IDMP: An opportunity for information integration across the pharmaceutical value chain

Author
V. "Bala" Balasubramanian, *President & CEO, Cabeus Inc, US.*

Keywords
Identification of medicinal products (IDMP); Regulatory information management (RIM); European Medicines Agency (EMA); Cross-functional integration; Enterprise architecture (EA); Master data management (MDM); Information services bus; Data warehouse.

Abstract
The need for end-to-end visibility of regulatory information has been the driver for implementing integrated regulatory information management (RIM) solutions within the pharmaceutical industry. The European Medicine Agency's identification of medicinal products (IDMP) requires even greater integration across multiple functions and systems such as regulatory, labelling, safety, manufacturing, supply chain, clinical and quality. In addition to meeting the EMA's compliance requirements, it is believed that IDMP is coming at a time when there is need for end-to-end information integration across the pharmaceutical value chain.

This paper describes how an enterprise architecture (EA) approach is best suited to integrate multiple systems together across multiple functions. It discusses the relevance of three EA constructs, namely, master data management (MDM) for managing a single source of truth around product data, information services bus for the purposes of integration and a data warehouse to manage integrated data for aggregated reporting.

Introduction

The European Medicines Agency (EMA) is gearing up towards the implementation of the ISO identification of medicinal products (IDMP)[1] with a target deadline for full implementation being moved from July 2016 to Q4 2017 for medicinal products and Q2 2018 for investigational products. The IDMP standard comprises five major standards covering a broad set of pharmaceutical information such as medicinal product, packaged medicinal product, pharmaceutical product, ingredient/substance information, clinical particulars, authorisation, manufacturing information, dosage form, route of administration, packaging, units of measurement, etc. Industry is preparing in terms of performing readiness assessments, data gap analysis and other activities while simultaneously trying to understand the real scope of implementation by the EMA.[2] In a previous article in *Regulatory Rapporteur,*[3] Joel Finkle provided an overview of the IDMP standard as a data format capturing product profile, safety, packaging, authorisation, manufacturing and related key information to be submitted to the EMA and other regulators worldwide.

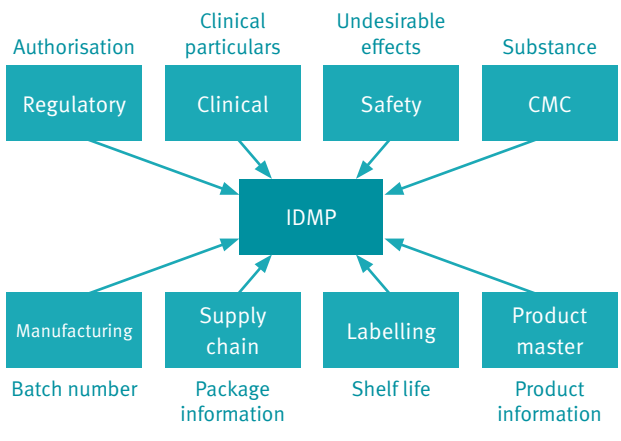
IDMP poses several challenges to the pharmaceutical industry, the key being the ability to integrate disparate data from multiple systems managed by multiple functional areas within an organisation. While being a technology and an integration challenge, IDMP also poses organisational and political challenges given that it requires the collaboration and cooperation among many functional units, which have been traditionally independent and siloed for a long time.

This paper proposes that industry looks at IDMP as an opportunity for enterprise integration of information across the pharmaceutical value chain, offering insights into how such integration could be accomplished using established EA approaches. This article is geared towards regulatory operations and information management professionals who are part of regulatory affairs organisations, as well as IT professionals supporting regulatory in building capabilities to support the needs of regulatory affairs and operations. The article builds on the EA approach to IDMP presented by the author at the DIA EDM/ERS Conference in 2014[4] and also the relevance of Master Data Management to IDMP presented by the author at the DIA eRegulatory and Intelligence Conference in 2015.[5]

Business drivers

The primary business driver for the introduction of IDMP by the EMA is to monitor the safety profile of products on the market, especially with respect to safety signal detection.[2] EMA's key objectives are to have a clear understanding of all pharmaceutical products marketed within the EU, coordinating safety-monitoring and pharmacovigilance activities of medicines across the EU and facilitating international harmonisation activities. A by-product of this effort could be to monitor quality issues that may have an impact on the safety of products that are on the market. While compliance to the IDMP standard is a key business driver, IDMP has the potential to bring about efficiencies in information management across a large portion of the pharmaceutical value chain since it requires information to be collated, curated and maintained

Figure 1: Cross-functional input to IDMP with example data elements.



across multiple functional areas such as regulatory, quality, safety, clinical, manufacturing, supply chain, labelling, etc.

