A Whitepaper from DDi

Why Regulatory Digitization is important for Diagnostic Companies?

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Regulatory Information Management (RIM) refers to the systems and processes used to manage regulatory data and documents across the product lifecycle. RIM is a common concept for pharmaceutical companies. However the notion of RIM is less prevalent in the Diagnostic space. Although RIM may be a new term for many manufacturers, there are key requirements that make good RIM critical for Diagnostic companies to remain in compliance and achieve greater operational efficiency.

Unique Device Identification (UDI)

In September of 2014, FDA began requiring manufacturers to submit data to the Global Unique Device Identification Database (GUDID) and to maintain that data over the life of the product. Class III products were the first face this requirement. Class I and unclassified devices are the last group of products to be phased in, and will be required to submit and maintain GUDID data by September 20201. GUDID data includes key regulatory information (such as approval number, risk class, and GMDN Code) and requires regulatory information to be tied to product identification and labeling data. As a result, compliance with FDA's GUDID requires regulatory groups to have accurate data, and a process to trigger data submissions when information changes.

FDA's UDI regulation was based on guidance from the International Medical Device Regulators Forum (IMDRF). Other countries are working on similar requirements based on the IMDRF guidance. One of the most visible new UDI requirements is part of the new European In Vitro Diagnostic Regulation (EU IVDR). The EUMDR includes requirements for a EUDAMED database. Manufacturers will be required to submit product data to EUDAMED prior to initial submission, and to maintain regulatory data over the product lifecycle.

As other countries implement similar systems, the ability to quickly and accurately track regulatory data, in a way that triggers data update submissions will be essential to remain in compliance. RIM systems provide a controlled location to track GUDID and EUDAMED regulatory data, and to track submissions made to these systems.

Medical Device Single Audit Program (MDSAP)

MDSAP is an initiative sponsored by IMDRF that allows certified auditing bodies to conduct a single audit of a medical device manufacturer that meets the requirements of multiple regulators. Beginning in January of 2019, Health Canada will require that manufacturers submit an MDSAP compliant Quality Management System (QMS) certificate with medical device license applications. It is likely that other regulators will implement similar requirements in the future.

Manufacturers planning an MDSAP audit are asked for advance data about the audit site by the auditor. Requested data typically includes a list of all products manufactured at the site to be audited, and the global regulatory status of those products.

Control of Product Release and Shipment

Diagnostic companies are expected to control shipment of products to ensure only products which meet regulatory requirements are placed on the market. Because the decision to release or ship a product is not always be made by the regulatory group responsible for the approval, access to accurate real time data about the regulatory status of the product is critical.

Following initial product release, Diagnostic products often undergo frequent design and manufacturing changes. This makes real time access to the regulatory status of a product configuration in all markets critical. Lack of access to such information increases the risk of compliance issues and product escapes. A well maintained global RIM database of approvals and products helps decrease the risk of product escapes by ensuring that regulatory staff responsible for product release have access to the global data required to make accurate product release decisions.

Regulatory Assessment of Product Changes

Diagnostics undergo many design, labeling and manufacturing changes during the product lifecycle. Each change to a product requires a regulatory assessment to determine what regulatory action(s) may be required. Effective assessment of the change impact requires that regulatory staff know where (in which countries) a product is currently approved. A RIM system can provide this information easily, and will help avoid unnecessary regulatory assessment for countries where the product is not currently approved.

Once the regulatory assessment for each applicable market is completed, the required regulatory action in each country must be tracked and coordinated with the manufacturing implementation of the change. In countries where no regulatory action is required, documentation of that decision and the rationale behind it must be retained to demonstrate compliance. When regulatory submission of the change is required, approval may take months in one market; while in other markets a simple update of internal company documentation may be sufficient.

A good RIM system enables management of assessment documentation, tracking of the planned actions to implement a change, and can provide an efficient global view of the regulatory change implementation. As data about product changes and regulatory assessments are collected in the RIM system over time, this information can then be used to aid in assessment of future changes. This may further improve efficiency and aid in consistent regulatory decision making.

