

Introduction



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Agenda

01 Business Problem

02 Solution - Digital Shelf

03 Design History File (DHF) Use case

04 North Star



Every Critical Business Process in MedTech Generates Documents - But Insights remain unlocked

Processes

Documents

Systems



New product Introduction

*Design Inputs
DHFs
Risk Assessments*



Clinical and product trails

*Protocols
Validation Reports
Test Results*



Product change requests

*Change Orders
Impact Assessments*



Packaging and Labelling

*Artwork Specs
Regulatory Submissions*



Post-Market Surveillance

*Complaints
CAPA reports*



PLM



QMS



Labelling System



PIM

Information is scattered and Disconnected



Information is siloed across systems and formats



No unified view to connect related insights across R&D, Quality, Regulatory, and Manufacturing



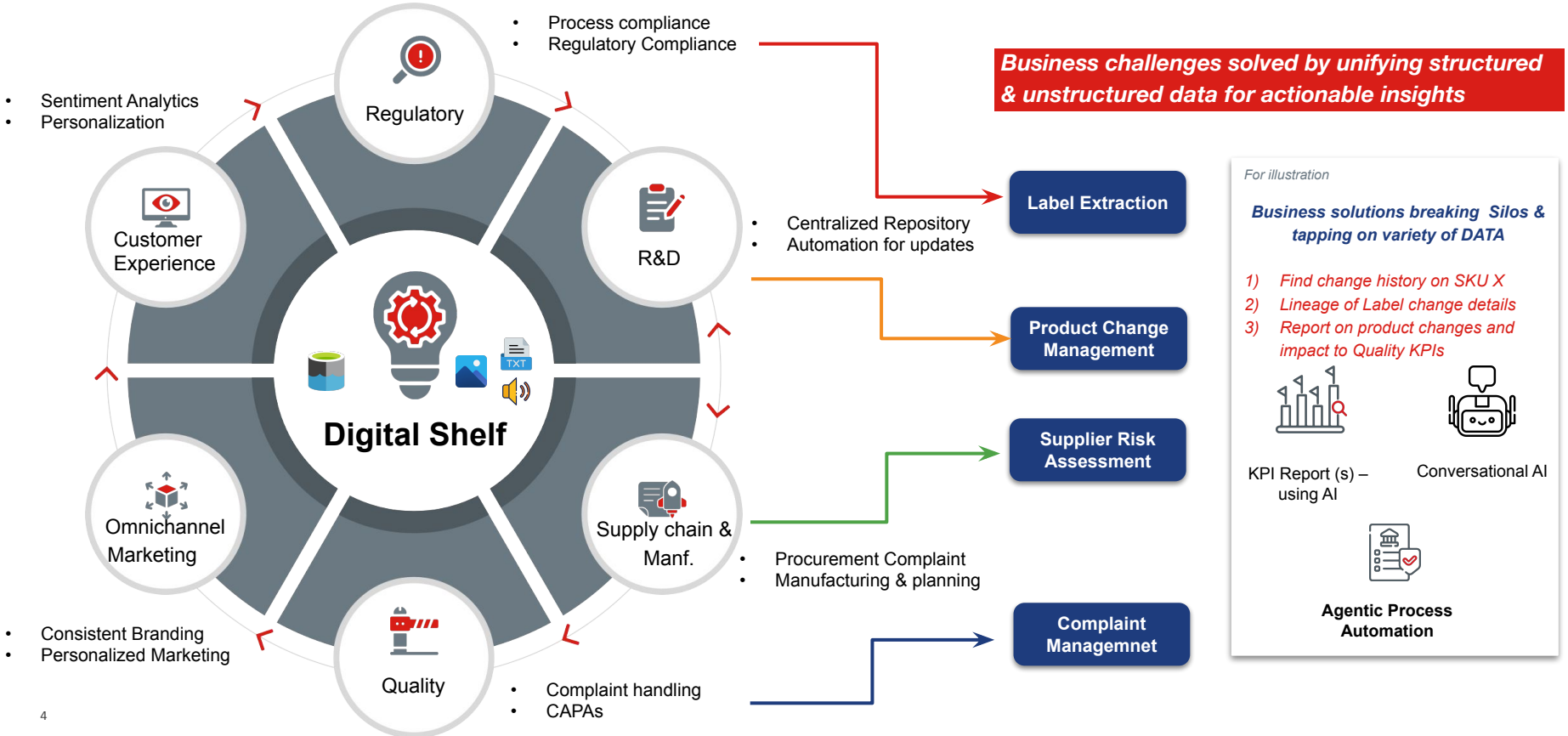
Teams spend time searching rather than analyzing



Knowledge is recreated instead of reused

Result: Vast knowledge is trapped in documents - limiting visibility, slowing decisions, and constraining innovation.

