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White Paper

Best Practices: Master Data Management Impacts on Regulatory Affairs

Master data management is increasingly an important consideration in developing a regulatory platform and by definition it is critical to the pharmaceutical industry. It can directly affect the internal reporting of the quality, safety, and efficacy of products. In turn, if this data is consumed by a regulatory system or process then inaccurate, inconsistent, or incomplete data included in regulatory submissions (data or documents) can result in delayed approvals, product recalls, and regulatory penalties. It is therefore essential for companies to establish and follow generally accepted principles for managing master data when incorporating master data into their corporate processes.

This best practice outlines the principles of master data management, its effect on the Regulatory Affairs function and how best to integrate master data in your regulatory strategy. It is intended to illustrate how master data can practically impact Regulatory Affairs. Often Regulatory Affairs groups do not realize the involvement of master data in their day-to-day management of submissions. It is therefore important to have an appreciation of the principles and practices, particularly if you are involved in developing your regulatory platform.

What is Master Data Management?

The purpose of master data is to remove conflicting and redundant information, maintain a central view and provide teams that consume this data with the confidence that it is correct. In other words, master data helps to reduce data volatility and increase consistency, so that it can be used multiple times as a single corporate language. It prevents inconsistencies of data in different parts of business, including processes, operations, and analytics and reporting.

Master data management (MDM) is a technology-enabled discipline in which business and IT work together to ensure the uniformity, accuracy, stewardship, semantic consistency and accountability of the enterprise's official shared master data assets. The most commonly found categories of master data within the regulatory sphere are parties (individuals and organizations, and their roles) as these are reportable to regulatory agencies and of course medicinal products descriptors.

Regulatory Affairs is generally a down-stream consumer of core product master data e.g. product descriptors such as strength, composition, packaging. However,Regulatory Affairs can also contribute to the master data pool in such ways as registrational status, variation changes and controlled change process, label approval and ultimately batch release. Remember this is providing information to a data pool rather than just transferring data to the next department in the chain.

MDM primarily focuses on processing "reference or dimensional" data for key business entities (e.g., customer, products, policy, agent, location, employee) that have been agreed on by all stakeholders as a "corporate shared asset" and is shared across an organization. As Regulatory Affairs is potentially a major consumer/producer of this information it is important to be at the table. After all, it is often external influences through regulatory interactions and approvals which determine some of the master data used internally, e.g., product names, approval dates etc.

The underlying principles of Master Data are not dissimilar to the concepts we already apply to other data based systems and processes such as xEVMPD and IDMP. After all, these are just a wider usage of data. Key to these are data consolidation, data governance, and data quality management which are similar to master data and dictate our Master Data good practices:

Establish a Data Governance Framework

The data governance framework should include policies and procedures for data management, such as data ownership, data access and sharing, and data retention and archiving. It should also define roles and responsibilities for data stewards, who are responsible for ensuring data quality and consistency, and for data custodians, who are responsible for maintaining and securing data.

Define and Maintain Data Standards

Data standards should be developed in collaboration with all stakeholders, and should be periodically reviewed and updated. They should cover all aspects of master data, including product information and clinical trial data. A data dictionary should be developed to document the meaning and usage of each data element. This will include controlled terminology and a universal understanding of this terminology particularly if derived from an external source such as IDMP.

Implement a Master Data Management System

When selecting a master data management system, it is important to consider the needs of the business and IT, such as integration capabilities, scalability, and support for multiple data domains. This is aligned completely with the single source of truth concept so commonly discussed by regulatory software vendors. The system should also support data governance,compliance and security requirements, be designed to meet the needs of both technical and non-technical users and be aware of downstream systems that consume this data. As already discussed, Regulatory Affairs can equally be a consumer and a producer of critical data.

Ensure Data Quality

Data quality is the degree to which datasets, information or statistics meet a user's requirement to improve or meet a threshold of accuracy, for reporting and decision making either internally, by the Regulatory Affairs group or externally by a regulatory agency. Data quality should be monitored on an ongoing basis using data profiling and data quality tools. Data profiling involves analyzing data to identify patterns, relationships, and anomalies. Data quality tools should include data cleansing, which involves identifying and correcting errors, duplicates, and inconsistencies in master data. Data profiling and quality is particularly important when transitioning from one RIM system to another or changing your document management system.

Establish Data Security and Privacy

Security controls should be implemented to protect master data from unauthorized access, modification, or disclosure. Access controls should be established to ensure that only authorized personnel have access to sensitive data. While data encryption is one option for securing data in transit, we also recognize that a secure connection can provide better performance. As such, we recommend evaluating both options to determine the best fit for your organization's needs. A large aspect of data security are data privacy laws involving a data privacy office/function, taking into account requirements in regions where data originates and is used. The obvious example of this is clinical trial information but you should also consider insider dealing rules etc. and therefore the partitioning of data and documents even to specific groups or members of the Regulatory Affairs team.

Ensure Compliance with Regulations

Compliance with regulations should be a top priority in managing master data in the pharmaceutical industry. Regulatory requirements should be considered when developing data standards, implementing a master data management system, and monitoring data quality. Auditing and reporting capabilities should be built into the system to ensure compliance with regulations.

