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EMPOWERING EFFICIENCY

Achieving benefits of IDMP-ready holistic RIM

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Implementation of holistic RIM is an achievement

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Satappa Kambale working in the capacity of Manager, Regulatory and Business Continuity at SUN Pharmaceutical Industries Limited, Mumbai, India.

I’m having 16 years of rich experience in regulatory affairs operations with a strong professional skill in electronic submissions, world-wide regulatory requirements for APIs and medicinal products, regulatory information management system, publishing , document management, software implementation and digital transformation.

01

SUN Pharma briefly

Leading global specialty generic company*

Global presence	• Operates in over 100 countries
Diversified business	• Specialty products, branded generics, generics & APIs
Global Specialty	• Focused therapy approach, commercial infrastructure in key markets
US Generics	• 9th largest in US generics market##
India	• Largest pharma company in India**
Emerging Markets	• Scaled up operations in over 80 countries
Rest of World	• Expanding presence in Ex-US developed markets
Manufacturing footprint	• 43 manufacturing sites across the world
Quality compliance	• Several facilities approved by global regulators incl. USFDA
R&D and Manufacturing	• Global clinical trial expertise. Generic capabilities across injectables, sprays, ointments, creams, liquids, tablets and capsules
Employees	• 38,000+ global employee base

*Source: Evaluate Pharma Estimates for 12 months ended Dec 2021 ## Source: IQVIA data for 12 months ended Dec 2022 ** As per AIOCD AWACS data for 12 months ended Dec 2022

02

Problem Statement

Regulatory Challenges

Problem Statement

- Managing Regulatory information is a complex operation especially when supporting many global markets and everyday events such as manufacturing change or health authority requests, which triggers waves of necessary activities, as you assess impacts, submit updates, and ensure affected regions remain in compliance.

- Each step is made harder by the fragmented nature of legacy regulatory systems.

Common real-life example

Let's look at a typical process like **a product-related change**.

- We conduct a regulatory impact assessment by checking registration tracking system, requesting information from affiliates and following up with calls or emails. Next, we aggregate the information in our project tracker and add placeholders in our submission schedule.

- Then we manage submission authoring and reviews in a separate system and export the submission content to another system for publishing. After dispatching the submission to health authorities, we need to update trackers with each response.

- Finally, we store the completed dossier with thousands of others in a separate repository or file share.

Some Observations

With planning, execution and tracking in separate, disjoined systems, compliance is challenging, and end-to-end visibility is nearly impossible.

In addition, we will face soon an important transition from the current XVEMPD transmission of data to the new ISO IDMP data standard. This is going to add complexity increasing the amount of data to be collected, managed and transmitted and it will have an important impact on the internal procedures.

03

The Solution

Visualize the benefits of the solution

The Solution

In this scenario the regulatory information management system will be even more important with the core capabilities like …

Manage **submission relevant content and documentation**

Create, **compile** and **publish submissions** throughout the entire product life cycle

Regulatory planning and tracking on global and local level throughout the entire product life cycle