An opportunity for information integration

IDMP provides a great opportunity for pharma companies to review their information management approaches and create the necessary infrastructure and frameworks to support an integrated approach to gathering and managing information across the entire value chain. Most organisations are already working towards end-to-end visibility of regulatory information, which has been the driver for implementing integrated regulatory information management (RIM) solutions. Many organisations have already been exposed to the complexity of gathering data from multiple functions (albeit not as many as required for IDMP) through their efforts to meet the EVMPD/XEVMPD requirements of the EMA in July 2012. IDMP requires even greater integration of information across multiple functions and systems such as regulatory, labelling, safety, manufacturing, supply chain, clinical and quality as shown in Figure 1. This paper will discuss how an EA approach is best suited to integrate multiple systems together across multiple functions. It will introduce the relevance of three major components to accomplish enterprise integration to achieve the information needs of IDMP:

1. Master data management to manage key product, registration and other non-transactional information as master data
2. An information services bus to integrate multiple systems across multiple functions
3. A data warehouse to manage aggregated data for the purposes of reporting/transmitting IDMP data to regulators.

Enterprise architectural approach to IDMP

A brief overview of a generalised EA framework is given here. Essentially, there are five major components or layers related to EA:[6]

- *Business architecture* deals with the business process and organisational aspects of any capability implementation along with policies and procedures and governance
- *Application architecture* deals with how an information management application solution is designed, constructed and managed
- *Information/data architecture* deals with how the data/information is modelled in terms of entities and relationships reflecting the information needs of the business
- *Integration architecture* deals with how applications and/or data are integrated to satisfy the needs of a greater organisational purpose apart from satisfying individual departmental or functional needs
- *Technology architecture* deals with the underlying hardware and software infrastructure supporting the overall application and integration needs.

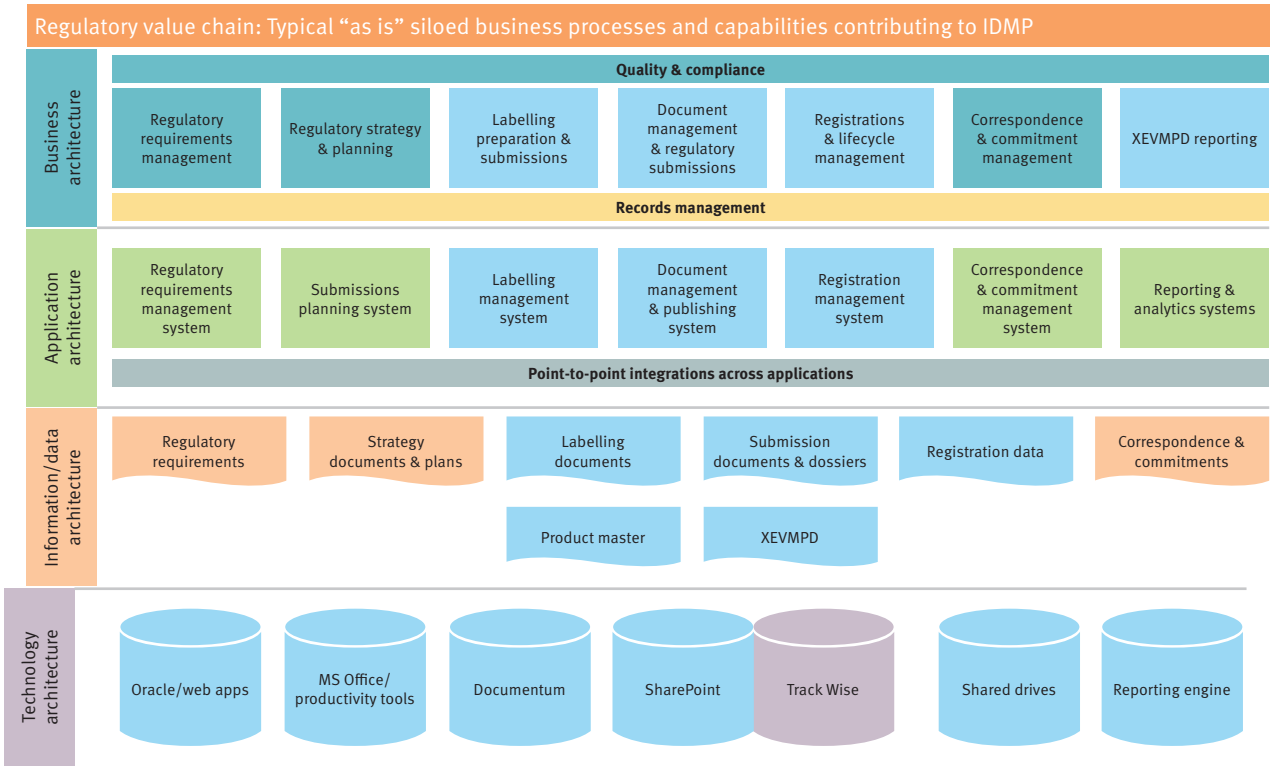
While business architecture and technology architecture are equally important as the other components of this framework, this article focuses only on application architecture, information/data architecture and integration architecture components with respect to IDMP.

