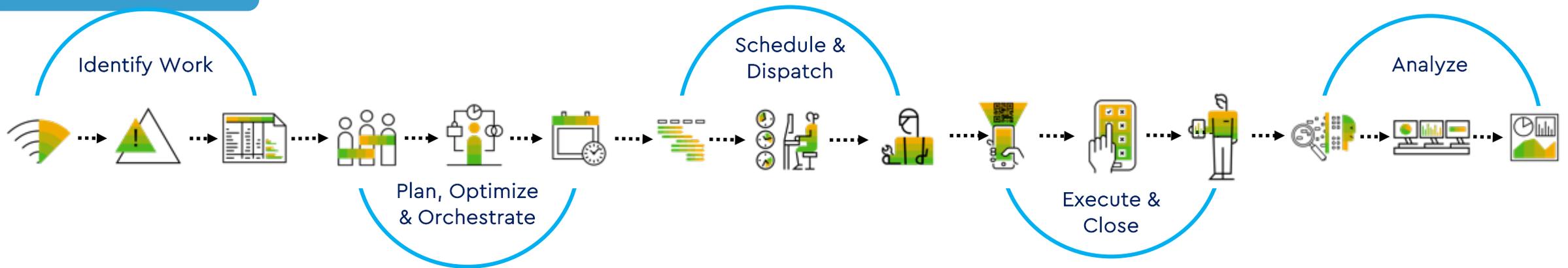


Asset Management & Maintenance

6

Intelligent Asset Management

Intelligent Asset Management End-to-End Capabilities



Sustainability

How is maintenance work generated?

How do you prioritise and prepare work packages and monitor order readiness?

How do you manage capacity, utilization & optimize resources?

How do you perform work quickly, correctly and safely?

How can we continuously improve maintenance strategies, costs, and equipment uptime?

- ✓ Reactive Maintenance
- ✓ Proactive Maintenance
- ✓ Improvement Maintenance
- ✓ Operational and Overhead Maintenance
- ✓ Condition Monitoring
- ✓ IoT/Predictive Monitoring

- ✓ Maintenance Process Phases
- ✓ Screen Maintenance Request and Backlog
- ✓ Risk Based Event Prioritization
- ✓ Group work based on scope or time
- ✓ Approval and Preparation

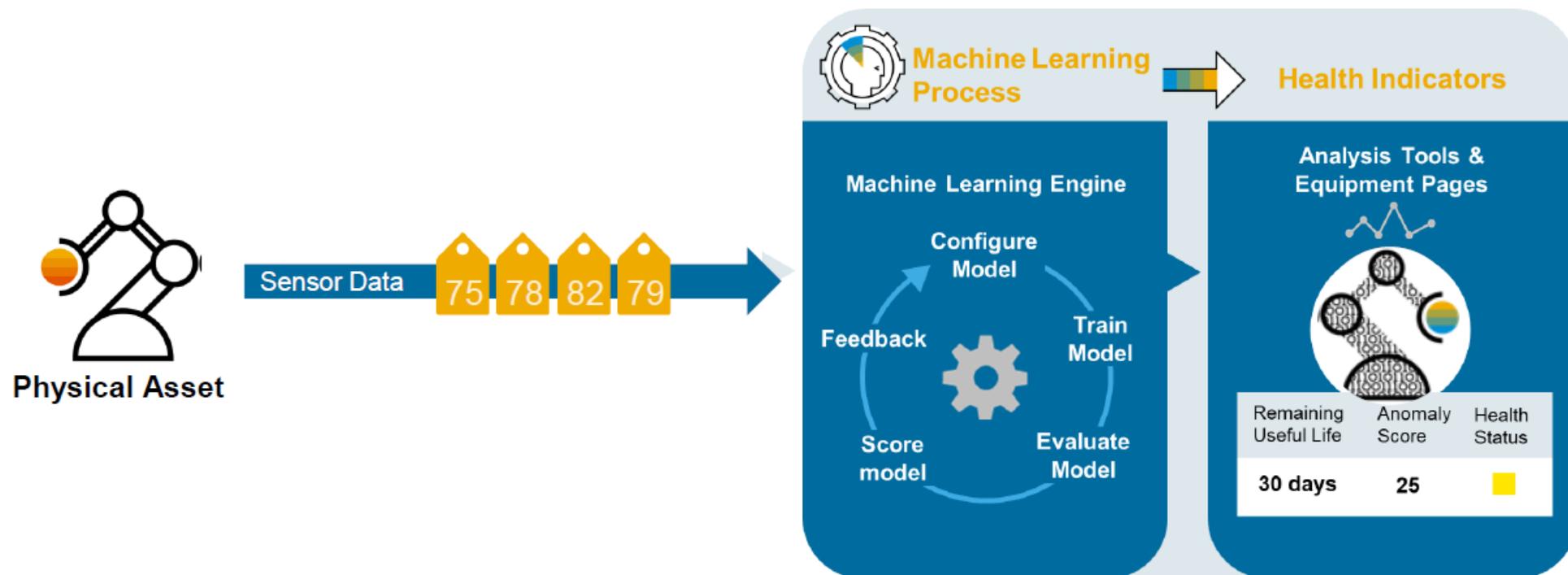
- ✓ Manage Work center utilization
- ✓ Maintain Flexible Schedule periods
- ✓ Monitor non-working times
- ✓ Must-Start on constraints and last acceptable completion
- ✓ Share and collaborate schedules
- ✓ Monitor Schedules

