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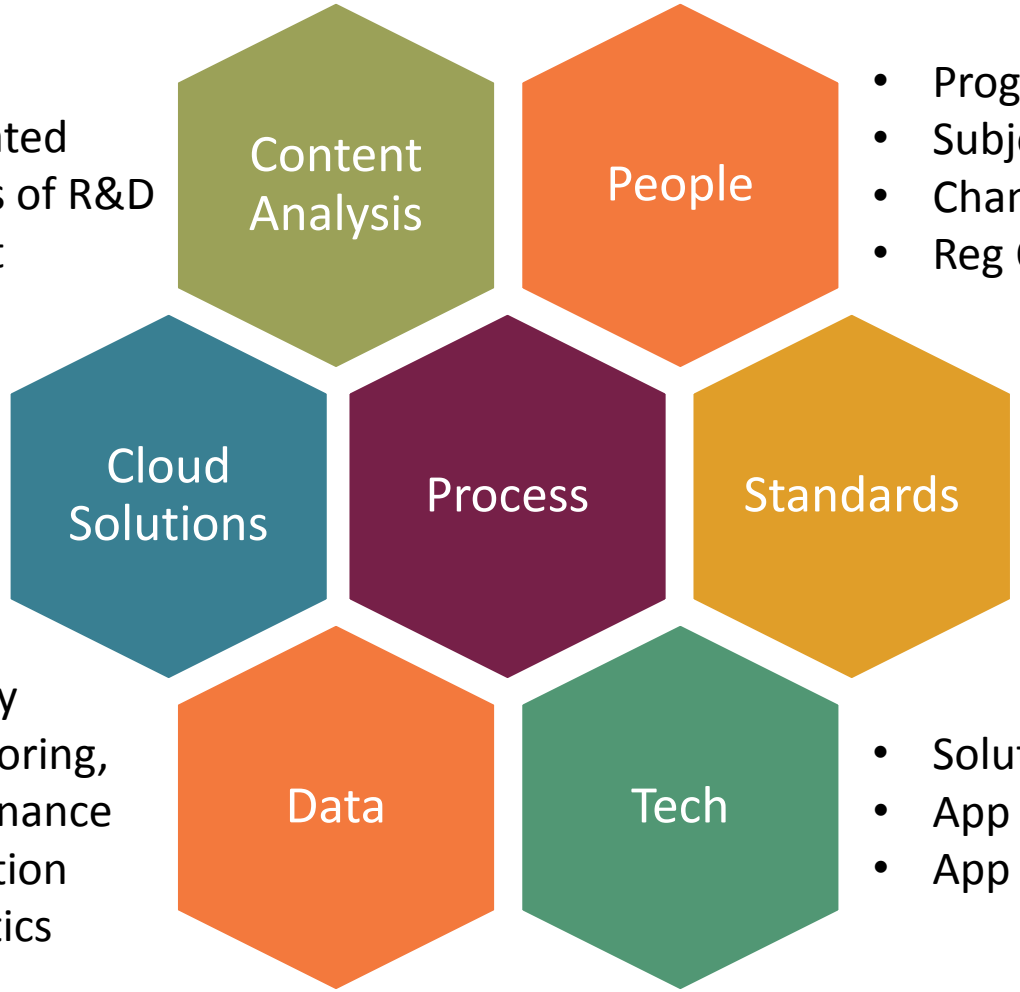
Unearthing Potential

RIM Case Studies

August 20, 2018

Offerings



- Automated Analysis of R&D Content

- Program Management
- Subject Matter Expertise
- Change Mgmt/Training
- Reg Operations

- Regulatory and Quality

- IDMP
- RIM Reference Model
- EUMDR
- GDPR

- Quality Monitoring,
- Governance
- Migration
- Analytics

- Solution Design
- App Dev/Integration
- App Support/Maintenance

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Product-Enabled Services

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Enterprise Architecture Assessment for RIM

Client: Global Bio-Pharmaceutical Company Initiative: Enterprise Architecture for RIM	
Challenges	Fragmented enterprise architecture within Regulatory
Solution	Define vision and foundational architecture for RIM

Services	• Performed analysis of enterprise architecture against Enterprise IM framework
	• Identified architectural elements that are in place including gaps
	• Recommended architectural elements to be implemented
	  • Product master
	  • Service Bus
	  • Data warehouse for RIM
	  • Analytics capabilities

Outcomes	Recommendations accepted and implemented in a multi-year RIM transformation initiative