Current state: siloed capabilities

As mentioned earlier, IDMP requires integration of information from multiple systems across multiple functions. In the regulatory function alone, typically there are eight to ten business processes satisfied by as many or more number of systems, each having their own information/data architecture and their own technology components. Among them, there could be at least three different systems managing information relevant to IDMP, for example:

- A *registration management system* managing, for example, medicinal product, packaged medicinal product and authorisation information
- A *labelling management system* managing the labelling content and documents such as the summary of product characteristics

Figure 2: Siloed regulatory current state with respect to IDMP.



(SmPC). Note that much of the product information, indication, clinical particulars, etc, are found in documents which are essentially unstructured

- A *document management/submission system* managing chemistry, manufacturing and controls (CMC) information such as ingredient, substances etc, in documents.

Figure 2 shows the typical current state EA view of this situation, only within regulatory.

The following are typical challenges with respect to the current state while trying to meet IDMP requirements:

- Multiple source systems spread across multiple functions; usually siloed and with point-to-point integrations or not fully integrated. Point-to-point integrations have a number of disadvantages especially due to the "spaghetti effect" when multiple systems are in play – they are not easy to maintain and are not cost-effective.[7]
- Some of the data exist in unstructured documents, making it difficult to readily extract data.
- Multiple systems imply data inconsistencies, data duplication, data quality issues and integration challenges.
- Different nomenclatures for similar data elements across multiple systems.
- Differences among globally planned, locally requested and nationally approved information.

The above is true not only within regulatory but across other functions and systems as well.

Future state: integrated capabilities

While end-to-end capabilities are difficult to achieve, as seen by efforts across industry to address RIM needs, integration of disparate applications can be accomplished using well-established integration frameworks and approaches. Three key integration approaches are suggested here:

- *Master data management (MDM)*. Master data are defined as common data about customers, suppliers, partners, products, materials, accounts and other critical "entities", that is commonly stored and replicated across IT systems.[8] Master data include data that do not change frequently compared with transactional data. In the case of IDMP, typical master data elements include generic name of product, dosage form and strength, indications, etc. These key masterable data elements can be managed in an MDM system, which benefits not only IDMP but other organisational business needs as well. MDM also results in lower costs by eliminating duplication of key data and minimising errors due to inconsistencies in data across multiple systems, etc. Many pharmaceutical organisations have embarked on MDM initiatives which can be leveraged and extended to suit the needs of IDMP. Not all IDMP data can be treated as master data (some IDMP data such as batch information are transactional); however. master data within an organisation could be utilised to source IDMP data needs.
- *Information services bus*. The concept of an "information services bus" or "enterprise service bus" has been around for a while; it is a mechanism to introduce a service-oriented architecture to integrate multiple applications through service definitions where consuming and producing applications have agreements on what data are available for exchange, and how they are exchanged. An information services bus eliminates the need for point-to-point integrations across multiple applications, which become unsustainable and cost-prohibitive over a period of time.[7] For the purposes of IDMP, the applications that could be connected together through the service bus include RIM, MDM, safety system, supply chain management, manufacturing, etc.

