New regulations for the identification of medicinal products (IDMP) are in the process of being finalized by the European Medicines Agency (EMA), the Food and Drug Administration (FDA), and, in all likelihood, other authorities as well. They will be based on a series of standards that were created by the International Organization for Standardization (ISO) and will go into effect in Europe July 2016. The regulations provide a common framework for identifying medicinal products and should lead to better drug safety. While IDMP started as a European initiative, its impact actually extends far beyond Europe. As the FDA and other ICH region regulators adopt IDMP, the regulations will affect every pharmaceutical company that manufactures or sells medical products in the respective regions.

As such, all pharmaceutical companies intending to market products in ICH regions need to develop an IDMP compliance strategy. Companies found to be noncompliant risk fines or exclusions that are not trivial. European regulators may fine non-compliant companies—even those only selling products in Europe—to the tune of 5% of the products' annual gross revenues from the European region. Should the company be found to be out of compliance on a recurring basis, that company could be barred—completely—from doing business in Europe until such time as it can prove IDMP compliance. The FDA has not yet published non-compliance penalties, but they are expected to be on par with those imposed by the European authority.

Yet there lies the real issue: How do you develop—let alone implement—a compliance strategy when the authorities have not yet agreed upon the final standards? If you prepare a strategy based solely on the ISO Standards and the authorities either decide not to implement all of them (or decide to implement some of them in an unanticipated manner), you may find yourself having put considerable effort moving down a dead-end path. If you wait until the IDMP standards are approved then you may find yourself left with little time to implement your compliance strategy. Indeed, according to the outcomes of a recent ISO TC 215 meeting in Japan, the European authority driving the IDMP process intends to provide a final draft of the IDMP guidelines only 11 months in advance of the July 2016 compliance date. The “official” guideline will not even be published until five months after the final draft is released, which realistically leaves no option to wait until the official IDMP standard becomes available! Moreover, as of this writing there is no clear provision for a compliance extension or grace period. Regulators in all the regions expect that your company will be IDMP compliant starting in July of 2016.

**Understanding the Compliance Requirements**

So what does IDMP compliance look like? Fundamentally, IDMP requires that information about your medicinal products be expressible in terms of a set of standard identifiers. The identifiers are not altogether new: they build on an identification hierarchy that you may already have created in the course of building an EudraVigilance Medicinal Product Dictionary (in its original form [EVMPD] or in its extended form [xEVMPD]). They likely will also have overlap with information filed within Structured Product Labeling (SPL) filings used in the U.S. and other product registries globally.
However, IDMP is a quantum leap beyond EVMPD, xEVMPD, and SPL. There are new identifiers, new categories, and new ways to express the relationships between the elements in the data model. While it may have seemed possible (not advisable, but possible) to maintain the data for an EVMPD or even an xEVMPD via spreadsheets, that's simply not going to be possible with IDMP. IDMP should be integrated into the DNA of the enterprise itself. It needs to drive the construction of data models throughout your enterprise. Your IT infrastructure can then recognize it, even across multiple systems, processes, and organization divisions. So will your R&D, testing, documentation, and manufacturing processes.

**Reframing the Requirements**

For a pharmaceutical company, the question surrounding the matter of IDMP compliance is fundamentally a strategic one: how you integrate these identifiers into your enterprise to achieve compliance? There are really only four paths open to you. You could redefine all your existing products, processes, and procedures in terms of the new IDMP data models and schemas. For any but the smallest startup this is likely to be an extreme response—in terms of cost, effort, and virtually any other metric you might consider.

A second possible approach to IDMP could be the “Integral Approach,” in which a Regulatory Information Management (RIMS) solution holds all the data required to create and manage IDMP submissions. But since most pharmaceutical companies already have established systems for regulatory affairs, supply chain, packaging, and the management of product documentation (national and global labeling, submissions), IDMP data would have to be entered multiple times, which not only creates redundancies but also exacerbates the risk of introducing data errors and inconsistencies. Thus, like the first path described above, the “integral approach” is likely to be an option for smaller companies that are starting with a “green-field” IT infrastructure.

A third path to compliance involves creating a data warehouse that could systematically extract and transform information about medicinal products whenever an IDMP-compliant view of medicinal products is required. Proponents of this approach suggest that it might avoid having to retrofit existing information into a new data model while still enabling you to provide IDMP-compliant reports that regulators might require at any point.

