Collibra

Solution Brief

Data Governance in Pharma

The pharmaceutical industry is heavily regulated, and non-compliance directly affects top line revenue. GxP quality guidelines and regulations are extremely important and grounded in the organizational culture. Applying Data Governance with the Collibra platform provides the level of control needed for regulatory compliance, the engagement to achieve adoption from various parts of the organizations, as well as a repository of knowledge that increases the overall efficiency around data management in critical business processes.

Context

The pharmaceutical industry is one of the most intensely regulated industries in the world. According to The Pharmaceutical Research and Manufacturers of America (PhRMA), it takes an average of 12 to 15 years and up to $ 1.7 billion for a drug to go from discovery to market.

Regulation governs every aspect of the drug development process: from the chemicals and materials used in drug discovery and clinical trials to the packaging container used to hold the final product, including corresponding marketing material. There is a clear and direct effect on the top line of a pharmaceutical company: non-compliance means no entry to the market.

Drug development is risky as well as costly. Out of 5,000 to 10,000 tested compounds, only 250 enter preclinical testing, five enter human clinical trials, and one is approved by the Food and Drug Administration. (PhRMA)

This constant pressure from regulatory authorities shapes every aspect of a pharma firm's organization, operations, and culture. This means that risk is a big issue, and every change must be tightly controlled through the appropriate policies and procedures.

System development in the pharmaceutical industry is associated with stringent record-keeping requirements. Traceability is crucial: it is necessary to create a chain of decisions that lead from user needs and business goals down to the system design decisions, and the verification of proper system installation and operation.

GxP Compliance

Deeply engrained into a pharmaceutical company's organization and culture is quality: every business process is touched by it so as to guarantee that a product is safe to use and meets its indented use. This is usually captured in a set of Good Practice (GxP) quality guidelines and regulations (e.g., GMP or Good Manufacturing Practice, GCLP or Good Clinical Laboratory Practice).
The most central aspects of GxP are:

- **Traceability**: the ability to reconstruct the development and manufacturing history of a drug or medical device
- **Accountability**: the ability to resolve who has contributed what to the development and when.

Data Governance

Data Governance brings the right mix of people, process & technology in the organization to control the data management process. It can be broken down in four dimensions:

• **Organization**: is there a Data Governance Committee and what are its responsabilities? What are the organzitional responsibilities of the different business functions (R&D, Manufacturing, Sales and Marketing...)? For example, which data elements and domains does R&D own, and which does Manufacturing own? Who is the owning organizational unit of "Material Number" or "Compound"?

• **People & Process**: who has what role, permissions and responsibilities? How do people interact in a workflow? For example, how is a new data element introduced, reviewed for completeness and impact before it can be approved?

• **Documentation**: what are the business & data definitions, taxonomies, rules...? For example, what rules apply to "Material Number" in R&D versus in Manufacturing? What different types of "Compound" exist, and what differentiates them?

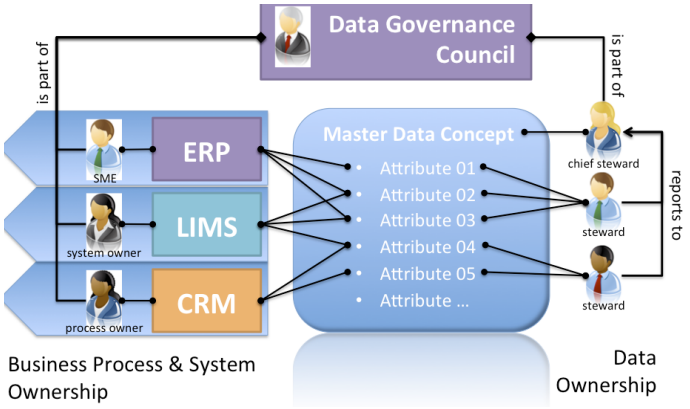
• **Operationalization**: how do you apply the decisions on organization, people, process and documentation in your existing infrastructure? How do you integrate this in existing applications & desktop environments?

Data Governance in Pharma

A pharmaceutical company has many different business processes, usually supported by different siloed systems (e.g., ERP, LIMS...), process owners and system owners. The organization is set up around these processes: people in procurement handle material acquisition in the ERP system, while people in R&D investigate and develop materials supported by their LIMS.

