Deloitte.

Master Data Management: Building readiness for regulations

Compliance can benefit, but so can internal speed and efficiency

What's at stake?

As part of their obligation to communicate accurate and changing product information to regulators throughout the life cycle of a product, pharmaceutical companies will have to adhere to new "product master data" standards for identification of medicinal products (IDMP) and the U.S. Food and Drug Administration's Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies (PQ/CMC). But master data management (MDM) is likely a more enduring and far-reaching concern—and the regulatory compliance is only one of many reasons to put a strong MDM discipline in place.

Although IDMP implementation has been significantly delayed, many companies recognize the value of implementing MDM extends well beyond meeting IDMP requirements. In a recent industry study conducted by the Implementation of Regulatory Information Submission Standards (IRISS) Forum, only 3 of 35 study participants stated the IDMP delay would have "significant impact" on their MDM programs.[1] Other participants noted the delay would have some impact on part or all of the program while a significant number, 9 of 35, stated there would be no impact.

What is master data? By definition, it is information that is uniquely identifiable, accurate, and shared across multiple business transactions. Business functions and even third parties can share it easily without data translation, and everyone across the organization agrees on its definition, standards, accuracy, and authority.

With this in mind, the discipline of MDM is designed to treat enterprise information as a strategic asset and govern it so it provides end-to-end business oversight, a foundation for strategic capabilities, and operational excellence. Master data management is more than an IT issue—it is a business need. Successful MDM programs include strong business leadership and commitment.

MDM offers more than just a cleaner path to regulatory compliance. As better, more accessible data helps streamline processes and speed strategic decisions backed by analytics and data-driven insights, the resulting clarity and consistency can also drive internal benefits. It can also leave organizations better prepared to satisfy information exchange needs, whether from other company functions, from governments, or from other third-party partners such as CROs and CMOs. It can help simplify mergers and acquisitions. Consequently, these qualitative benefits can have financial benefits from which a strong business case can be developed.

Clearly, a better mastery of data, its accuracy, and its integrity is worth the effort it will take to conquer today's informational silos. A deliberate approach to MDM can establish common terms of reference and pave the way to working with standards. So, while IDMP and PQ/CMC are the standards on the radar right now, they aren't the only changes unfolding in the industry. The broad application of MDM across product data would be long overdue with or without the new standard.

There are five distinct IDMP standards, developed by the International Organization for Standardization (ISO):

- ISO 11615 - Regulated medicinal product information
- ISO 11616 - Regulated pharmaceutical product information
- ISO 11238 - Structured substance information
- ISO 11239 - Dose forms, units of presentation, routes of administration, and packaging
- ISO 11240 - Units of measurement

The adoption of these standards will touch many functions in pharmaceuticals, for example, regulatory, clinical, pharmacovigilance, technical operations, manufacturing, and supply chain. All those operational areas will have to be able to work together to align to a common set of product master data. While standards are a great catalyst for change, the biggest enabler to achieving standardization and process efficiency is for organizations to master their data, and that is a discipline in itself.

Our take

What Master Data Management makes better

Large, complex organizations that manage large volumes of information can benefit from MDM to improve data quality. If data quality is poor now, it's likely due to several factors that are common in organizations.