- ✓ Process all work types
- ✓ Leverage work instructions
- ✓ Capture work history, failure modes, labor time and materials consumed
- ✓ Work Permits
- ✓ Mobile enabled process for Offline execution

- ✓ Analyse MTTR and MTBF
- ✓ Identify Bad actors and common failures
- ✓ Monitor costs-baseline, planned and actual across work

Predictive Maintenance & Service

Leverage real-time operational data from asset sensors and apply machine learning to **detect emerging issues, analyze root causes and predict future performance.**



Create a sustainable world together

SAP Cloud for Sustainable Enterprises

Holistic Steering and Reporting



Combine, connect and link financial and non-financial views metrics into one holistic reporting. Embedded, validated, real-time data to effectively understand, analyze, and guide compliance, reporting & opportunities



Zero Emissions with **Climate Action**

Manage environmental footprint including compliance, regulations & carbon-trading



Zero Waste with **Circular Economy**

Redefine design, production, demand and supply of products through their use cycles for reusability, waste reduction and new value creation



Zero Inequality with **Social Responsibility**

Safeguard social responsibility across workforce, sourcing, and procurement to enable equality and social equity

Industry Relevance

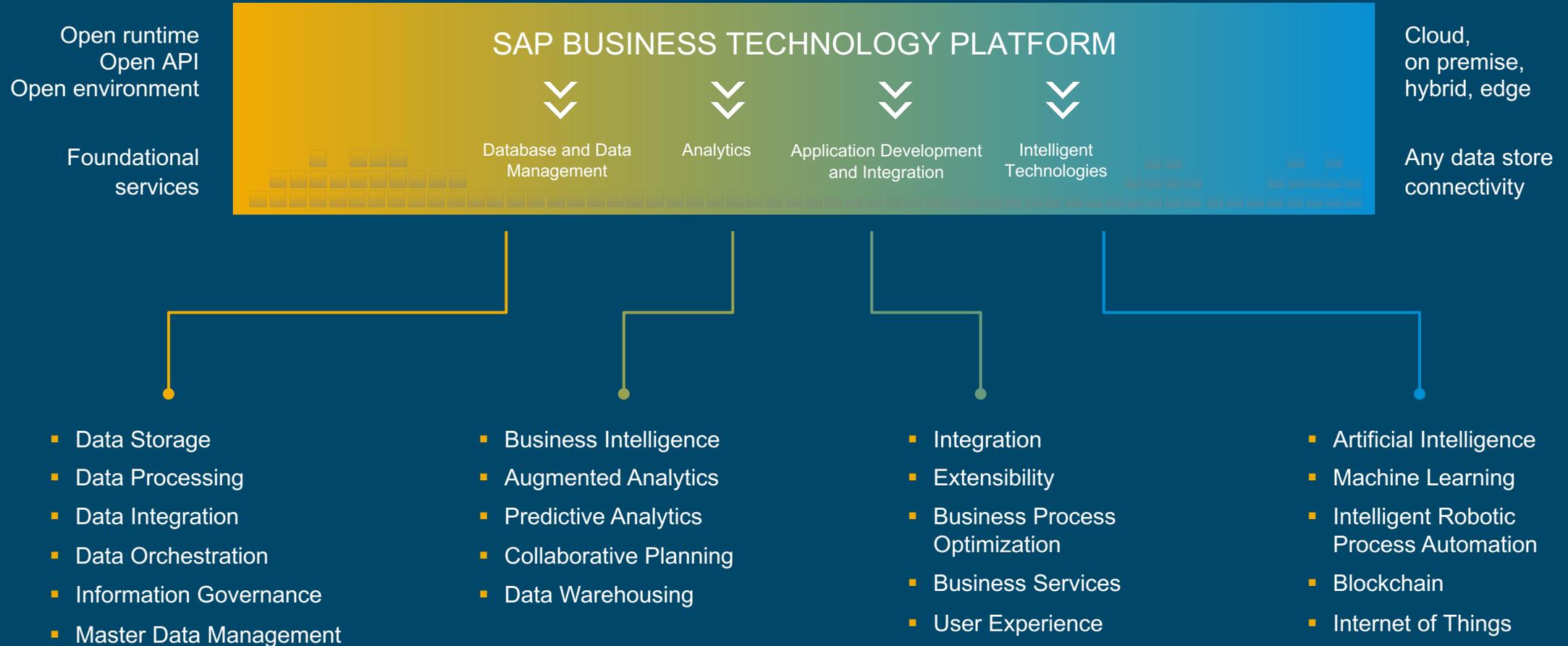
Generate additional value by incorporating industry-specific solutions from across our Partner Ecosystem and Industry Cloud

How SAP Solutions help with Organizational Sustainability goals ?

	EHS Environment Management	Measure, track, monitor, and report air, water and waste emissions
	EHS Incident Management	Detect and resolve safety issues and learn from incidents
