Harnessing ERP for enhanced compliance

Session By

Raghuram Janapareddy
Partner & Managing Director India
Tenthpin Management Consultants
Harnessing ERP for enhanced compliance

IPA Conference
04 Oct 2023

Raghuram Janapareddy
Managing Director - India
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
- 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
- SAP Intelligent Clinical Supply Management (ICSM)
- SAP Cell & Gene Treatment Orchestration (CGTO)
- SAP Batch Release Hub (BRH)

Value Chain Optimization
- 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
- Digital Strategy Advisory & Digital Transformation Support
- Business Value Discovery
- Automation (RPA) and Artificial Intelligence (AI)
- Enterprise Data Management

Transformation Management
- Post-Merger Integration and Divestment Management
- Program/Project Management and Quality Assurance
- Organizational Change Management & Communications

Tenthpin Solutions
- 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

- SAP S/4 HANA Implementations
- Public Cloud, Private Cloud, On Prem
- Implementation of Specialized skills ATTP, GBT, IBP, EHS, TM, EWM
- BPML, RPA, Analytics, Integration services, Business Process Modelling
- Migration, Upgrade Services and Carve Out projects
- Application Management Services for general and specialized skills

Co-Innovation Portfolio. Developed ICSM, BRH, CGTO on BTP

Copyright © 2023
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 Tenthpin.
Changing Regulatory Environment
Status Quo in Life Sciences is being disrupted

Indian Context

1. Complex Global Supply Chains
2. Shrinking R&D Timelines
3. Price Regulations impacting profitability
4. Drug Traceability is impending
5. Stringent Documentation Requirements

New Challenges require ...
...new Core Capabilities
The Supply Chain is becoming more networked

CMOs

Complex Markets

Design

Suppliers

Plan

R&D

Quality

Regulatory

Manuf.

Warehousing

Logistics

Operations

Customers

Cost + Quality + Compliance

Market Share + Patient Centricity + Reputation
Supply Chains are now networked Value 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

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

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

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

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

Recipe Development & PLM
- Gather patient feedback to leverage experience data
- Develop recipe formula & generate BOM
- Product Lifecycle Costing
- 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.

Recipe Development & PLM
- Gather patient feedback to leverage experience data
- Develop recipe formula & generate BOM
- Product Lifecycle Costing
- 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.

Recipe Development & PLM
- Gather patient feedback to leverage experience data
- Develop recipe formula & generate BOM
- Product Lifecycle Costing
- 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.

Recipe Development & PLM
- Gather patient feedback to leverage experience data
- Develop recipe formula & generate BOM
- Product Lifecycle Costing
- 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.

Recipe Development & PLM
- Gather patient feedback to leverage experience data
- Develop recipe formula & generate BOM
- Product Lifecycle Costing
- 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.
ERP is at the Core - But there is more
Some of the Key Areas where ERP is least explored

- Quality
- Planning
- R&D
- Traceability
- Batch Management
- Plant Maintenance

GxP compliant solutions
Quality Management
• Closed loop inspection planning incl. FMEA (Failure Mode and Effects Analysis) and control plan
• Stability study
• Master data and change management
• Supplier management

• Plan and perform calibration inspections for test equipment

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

• 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

• 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

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

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

SAP Quality Management (QM)

- Compliance with Regulatory Requirements
- Batch Management
- Document Management
- Real-time Analytics and Reporting
- Quality Auditing
- Laboratory Information Management
- Supplier Quality Management
- Quality Notifications and Deviations

Copyright © 2023
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.

T/QME integrates seamlessly 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 backend processes (from sample creation to recording results) with an enhanced user interface.

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.

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

T/QME is a technology innovator and platform provider.
Tenthpin Quality Management Evolved (T/QME)

Manage the data, resources and workflows of the laboratory

Integrate and connect various equipment's used in labs

Simplify the execution of methods and SOPs by guiding analysts through the process step by step.

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.
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.
### 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

#### 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, ...

#### 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

#### 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
Intelligent Asset Management
End-to-End Capabilities

Identify Work
- 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

Plan, Optimize & Orchestrate
- Analyse MTTR and MTBF
- Identify Bad actors and common failures
- Monitor costs - baseline, planned and actual across work

Schedule & Dispatch
- Reactive Maintenance
- Proactive Maintenance
- Improvement Maintenance
- Operational and Overhead Maintenance
- Condition Monitoring
- IoT/Predictive Monitoring

Execute & Close
- 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

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?
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?

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHS Environment Management</td>
<td>Measure, track, monitor, and report air, water and waste emissions</td>
</tr>
<tr>
<td>EHS Incident Management</td>
<td>Detect and resolve safety issues and learn from incidents</td>
</tr>
<tr>
<td>EHS Health and Safety</td>
<td>Proactively identify, analyze, and mitigate EHS risks</td>
</tr>
<tr>
<td>Management of Change</td>
<td>Manage operational changes with systematic reviews, risk mitigation, and approvals</td>
</tr>
<tr>
<td>Maintenance Safety</td>
<td>Control maintenance work through clearly defined safety instructions and permits</td>
</tr>
<tr>
<td>Sustainability Control Tower</td>
<td>Obtain Automated, timely and auditable data on KPIs such as GHG*, D&amp;I*, share of SRIs*, water, corruption, human rights; reporting along industry standards</td>
</tr>
<tr>
<td>Product Compliance</td>
<td>Manage Global Product Safety and Compliance Throughout the Product Lifecycle</td>
</tr>
<tr>
<td>Responsible Design and Production</td>
<td>Manage Extended Producer Responsibility obligations and plastic taxes</td>
</tr>
</tbody>
</table>

*GHG: Greenhouse gas, D&I: Diversity & Inclusion, SRIs: Sustainability-related indicators
SAP BTP, the Platform for the Intelligent Enterprise

SAP BUSINESS TECHNOLOGY PLATFORM

- Database and Data Management
- Analytics
- Application Development and Integration
- Intelligent Technologies

- Open runtime
- Open API
- Open environment

- Foundational services
- Cloud, on premise, hybrid, edge
- Any data store connectivity

- Data Storage
- Data Processing
- Data Integration
- Data Orchestration
- Information Governance
- Master Data Management
- Business Intelligence
- Augmented Analytics
- Predictive Analytics
- Collaborative Planning
- Data Warehousing
- Integration
- Extensibility
- Business Process Optimization
- Business Services
- User Experience
- Artificial Intelligence
- Machine Learning
- Intelligent Robotic Process Automation
- Blockchain
- Internet of Things

© 2021 SAP SE or an SAP affiliate company. All rights reserved. | CUSTOMER
Tenthipin : 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
Contact us at

Raghuram Janapareddy
Managing Director India
raghuram.Janapareddy@Tenthpin.com
Mob: +91 98440 37404

Legal Disclaimer
All data, information, statements, photographs, and graphic illustrations contained in this presentation are without any obligation to the publisher and raise no liabilities to Tenthpin Management Consultants or any affiliated companies, nor shall the contents in this presentation form part of any contracts, which may be concluded between Tenthpin Management Consultants companies and others referred to herein.

© Tenthpin Management Consultants 2023. All rights reserved. No part of this copyrighted work may be reproduced, modified or distributed in any form or by any means, or stored in any database or retrieval system, without the prior written permission of Tenthpin Management Consultants or its affiliates. Any such unauthorized use for any purpose is a violation of the relevant copyright laws
Back Up
Slides