Master Data Management: Why it's important, what it improves

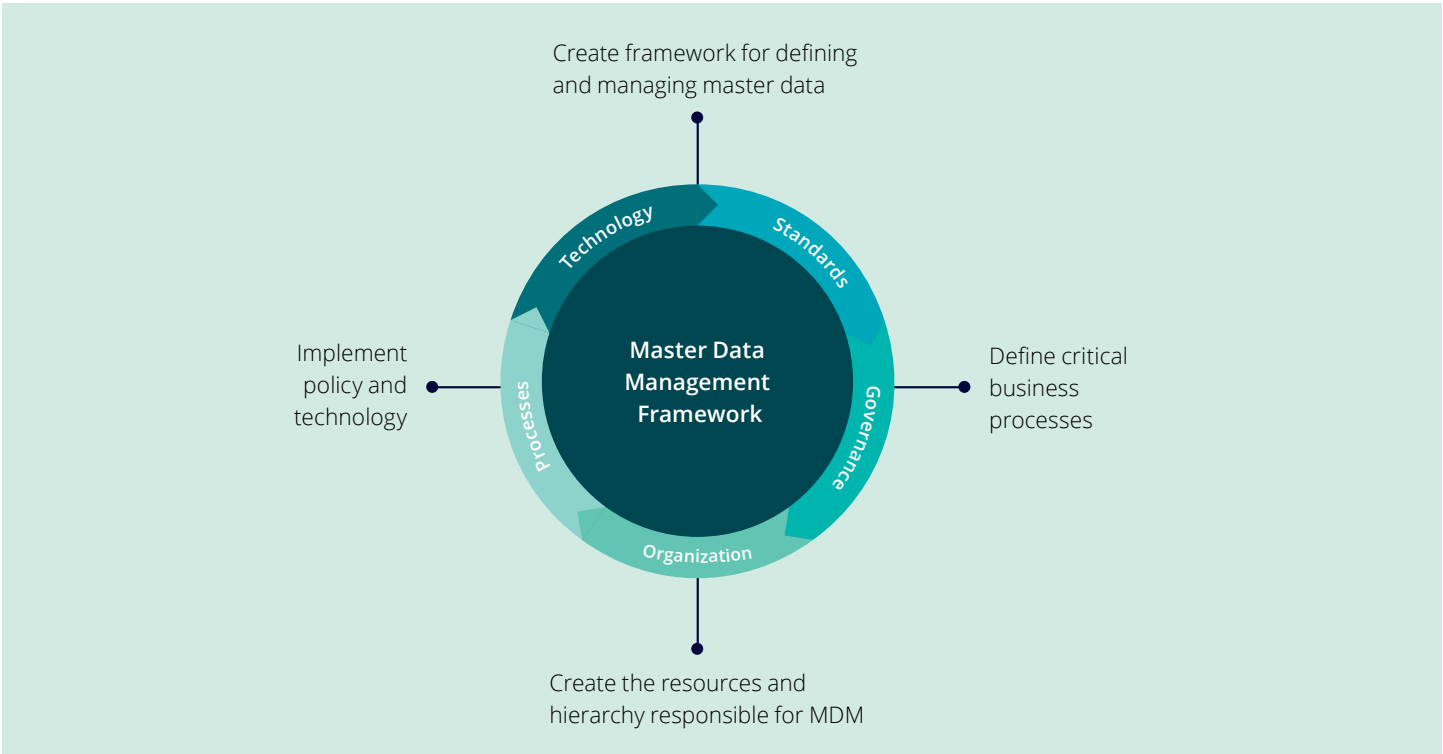
Data challenges without MDM	Improvements possible with MDM
Varying levels of granularity—when different systems store information at different levels, one system might consider a product family to be the product name, while another system considers also the dosage and formulation strength when defining a product name	A single source of the truth for product data across regions, product lines, and manufacturing facilities. An "enter once, use many times" approach can lead to improved process efficiency and hence lower operating costs
Inconsistent standards—discrepancies as small as capitalization or EU versus US date formats can make data difficult to use as intended	Improved data visibility and maintenance capabilities that reduce data duplications and inconsistencies throughout the enterprise can lead to increased data quality
Differences in timing—some systems like clinical data management systems (CDMS) use "frozen" dictionaries during a trial, which can cause data quality challenges when combining with other sources	Unique identification of medicinal products with consistency on data specifics and integrity around elements, structure, and relationships—permits better reporting and data insights that can in turn drive better strategic and operational decisions
Differences in definitions and context—words have different meanings to different people in different situations, so calling a drug "available" means one thing to manufacturing but something else in a regulatory setting	A standard definition of product attributes including the standard "list-of-values" can help ensure all the data has the same meaning and a set of values that can be shared both internally and externally
Lack of training, understanding, and compliance—as well as plain old mistakes—often prevents individuals from entering data correctly into systems, which leads to poor data quality	Alignment of controlled global vocabularies surrounding product information for use in working across multiple global regulatory directives and initiatives that make use of product master data can result in better preparation for anticipated new regulations across the globe, including IDMP

The fragmented status quo

Prior to IDMP and other developments, there has been little incentive for a pharmaceutical company's various business units and departments to use the same controlled vocabularies and master data. So what may be a metaphor in other industries is literal here: They are not speaking the same product language. These silos in data management can erode data quality and make processes inefficient, which can lead to unseen financial losses.

Identifying master data is only the first step in the challenge of putting it to work effectively. Proper implementation of master data components—such as data standards, governance, organization, processes, and technology—is also key to addressing many of the challenges.

- **Data standards.** Simple definition of terms, such as the field name or the items in the "pick lists," is critical—but because of varying contexts and locations, it's easier said than done. What should be the "source of truth" for each attribute?
- **Governance.** It's vital to determine who the data owner is and who should have input (and final word) into data standards and business rules. If a committee is involved, how often should it meet? Who's in charge? All the data governance items should be worked out and documented, then updated over time.
- **Organization.** For the process, there should be roles defined so the work gets done. The roles should be structured, defined, and communicated to the organization.
- **Processes.** Regulations change. Standards change. Data errors spike. For every event, there should be a process to follow. Data stewards should review and correct data on a regular basis. Developing and maintaining these processes isn't glamorous, but it's necessary.
- **Technology.** Most information management professionals say technology "is the easy part." Still, it's a challenge for organizations to manage a thousand or more attributes being originated from multiple systems that are not integrated. They must automate the application of business rules to handle granularity, manage timing, select data from the right sources, and apply data transformation and mapping rules. They must also provide a "publishing layer," which is a fancy way of saying "making data available to other systems." A properly designed MDM solution also provides a comprehensive audit trail that tracks all data inputs, transformations, and changes.



