Case study

Implementation of Veeva Vault RIM suite in the context of IDMP compliance

Customer Understanding

Customer:
Various Pharma & Cosmetics companies in France

Context Regular support from PLG to the client during the past 10 years around systems, processes, regulatory data management, project management, and implementation of new systems.

Usual challenges

- Implement the Veeva Vault RIM suite involves adapting and changing business processes in the context of IDMP/SPOR.
- Design: Gather and assess stakeholder requests, identify and organize setup of specific adjustments based on IDMP/SPOR industry standards, define workflows relevant to the customer and the permissions strategy that defines the level of access for each user or role.

- Migration challenges: all pieces of data need to form a global comprehensive end-to-end suite, which requires a migration strategy, including new functionalities to integrate the different modules within the suite
- Training: use by stakeholders when preparing clear training material, including videos and e-learning.

PLG's Project Support

- **Project management:** PLG was in charge of building the project plan and maintaining it during the project, as well as preparing and leading the Steering Committee.
- **Change management:** To redesign processes, we prepared business case scenarios in coordination with the main company stakeholders. We supported the internal communication plan by developing related deliverables (for example, production of videos for promoting Veeva system and use internally).

- **Migration and testing:** Our experts contributed to defining the migration rules, controlling the accuracy of the migration of the data extracted from the previous system and executing dry runs to test migration.
- **User manual and trainings:** Production of supportive documents for training end-users and user manual.

The journey toward IDMP compliance

Data migration happens in different phases: usually customers migrate data as it currently exists, and then data need to be checked and completed to be IDMP compliant.

PLG can support this journey toward compliance with an IDMP gap analysis, data cleaning and enrichment, as well as adapting different submission processes and implementing a master data governance, aligned with regulations (for example, SPOR in Europe).

PLG can also support customers to interface the RIM suite with the other internal systems, such as enterprise resource planning.

PLG ADDED-VALUE

EXPERTISE AND EXPERIENCE	BROAD KNOW-HOW (regulatory affairs, pharmacovigilance, manufacturing & supply,...)	END-TO-END RIM VISION TO SUPPORT CLIENT STRATEGY
Consolidated experience of Veeva tools	Ability to build a global vision and benefits of the system for all functions	Expertise in analyzing RIM data versus document alignment, including alignment to IDMP standards
Ability to design business processes	Ability to support change management, build a communication plan, and training materials	Ability to support customers in building an end-to-end information workflow
Knowledge of Health Authorities' requirements		