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Process Design for RIM

Client: Global Bio-Pharmaceutical Company Initiative: Process Design for RIM Transformation	
Challenges	Design/Re-design processes as part of RIM transformation initiative
Solution	Define end-to-end RIM Processes encompassing R&D Planning, Regulatory, Safety and Change Control
Services	• Designed/re-designed and harmonized 15 RIM processes: for e.g., Regulatory, Safety, CMC Change Control, Correspondence/Commitments • Facilitated workshops and business/data/reporting requirements analysis sessions • Documented process narratives, business and data requirements • Defined operating model processes for ongoing operations, data quality monitoring, governance, etc.
Outcomes	Improve process efficiency by 30%, end to end visibility of data and fine tuned for Veeva configuration

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RIM Integration with Enterprise Capabilities

Client: Global Bio-Pharmaceutical Company Initiative: Veeva Vault RIM Integration	
Challenges	Integration of Veeva Vault RIM with several legacy, enterprise applications
Solution	Architected and designed cloud to enterprise integrations
Services	Responsible for end-to-end integration of 7 applications across two phases • Project management following agile methodology • Leveraging approaches and assets created during Phase 1 integration • Requirements analysis and functional design • Oversight of detailed design/development • End-to-end unit testing • Support for system integration testing and UAT
Outcomes	Planned for 30% time improvement on response, improved data quality and 40% cost savings in regulatory activities.

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Migration Strategy for RIM

Client: Global Bio-Pharmaceutical Company Initiative: Migration Strategy for RIM	
Challenges	Legacy data migration from disparate sources as part of RIM transformation initiative
Solution	Define data migration strategy for RIM; e.g., Active Products, Active Mature Products and Globally withdrawn, etc.
Services	Defined different strategies for: • Active : Migration of all lifecycle submissions chronology • Active Mature Products : Migrate limited submission chronology • Globally Withdrawn : Archive (no data quality or remediation)
Outcomes	Recommendation accepted and implementation of migration underway

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Change Management/User Adoption of RIM

Client: Global Bio-Pharmaceutical Company Initiative: Change Management for RIM Deployment	
Challenges	Change Management for a major Regulatory Information Management Transformation Initiative
Solution	Implement global change management and user adoption program
Services	• Define change management and communication program and initiatives • Defined Client Engagement Liaison (CEL) Role and Responsibilities (see next slide) • Defined operating model for global user engagement, user adoption of new processes and systems, training, data quality assessments, hypercare • Enabled by Cabeus CELs in North America and Asia Pacific along with other members
Outcomes	Successful user adoption of RIM transformation, yielding greater efficiency and better data quality

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RIM Change Management Liaison

- Defined and stood up a group of global Change Management Liaisons to support the global deployment of Veeva RIM
- Key Responsibilities include:
  - Being a champion of change and the key point of contact for end users
  - Encouraging the active use and adoption of RIM business processes and system
  - Proactively supporting the global deployment of RIM business processes and system capabilities
  - Ensuring data is of highest quality
  - Supporting/delivering clear, simple and comprehensive training on RIM processes
  - Being aware of cultural change issues and driving appropriate change in the organization
  - Overcoming constraints and challenges
  - Driving acceptance and commitment during deployment
  - Communicating and assisting in the establishment of a clear link between the organization's goals for high data quality and users' individual role in achieving these goals and objectives.

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IDMP Gap Assessment and Business Case

Client: Global Bio-Pharmaceutical Company Initiative: IDMP Gap Assessment and Business Case	
Challenges	IDMP Readiness Assessment as deadline loomed large in 2016
Solution	Provided IDMP knowledge and expertise to perform assessment
Services	• Performed analysis of data sources satisfying IDMP requirements • Identified about 55% of data was in unstructured documents, about 30% in structured data sources/systems and remaining to be gathered • Proposed an action plan and roadmap • Defined business case along with cost estimates for an IDMP Program
Outcomes	Successful identification of data sources for IDMP and development of a business case

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QMS Process Design/Program Management

Client: Global Bio-Pharmaceutical Company Initiative: QMS Process Design/Program Management	
Challenges	Outdated QMS systems with a vast footprint and high TCO
Solution	Led Quality Systems Effectiveness efforts to ensure integrity, repeatability and robustness of quality processes/systems
Services	• Performed process analysis and design exercises • Designed, optimized and harmonized quality processes across R&D and commercial organizations using Lean Sigma • Vendor selection • Program and project management responsibilities • Resource organization & coordination • Managed requirements, risks and issues tracking
Outcomes	End-to-end processes and business requirements defined in time for Veeva configuration

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Contact Information

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