Enterprise Digital Shelf to unlock the insights from the documents created in the process



Finding Efficiencies in Product Information Management



Solution components



Seamless Data Integration to Unlock Enterprise Value

- Allowing **integration of structured & unstructured data** from key source systems such as SAP which unlocks critical business use cases for R&D, Supply chain, marketing.



Bespoke Conversational AI

- Agentic bot that understands **MedTech context** answering question in multiple categories.
- **Low effort scalable solution** to other Bus.
- High search relevancy with **90 – 95% accurate answers.**



Background & Objective

Background

- A change request for any SKU requires Planning, Development, Design transfer & release steps.
- Multiple documents need to be read & analyzed to get consolidated information.
- These are a series of complex & time-consuming tasks for R&D

Key Objective

- This project aims to make this entire process **seamless & efficient**, resulting in 30-40% faster execution for any change request project.
- The solution helps create foundation that can serve multiple similar uses cases such as contract analytics, pricing etc.

Solution features developed to solve the problem areas identified



Search



Summarization



Linkages



Immediate Business Impact

Scalable

Scaled the solution across all **BUs and Regions**

Optimized close to **150 projects** per year

Overall Improvement

19% Efficiency gain

4 New Projects Each Year



Business value



Significant Time Savings

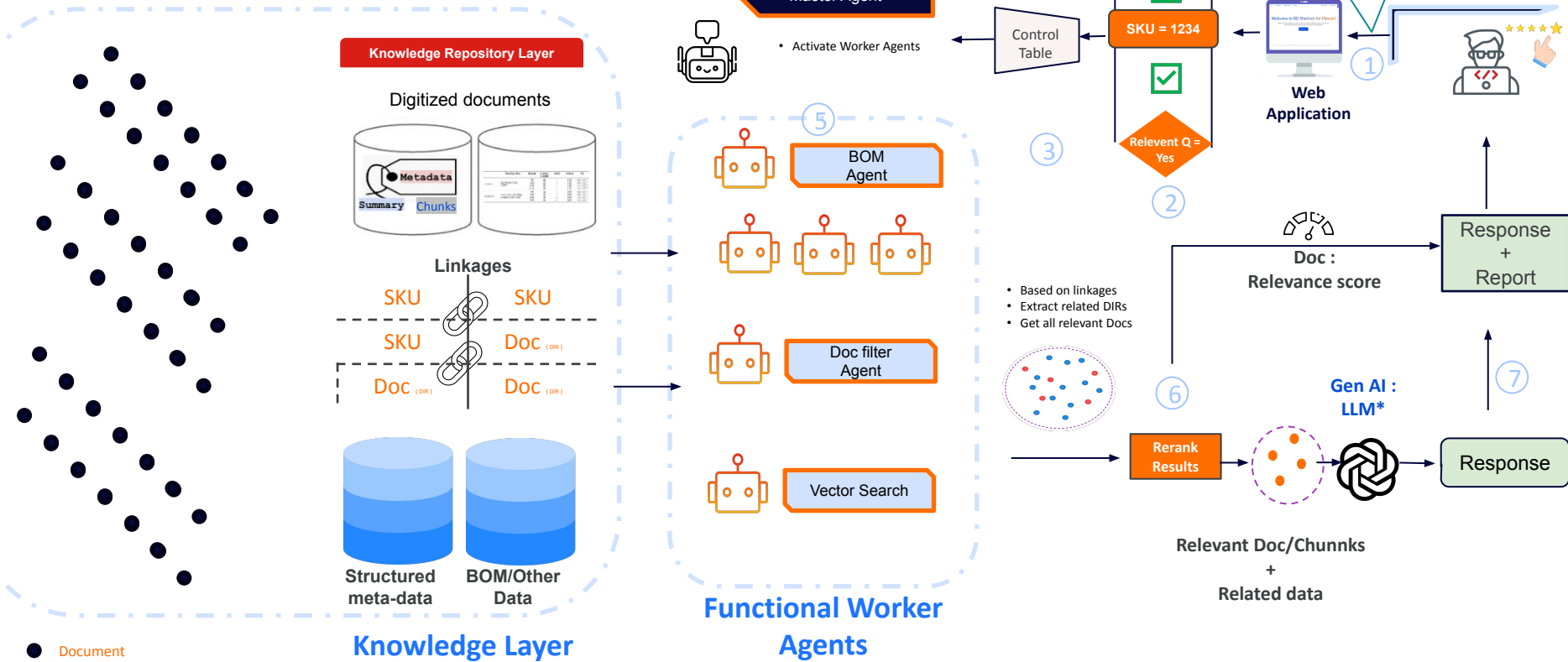


Accelerated Planning & start



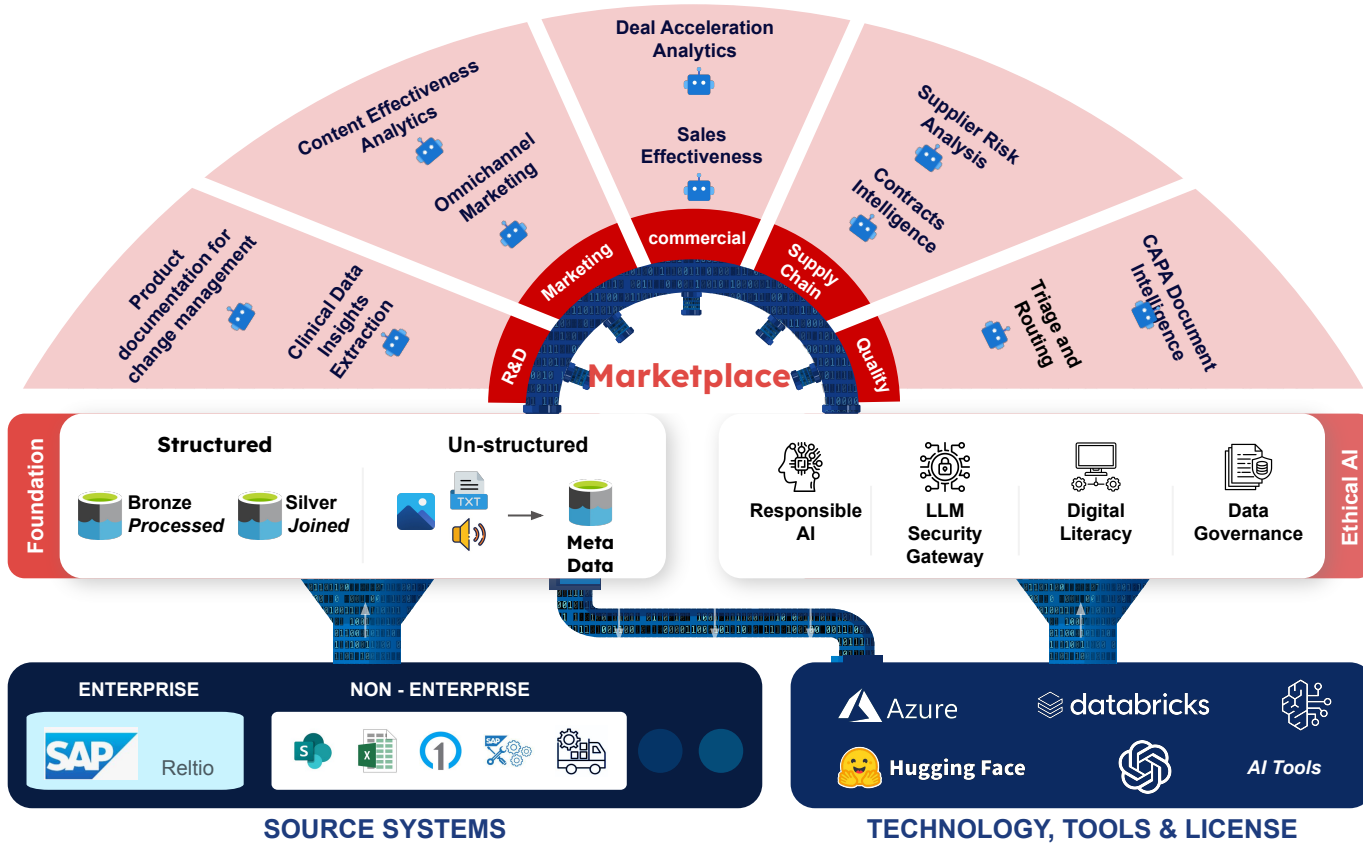
Increased Focus on Innovation

Example flow to get Query answered



* Query embedding is fed with relevant chunks – RAG Architecture

A FAIR Digital Ecosystem



Thank You