We at HighPoint consider the data warehouse approach unadvisable—for several reasons:

- A data warehouse is typically built to reconcile disparate data sources with reporting outcomes in mind, but IDMP is more about understanding and managing the relationships between data entities. As such, solving for IDMP is more of an upstream challenge, one that requires tools for managing data relationships and the data model itself.
- We don’t know how IDMP regulations may evolve over the coming decade, but we can confidently predict that evolving a data warehouse implementation to accommodate changes in IDMP regulations will be a costly and complicated endeavor.
- The extract/transform processes associated with a data warehouse project assume the integrity and quality of the source data itself—and assume that all the data that might be required for IDMP compliance is already present in the existing data stores. These assumptions may not be valid, and a data warehouse is not designed to address quality and completeness issues.

IDMP should be integrated into the DNA of the enterprise itself. It needs to drive the construction of data models throughout your enterprise.
Ultimately, a data warehouse may be part of an overall information management solution, but by itself it will likely be an insufficient solution for IDMP.

Instead of looking at IDMP compliance as a pharmacovigilance reporting challenge, it’s worth stepping back and taking a second look: IDMP is really a challenge around visibility and insight into the essential elements that inform your business. Most organizations and processes have grown—either organically or through acquisition—in ways that occlude the insight that IDMP demands. You may still have data silos that limit visibility, different ways of describing doses or units of measurement among product lines, and/or a variety of substance naming conventions that vary from product to product. IDMP is really all about enabling a single, consistent view of all medicinal products—aggregated across all regions, processes, and business functions.

Viewed this way, we at HighPoint firmly believe that IDMP should be seen less as compliance challenge and more as an operational opportunity. Any company that wants to operate more efficiently, effectively, and nimbly in a rapidly changing world would do well to have a central, standard way of understanding their product data across (and outside of) the enterprise. This view presents a fourth path to IDMP compliance.

**A Master Data Approach to IDMP Compliance**

From HighPoint’s perspective, the underlying challenge of IDMP is fundamentally a master data challenge. Thus, the fourth channel to compliance is to leverage a master data-driven methodology to solve for IDMP. Your organization must discover how and where key data elements relating to IDMP exist within the organization, cleanse and transform certain data elements for consistency (as required), and then harmonize those data elements and definitions across the enterprise. Thus, the name of each substance becomes consistent across the enterprise, as do units of measure, the names of vendors and suppliers, and so much more. In turn, with a master data-driven approach you can effectively refine your underlying data schemes and relationship models as necessary to map to the IDMP standards. You will even be positioned to discover where certain data elements may be missing from the data scheme you are using—and with that insight you can determine a best course of action to account for that data element in any reporting that may later be required.

By approaching IDMP compliance as a master data challenge you can avoid many of the drawbacks associated with the aforementioned data warehouse approach while still achieving the goal of regulatory compliance. When it comes time to prepare compliance reports in response to a request from the authorities, you will be reporting on the actual master data—not an extract of that raw data that must first be transformed and refined on the fly to provide the information a regulator requires. Having performed the analysis requisite to undertaking a master data project, you will be able to report on that data with a much higher level of confidence than you would when reporting on extracts of data from a data warehouse.

Along the way, you will gain something else, too: by solving for IDMP with a master data-driven methodology, you will gain that single, trusted view of your product data—across product lines, across facilities, across geographies, and more. Such insight positions you to make better strategic and operational decisions because you’ll have a greater understanding of the impact of small decisions on the whole of your operations. You’ll be able to respond to change—whether imposed from without or elected from within—with greater agility, greater speed, and a greater understanding of the ramification of the changes you make.
Indeed, approaching IDMP compliance as a master data project enables you to deliver benefits far beyond the ability to report accurately to health authorities. Some of the benefits that accrue to different parts of your organization include:

- Regulatory can easily determine the currency and geography of marketing authorizations.
- Manufacturing can easily and accurately compare production across sites (internal and external). This includes single-version-of-the-truth insights into quality, production costs, and overall equipment effectiveness (OEE).
- With clean, consistent, well managed master data, manufacturing also gains insight into raw material and work in progress inventory for improved planning.
- Supply chain managers gain global inventory visibility and an improved ability to plan.
- Procurement gains a consistent and complete view of spend across the entire enterprise, which improves the organization’s ability to negotiate and take advantage of volume-based discounts.
- Finance gains accurate insight into inventory and stores, which can result in lower requirements for working capital and improve cash flow.
- Customer/Patient Services gains complete information on products, increasing patient/prescriber confidence and reducing call center time per call.
- R&D gains better and faster visibility into molecule performance in the market, beyond clinical trials.