New rules for a bigger, faster game

New regulations like IDMP and PQ/CMC are part of a trend toward more transparency, traceability, and standardization. They are also a response to a worldwide demand for better data quality and cross-border information exchange to support use cases such as patient safety, falsification of medicines, and electronic prescriptions. If the mandate is adherence to and the use of standards, then mastering product data is a necessary precursor to making that happen.

Whether a company is launching a new manufacturing site, changing a machine on an assembly line, or changing a label based on a newly discovered drug interaction, health authorities in each jurisdiction need to know about product information changes.

But the information necessary to recognize, collect, and report these changes more efficiently often resides in separate places. Different systems use different vocabularies to manage, search, and communicate product data, and operating across those divides—those silos—makes it harder to link product data together.

The result is typically a cascade of inefficiencies: data entered multiple times into multiple systems using different vocabularies, manual double-checking and verification across systems, inability to link and report on information across systems, delayed or unclear communication among departments, and a failure to derive the insights quickly that data should yield.

In contrast, organizations that use MDM find they can work with an unprecedented level of data quality, integrity, and transparency. Standardization of product information and controlled vocabularies is a crucial step.

What's in a name?

When executed correctly, the discipline of MDM can improve process efficiency, speed decision making, bring companies into compliance, and financially add value. The pharmaceutical industry works with many types of master data across the product life cycle.

Some of the master data types found across the product life cycle:

- API molecule
- API source
- Blister size
- Blisters per carton
- CAS number
- Form
- GTIN
- Item status
- Item type
- Indication text
- Market
- NDC11
- Product family
- Product ID
- Product name
- Product registration name
- Route of administration
- Shelf life expiration date
- Shipping temperature
- Strength
- Therapeutic area
- Therapeutic code
- Trade name
- WH storage condition

Smart first steps: Getting started with product MDM for IDMP

Even if a company is prompted to adopt MDM because of a specific delivery need—such as IDMP and PQ/CMC—any framework should be foundational, so it can support multiple standards, regulations, and capabilities. In most cases, it makes sense to build the solution in stages, so planners can learn as they go and deliver incremental benefits to the business.

Here is one way to envision the stages through which an MDM solution can evolve:

1. Educate.

For many leaders, MDM is a new concept.

2. Define.

What are the objectives and scope of the project? Who owns it? Enterprise-wide data harmonization might be a lot to bite off. A scope defined by specific business problems can be more manageable.

3. Prepare.

What is the data you'll need, and how many systems does it live in now? What are the authoritative sources of each of the data elements? Who are the current data owners? It should be identified, verified, cleaned, and unified to represent an authoritative record.

4. Design.

MDM implementation needs processes and a governing model. Existing frameworks may help, but only if you're sure they apply. The project will require decisions about data stewardship, governance policies, and roles and responsibilities. The design phase will also include decisions on technology and data integration.

5. Pilot.

Once the company designs the process, it should test it on a small scale—using real data and real situations. Typically, a pilot program is used with a limited set of user groups or a limited set of consuming systems.

6. Implement.

The organization should roll out the necessary changes in people, process, and technology, train users of the new system, and consider the validation and compliance aspects. Implementation will likely be a phased approach starting with building a robust platform that will support future growth.

Conclusion

Pharmaceutical and biotechnical companies are under pressure to deliver more consistent data with integrity that lives up to increasingly stringent standards. Upcoming regulations are a prominent source of this pressure, but not the only one. To answer the call, organizations will first need to master their own information, starting with detailed product information. MDM is a discipline that can make that happen in an organized, governable way.

Short-term benefits will likely appear both inside and outside the company. In the long run, regulators and patients can benefit from the linkage that occurs when global agencies and health care systems all share the same standardized product data and safety information.

Because IDMP and similar mandates involve multiple interactions with multiple health authorities over a span of years, an organization should plan an iterative MDM solution. An iterative one—but not a leisurely one. Organizations should start planning today. By using tools to capture and curate data over the long haul, companies can position themselves ahead of the game and be ready to meet new requirements as they arise.

Regulatory compliance may be the reason you take on MDM today, but the journey does not end there. When done right, a strong, foundational MDM solution will help support ongoing data quality maintenance and controls, and drive compliance and operational efficiencies in many areas for years to come.

Endnote

1. IDMP Industry IRISS Survey, August 2017, www.iriss-forum.org.

Contacts

Kurt Conger
Director
Deloitte Consulting LLP
+1 215 446 3417
kconger@deloitte.com

Marcel Lissinna
Specialist Leader
Deloitte Consulting LLP
+1 973 602 5016
mlissinna@deloitte.com

Fiona Maini
Director
Deloitte & Touche LLP
+44 20 7303 4767
fmaini@deloitte.co.uk

Michael Andreas Graf
Partner
Deloitte AG
+41 58 279 7345
mgraf@deloitte.ch

Deloitte.