	EHS Health and Safety	Proactively identify, analyze, and mitigate EHS risks
	Management of Change	Manage operational changes with systematic reviews, risk mitigation, and approvals
	Maintenance Safety	Control maintenance work through clearly defined safety instructions and permits
	Sustainability Control Tower	Obtain Automated, timely and auditable data on KPIs such as GHG*, D&I*, share of SRIs*, water, corruption, human rights; reporting along industry standards
	Product Compliance	Manage Global Product Safety and Compliance Throughout the Product Lifecycle
	Responsible Design and Production	Manage Extended Producer Responsibility obligations and plastic taxes
		<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="background-color: #808080; color: white; padding: 5px; font-size: 0.8em;">Asset Management</div> <div style="background-color: #808080; color: white; padding: 5px; font-size: 0.8em;">Human Resources</div> <div style="background-color: #808080; color: white; padding: 5px; font-size: 0.8em;">Contractor Management</div> <div style="background-color: #808080; color: white; padding: 5px; font-size: 0.8em;">Implementation Add-ons</div> </div>



SAP BTP, the Platform for the Intelligent Enterprise



Tenthpin : Packaged Implementation Services

- SAP QM Packaged Implementation Service
- SAP ATTP Packaged implementation service
- SAP EWM & TM Packaged implementation service
- IBP Packaged Implementation Service
- GBT Packaged Implementation Service
- BRH Packaged Implementation Service
- ICSM Packaged Implementation Service
- CGTO Packaged Implementation Service
- BTP Packaged Implementation Service
- Solman/Signavio Packaged Implementation Service

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