Data to Build Regulatory Strategies

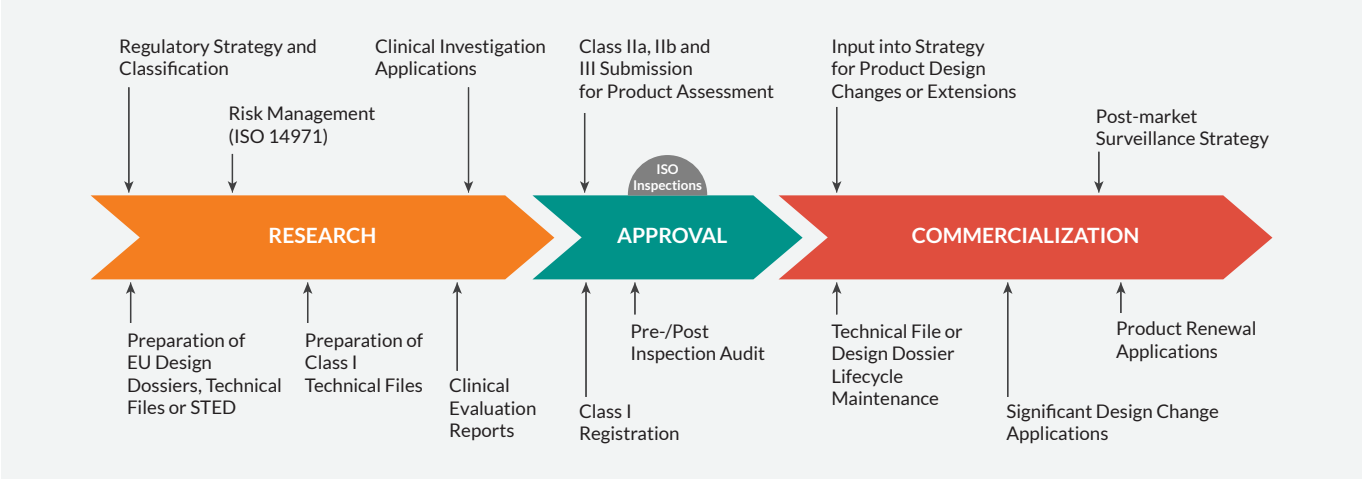
When planning a new Diagnostic, the regulatory strategy often depends on the past regulatory approach used for similar products. Effective RIM systems for products may allow companies to track existing products which are similar in technology and indications as "predicate products". Analysis of the risk classification, submission types and submitted documentation for predicate products allows creation of a more effective regulatory strategy for the new product based on past experience.

Some RIM Systems may also track regulatory intelligence data. Examples include the cost to register a product, required documentation, average approval time, and pending new requirements. Access to this type of information in a RIM system can dramatically decrease the time required to create a global regulatory strategy for a new product.

Planning of Regulatory Resources

The number of regulatory resources needed to support work in the coming year is often difficult to predict. Variables that may influence required resources include the number of new products in development, the risk class of those products, the number changes planned for products currently on the market, and changing regulatory requirements.

An effective global RIM system containing past submissions, approvals and products on the market enables reporting and analysis of historical data as a baseline for future regulatory resource planning. Some RIM systems also allow tracking of planned regulatory activities. This allows known future activities (for example annual reports) to be accounted for in resource planning. The combination of RIM system data and regulatory resources available the during that period can enable more effective staffing to meet future demand.



Conclusion

GUDID data submission in the US, plans for EUDAMED in Europe, and requests for pre-MDSAP audit data all demonstrate a trend of new requirements to maintain and submit accurate, up to date regulatory data across the product lifecycle. Regulators increasingly expect manufacturers to effectively manage their global regulatory information, and produce it accurately and quickly upon request. RIM is a relatively new concept for Diagnostic manufacturers. But it is a concept that will help the companies meet these increasing requirements, while also helping manufacturers increase efficiency in product release, assessment of product changes, development of regulatory strategies and resource planning.

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