For many large pharmaceutical companies, the need to manage organizational data more effectively has been known for some time, and the compliance requirements of IDMP provide just the excuse to implement a master data solution.
For many smaller pharmaceutical companies, though, the problem of inconsistent master data and the management complexities arising from data silos and disparate data structures are not as immediate. Smaller companies, even many mid-sized companies, may not feel those pains as acutely. No matter: you still need to achieve IDMP compliance. If you approach this effort from a master data perspective then you will set a foundation in place that will help you continue to avoid problems as you grow. Your efforts to manage your master data today should be viewed as proactive efforts to avoid master data problems tomorrow—because without a strategy and a solution for managing master data in the future you will find yourself struggling in future years. It really isn’t a question of whether; it is simply a question of when. Acting now, before the problem is acute, can help you avoid that problem later on.

**HighPoint and the IDMP Challenge**

HighPoint Solutions is singularly positioned to help pharmaceutical companies meet the challenges posed by IDMP. The final regulations remain subject to approval by the authorities, but we recommend that organizations plan ahead by developing and executing a strategy for compliance. While this might seem unwise, given the possibility that health agencies might not use (or might use differently) some of the ISO IDMP regulations, the approach to execution that we recommend makes it quite easy to adjust your efforts at a later date in compliance with any changes that may occur.

That flexibility arises in part from the master data-driven approach to which we have already alluded. Implementing a master data solution requires you to develop a comprehensive understanding of all the data structures within the enterprise—and there’s no reason to delay the commencement of that task. The health authorities may have approved the standards by the time your data structure inventory is complete, which will make it easier to determine how the data you already have will need to be transformed or normalized. Yet even if your inventory is complete before the rules are finalized, the project tasks involved with planning the transformation can continue—at least up to the point at which the data must be imported, cleansed, and transformed.

As noted previously, IDMP builds upon EVMPD. HighPoint has a prebuilt EVMPD solution that positions the organization to move to IDMP. As soon as the authority provides their final guidance on the IDMP standards, an organization that has already mastered its data into the schema outlined by the HighPoint EVMPD solution is well-positioned to evolve their data models into the schema approved by the authority (and achieve greater control of master data at the same time).

Some pharmaceutical companies will already have master data solutions for product data. The challenge facing these companies becomes one of evolving an existing deployment to meet the needs of IDMP. Companies in this position may be much closer to compliance than they know. More than anything, most companies with existing solutions will simply need guidance on how to evolve their solutions to accommodate the specifics of the data models and schema associated with the IDMP regulations. HighPoint consultants can provide that guidance as well as the hands-on expertise to facilitate that evolution.
Summary

July of 2016 is not far off and none of the options for achieving IDMP compliance are trivial undertakings. There are regulatory pressures to achieve IDMP compliance by 2016, just as there are operational pressures to wait until the authorities issue final guidance and approve the specifications. No organization wants to do this incorrectly, but no organization—currently—has a clear definition of what compliance truly looks like.

HighPoint’s solution to this conflict is to view the move toward compliance as a master data project. You can start today, using known methodologies and systems that will put you on the path to a sound and consistent data model across the enterprise and that will yield benefits in terms of your organization’s ability to respond to new, evolving opportunities in the marketplace.

At the same time, this approach positions you to move towards IDMP compliance as soon as the regulations have been approved. Once you have gained insight into your organization’s master data and done what needs to be done to harmonize that data across the enterprise, you are well positioned to map your data models to the final IDMP schema.

HighPoint can help you navigate this entire process—from the initial analysis of the master data in your enterprise all the way through to the incorporation of the IDMP data models and schemas into your own master data models and schema. In the end, you gain not only IDMP compliance, but you gain insight into your enterprise and its operations that will enable you to operate with greater efficiency, effectiveness, and agility for years to come.

To learn more about how HighPoint Solutions can help you achieve IDMP compliance, contact Lior Keet, Vice President, Life Sciences R&D Practice, HighPoint Solutions (Lior.Keet@highpointsolutions.com) or visit www.HighPointSolutions.com.

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