Master data is what links these business processes and systems. It provides key information to the business operations. It may include data about customers, products, employees, materials, suppliers, ... Master data is typically used by several functional groups and stored in different data systems across an organization.

For example, a procurement person will enter order information into the ERP system, selecting values from dropdown lists and entering other data in free text fields. Downstream, a person in R&D might use reports, exports, or even printouts from the ERP system. Without proper data governance, there is no coordination between the person in procurement and the person in R&D, which means that the R&D employee will often struggle with some of the data: reading from printouts, copy/pasting information, manipulating it through custom built excel files, reformatting it,... Neither procrument nor R&D is aware that they are not aligned.



In turn, this leads to inconsistency and duplication of this master data, typically exemplified by questions like 'For the Master Data Concept "Material", is the attribute "Material Number" in my ERP the same as in their LIMS?' or 'Are my compound types matching up with those in the ERP?'. The end result is a breakdown of business processes and costly reconciliation exercises. In the context of GxP, this means slow, error prone, often frustrating and tedious change procedures.

To handle this complexity and to ensure compliance with the regulator's demands, Collibra's pharmaceutical customers apply data governance. From an organizational point of view, they have set up decision bodies, such as a data governance council, as well as organizational ownership (e.g., Procurement owns the Material data domain). The cross-functional data governance council usually consists of a data governance officer or manager, data architects and business or chief stewards from various lines of business. Together, they provide strategy and direction through a clear mission, policies and procedures, to make sure that people within the organization are aligned. The data governance council is also the top-level decision body.

In most cases, the business or chief stewards are senior employees, often middle management or director level, responsible for a line of business or department. This could be necessary, as their level of responsibility, accountability and authority can move things forward. Some of the decisions they need to make will require significant effort to execute. In our earlier procurement / R&D example, the two business or chief stewards can finally understand the misalignment and the resulting process breakdowns so as to decide on a course of action (which might imply process or system updates).

The organization has identified and assigned roles in those organzational units of ownership, as well as their responsibilities. In the example shown in Figure 3 we have Process Owners, System Owners and Subject Matter Experts (SME), as well as Stewards and Chief Stewards with ownership around the Master Data Concepts (like Material). Their specific combined knowledge is required: details on the specific business processes and systems, together with an understanding of how certain attributes (like Material Number) are reused across multiple systems and processes.

Example roles in Data Governance: steward, business steward, data steward, master data steward, chief steward, data governance officer, master data architect, business analyst, subject matter expert, ETL developer, business reviewer, specialist, object owner, governance manager, steward delegate, strategic steward, tactical steward, operational steward, data owner ...

Another example is the Information or Data Architect, who needs to document rules around data quality. One of his responsibilities is to determine CIA details: when is the data Correct, how is it validated for Integrity, and when can it be considered Accurate). Once his or her input is approved (e.g., by the Chief Steward), Business Information Analysts and Subject Matter Experts cooperate to capture how that applies to the different types of "Material" that exist, as well as their specific details (e.g., structure, rules, usage...). To make this work efficiently and controlled in large, distributed organizations, it is essential to support data governance participants through the use of an automated workflow, which performs automated tasks and routes manual tasks so participants can do the right thing at the right time (e.g., an approval workflow to handle change).

From an operationalization perspective, we then need to make sure that these definitions, taxonomies and rules are applied properly. This is achieved through the workflow, as well as through integration of Collibra's data governance platform with other applications or toolsets (e.g., data modelling, metadata repositories, MDM hub, ...).

Conclusion

The pharmaceutical industry is heavily regulated, and non-compliance directly affects top line revenue. GxP quality guidelines and regulations are extremely important and grounded in the organizational culture. Applying Data Governance with the Collibra platform provides the level of control needed for regulatory compliance, the engagement to achieve adoption from various parts of the organizations, as well as a repository of knowledge that increases the overall efficiency around data management in critical business processes.

Regulatory authorities: U.S. Food and Drug Administration (FDA), European Medicines Agency (EMEA), Ministry of Health, Labour and Welfare, Therapeutic Goods Administration (TGA), Medicines and Healthcare products Regulatory Agency (MHRA), Health Santé Canada (HCSC), Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Helsetilsynet, Central Drugs Standard Control Organization (CDSCO)...