  As shown in Figure 3, an information services bus has a number of service definitions. In this example, it is shown that the service bus can enable master-data services by providing access to master data such as product name, authorisation status, etc, reference data services by providing access to reference data such as controlled vocabularies for indications, undesirable effects, and aggregation services by aggregating multiple data sources, etc.
- *Data warehouse*. While an information services bus enables integration of multiple applications, it does not directly support persistence of data. Sometimes, integrating data from multiple sources and producing IDMP data for submission to the regulators may not be sufficient, as an organisation may want to track what was submitted at a given point in time. In that case, persistence of data is required, and that is where the concept of a data warehouse becomes important. A data warehouse is a cost-effective way of integrating de-normalised data from multiple applications for the purposes of aggregation, reporting, analytics and metrics.[9]

As shown in Figure 4, IDMP data requirements can be met by sourcing and aggregating data from multiple applications across regulatory, safety, manufacturing, supply chain, labelling, etc, performing required transformation using extraction, transformation and loading (ETL) approaches and then managing the resulting data in a data-mart or a data warehouse. In turn, a reporting application can be leveraged to

Figure 3: Information services bus to integrate multiple applications for IDMP.

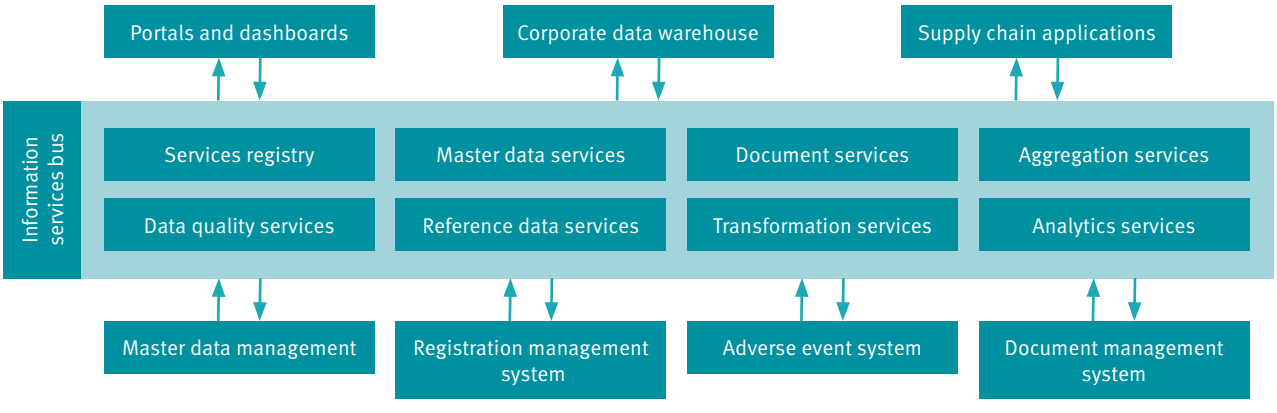


Table 1: Suggested approach for IDMP as an integration opportunity.

• Review the IDMP data model to understand data entities, relationships, data elements and their definitions
• Perform current state analysis on data sources across multiple functional areas within your organisation to map existence of data that may satisfy IDMP requirements; identify specific data elements, determine if they could be considered authoritative sources and also determine the quality of such data
• Identify gaps in data sources and data quality
• Define future state data architecture to satisfy IDMP data needs and also source systems from where data could be sourced
• Define an implementation strategy and roadmap
• Determine which data could be considered "master data" and accordingly define the MDM strategy and implementation approach. If MDM strategy already exists, determine if it has to be augmented to support IDMP data needs from a master data perspective. Leverage controlled vocabularies and reference data sources where appropriate
• Review integration approaches within the organisation such as service-oriented architectures or web services for the integration of multiple systems; this will avoid point-to-point integrations and instead build on service registries and other service-oriented constructs
• IDMP requires aggregation of both master data and transactional data; one way to accomplish this would be to leverage data warehouse approaches and capabilities that already exist within the organisation. Explore the use of an IDMP data-mart within the data warehouse so IDMP needs are met
• Data warehouse require extraction, transformation and loading (ETL) mechanisms; leverage ETL approaches that already exist in your organisation
• IDMP requires quality data to be submitted; this requires that source systems also maintain quality data and this requires ongoing data quality maintenance and governance, which is key not only to meet compliance requirements but also meet organisational objectives of efficiency, transparency, etc.