Meet XEVMPD and be ready for **IDMP data submission** requirements

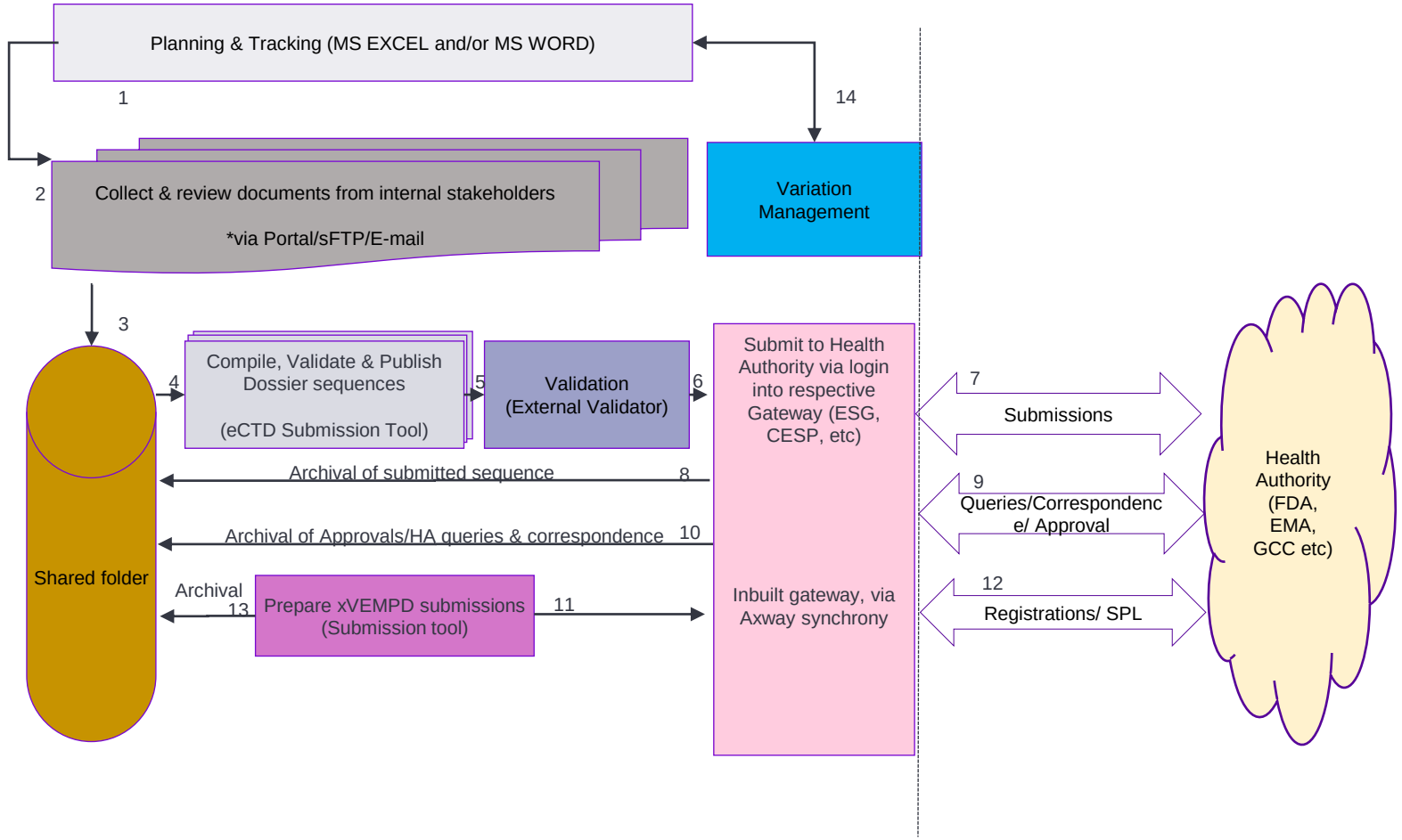
Surface the data with interactive **dashboards** and **reports**

04

Core Capabilities

What's in the holistic RIMS for SunPharma

Process Flow of RA Applications before RIMS Implementation



Challanges V/s Amplexor's Solution

Challenges	Amplexor-RIMS Capabilities	Benefits
Initial Marketing Authorization		
• Dossier document creation and versioning at a non-controlled IT environment.	• Advanced DMS module (R&DExpert) will help document import, creation and classification based on predefined document profile, types and support for templates, predefined workflows, roles, permissions and lifecycles providing controlled IT environment with no possibility of information missing.	• Removes duplicity • Easy availability of validated document
• Dossiers for extension to other markets are created individually by different teams which delays delivery and increases correction phase.	• Possibility to create customizable master dossier which we can split based on predefined rules and create country specific submissions.	• Reduces errors • Productivity
• Dossiers are created offline, need switching between IT systems (fileshare and publishing tool).	• Dossier creation in single interface (SubmissionExpert) within predefined submission structure with simple drag and drop from DMS.	• Compliance • Less time for compilation
• No dedicated tool for recording, reposition, tracking of Health Authority Q&As.	• Automated tracking of timelines with alerts. • RIMExpert will help to track correspondence, HA Q&As, commitments, regulatory decisions.	• Regulatory Intelligence

Challenges	Amplexor-RIMS Capabilities	Benefits
Business Continuity (LCM)		
• Difficult to retrieve information about actual marketing authorization status and associated documentation for Impact assessment. (ex. API Change, Nitrosamine assessment etc...)	• Registration records are created automatically based on regulatory activity (e.g., query response, variation, renewal)	• Easy availability of validated document • Expedite assessment
• No IT tool to track recurring re-registrations, annual renewals and reports.	• Reminders are automatically created based on the due dates that are entered.	• Compliance
Archival		
• No centralized repository across sites/countries. • Access of file servers, sharepoint, Laserfiche to review documents.	• All submission document and data stored and archived in a controlled repository with defined user access permissions. • Advanced search within document for easy review.	• Compliance

Challenges	Amplexor-RIMS Capabilities	Benefits
Reports		
• Different nomenclatures (names, identifier, values) usage leads to conflicts in data collation and high effort in manual re-entering of information for data reporting and Configuration	• IDMP compliant data model with flexible granularity • Data management automation as part of the end-to-end RIM • Embedded XEVPRM creation and EMA gateway communication • History and record tracking of medicinal product information	• Single source of truth, no additional Verifications
• No live status which any user can view as and when required	• Analytics view with predefined configurable reports	• 24x7 status across organization, • operational efficiency

05

CONCLUSION

Implementation of holistic RIM is an achievement

By implementing of Holistic RIM, we are going to achieve potential benefits from a unified approach that includes...

- Faster time to approval
- More efficient use of data, authoring and submissions.
- Better planning and tracking
- Improved HA interactions
- Operational oversights
- Compliant product release
- IDMP Compliance

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THANK YOU!