DIGITAL TRANSFORMATION, COMPLIANCE, INTEGRATION OF LEGACY SYSTEMS

CHALLENGE

The client operates across multiple systems for Quality Management (QMS), Document Management (DMS), and Laboratory Information Management (LIMS).

These systems, while efficient in their silos, lacked seamless integration, resulting in:

- Inefficient data and document flow between platforms.
- Manual interventions, increasing errors and delays.
- Compliance risks due to fragmented data visibility.
- Siloed decision-making, reducing agility in business operations.

Key Systems Involved:

- QMS: TrackWise (On-Premise)
- DMS: Documentum D2LSQM
- LIMS: Labware

SOLUTION

1. Integration Framework Design

- Conducted a comprehensive requirement assessment to understand data flow patterns, dependencies, and compliance mandates.
- Designed an integration architecture ensuring secure, bi-directional data flow between TrackWise, Documentum, and Labware.
- Enabled metadata synchronization across systems to ensure consistency.

2. Subject Matter Expertise (SME) Deployment

- Deployed Pharma SMEs specializing in compliance requirements, regulatory standards, and system workflows.
- Facilitated stakeholder workshops to map key use cases and integration pain points.

3. API-First Integration Approach

- Developed custom APIs to bridge communication gaps between on-premise QMS, DMS, and LIMS.
- Ensured real-time data synchronization and minimized manual interventions.

4. Automation and RPA Implementation

- Automated document flow processes using RPA tools.
- Reduced repetitive manual tasks, including data entry, approval workflows, and compliance audits.

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SOLUTION

5. Advanced Analytics Dashboard
- Built Power BI dashboards offering:
- Real-time visibility into quality processes.
- Compliance tracking across workflows.
- Predictive analytics for process optimization.

6. Compliance-First Approach
- Integrated regulatory compliance monitoring tools into workflows.
- Ensured adherence to FDA 21 CFR Part 11, HIPAA, and GxP standards.

7. Application Development for Enhanced Usability
- Developed custom mobile and web applications to enable remote access to quality and document systems.
- Improved operational efficiency for field teams and lab operators.

IMPACT

✅ **Seamless Integration Across QMS, DMS, and LIMS:**
- 100% data flow automation across systems.
- Elimination of manual interventions in document transfers.

✅ **Enhanced Compliance:**
- Automated compliance checks at every integration stage.
- 40% reduction in compliance audit timelines.

✅ **Operational Efficiency:**
- 50% reduction in manual document management tasks.
- Real-time insights enabled faster decision-making.

✅ **Improved Data Visibility:**
- Real-time Power BI dashboards improved monitoring and tracking across processes.
- Single source of truth for all quality and compliance data.

✅ **Scalable Architecture:**
- Flexible architecture supporting future system upgrades and third-party integrations.

✅ **Cost Optimization:**
- 30% reduction in operational costs due to process automation.