What does this mean for Regulatory Affairs?

We have established that Regulatory Affairs is a key stakeholder in master data management, consuming and potentially producing critical data. It is the regulatory infrastructure which will display master data and if required collect registrational data as part of its shared assets contribution. The regulatory platform is the user interface to this data both consumed and produced. This could be a Regulatory Information Management System (RIMS), Document Management System (DMS) or both, which in turn provide inputs to your publishing tool.

As there is no vendor that provides an end-to-end master data management solution including regulatory management, different systems through the company will provide data to a shared asset data pool or lake. Your regulatory vendor will then provide access to this data pool via a connector. The connector will be used to ensure data flow and be the gatekeeper for information into and out of the Regulatory platform, producing the illusion of a single platform sharing critical data assets. This will appear seamless to the regulatory professional using the system.

The Regulatory Platform will be dependent on upstream data and thus dictate that existing regulatory processes may need to be modified. This for instance could be the Regulatory Submissions meeting which might require certain steps to be taken before it can take place or a slightly wider participation to ensure the regulatory objective is understood and that data is correct and available at the right time.

If during the detailed analysis of data flow, the regulatory platform also produces critical data assets to be shared via the data pool or lake, master data requirements might dictate a connection with the regulatory platform that is bi-directional. This means that registrational data is returned back to the MDM system. These could be status, approval dates, process steps or approval parameters. This will result in regulatory business processes around these activities to be reviewed, perhaps metrics and KPIs enforced. Understanding these changes and the true meaning of KPIs is key to adoption and potential efficiency gains.

Breakdowns in business processes could result in delays to regulatory submissions and so regulatory affairs having an understanding of the data architecture is imperative. Regulatory Affairs now need a technical understanding beyond their regulatory platform and that of the Regulators'. Understanding who impacts them up-stream and the effect of their actions on functions downstream, which might not always be obvious.

What to do and what not to do…

The data governance framework should include policies and procedures for data management, such as data ownership, data access and sharing, and data retention and archiving. It should also define roles and responsibilities for data stewards, who are responsible for ensuring data quality and consistency, and for data custodians, who are responsible for maintaining and securing data.

The key to a successful marriage of MDM with a regulatory platform is making the systems speak and understand each other, which is challenging. Interoperability between these systems is key and to understand this you need to understand the data required and data flow, including where the data originates and where it is consumed. Although these systems are largely dynamic, exchanging data in near real time, this is not always the case and not always required. This may be for technical as well as practical reasons. But the point is that the temporal availability of data is just as important as the accuracy of the data itself. If you are relying on specific data to start a regulatory task, you will not be able to start early with placeholder information, as you have done in the past.

The organization of your master data model, dependent on its complexity is also a key decision. If basing this model on a regional standard, be certain this is the correct route for your company. It can make good sense providing there is a clear business case and objectives; e.g., a solely European based company may see advantages on a data model similar to IDMP. As with all things, start small with the most non-controversial data. You will probably see a dramatic improvement in data flow and quality with a relatively small initial set of data points. Following this you may see a reducing return as the data is expanded. Understanding the utility of the data shared as an asset is important. Therapeutic indication may be extremely critical for downstream processes even though it is difficult to map.

Make sure your IT ecosystem is stable. That there are no large shifts in applications or business processes. It is far more difficult to map data across systems if these are shifting and changing. This is often unavoidable as IT budgets tend to try and improve a number of related platforms in similar time frames. Suffice to say, it is going to be more challenging to implement a Master Data strategy as you are upgrading the Regulatory Information Management System (RIMS) within your regulatory platform.

Be under no illusion, developing a Master Data Model requires a huge amount of planning and understanding of the data, processes and the purpose of key activities.

Partner with a Specialized Software Vendor

Working with a software vendor that specializes in master data management can provide access to a team of experts in the field. These experts can provide guidance and support throughout the entire process, from initial assessment to implementation and ongoing maintenance.

A RIMS vendor like Ennov can help companies select a master data management system that best meets their needs, and can provide support for integration with Ennov systems and applications.

Both vendors can then play their part to provide training and support for users, ensuring that they have the skills and knowledge they need to effectively manage master data. Additionally, your RIMS software vendor can help ensure compliance with regulatory requirements, and can provide assistance with audits and reporting.

By working with a team of experts, pharmaceutical companies can more easily achieve best practices in managing master data, and can ensure the quality, consistency, and accuracy of their data.

Finally, master data management is critical to the pharmaceutical industry, and best practices should be established and followed to ensure data quality, consistency, and accuracy. A data governance framework, data standards, a master data management system, data quality, data security and privacy, and regulatory compliance are essential components of managing master data in the pharmaceutical industry.

If you're a pharmaceutical company looking to establish best practices for managing master data, it's important to work with a vendor that can provide the guidance and support you need. Ennov is a leading provider of regulatory data management solutions for Life Sciences, and our team of experts can help you take the first steps towards achieving best practices in managing your data. Contact us today to learn more about how we can help you select the right solution for your needs, and provide the support and guidance you need to ensure the quality, consistency, and accuracy of your data.