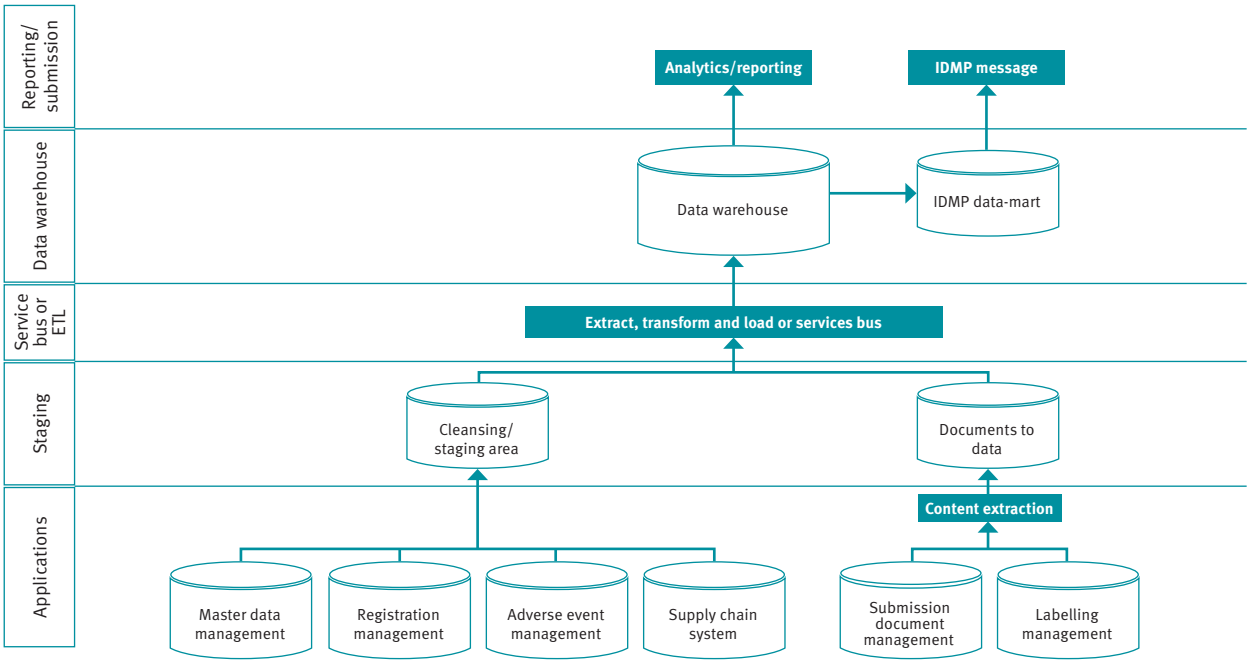
use the data warehouse to provide the necessary IDMP related reports or information. A suggested approach for IDMP as an integration opportunity is summarised in Table 1.

EA constructs such as MDM, information services bus and data warehouse together will address the needs of integrated information across the pharmaceutical value chain and hence the needs of IDMP as well. While there may be other approaches to accomplish the needs of IDMP, this article suggests more pragmatic approaches based on what may already exist in an organisation. It is possible for existing capabilities to be leveraged and/or extended to accomplish the needs of IDMP. It is time for industry to use IDMP as the springboard to embark on such initiatives, if this has not already been done, so companies can satisfy the business drivers of regulatory compliance, improved efficiencies and greater transparency.

Data quality and governance

It is well known that a system is only as good as the data within it. While this is true for all systems, it is more so for IDMP since it is going to be the aggregation of data from multiple sources. Industry as a whole must treat data and information as an enterprise asset, just as it treats

Figure 4: Data warehouse to generate IDMP data from multiple systems.



the pharmaceutical product which is prescribed to patients. Only when data are treated as enterprise assets will there be appropriate processes and controls to ensure the data in those systems are of high quality.[10] Pharmaceutical companies could learn a lot from financial and banking industries, where information is their lifeblood. It is key for people, processes and technologies across the entire value chain to ensure that data are of high quality.

The best way to assure data quality is to ensure adequate data governance mechanisms exist on the source systems, which naturally translates to quality data of the aggregated data, in this case IDMP. Of course, the ETL processes must also ensure that data quality is maintained throughout the process of data extraction, transformation and loading.

Conclusion

IDMP is a complex standard requiring cooperation and collaboration among many cross-functional units and integration of information across multiple systems. In addition, IDMP requires organisations to develop and sustain data quality and data governance approaches to ensure the right data are available all the time. While it will be challenging to achieve the requirements of IDMP, the standard has been introduced at the most opportune time, encouraging pharmaceutical companies to challenge their internal status quo around information management.

The constructs proposed in this article, such as MDM, information services bus and data warehouse, provide the necessary frameworks for integration across multiple functions and systems, thereby addressing the needs of regulatory compliance, increasing efficiencies, eliminating redundancies and increasing visibility to information across the pharmaceutical value chain.

References

1. ISO. IDMP Standards 11238, 11239, 11240, 11615, 11616. Available at: www.iso.org/iso/home/store/ (accessed 17 May 2015).
2. EMA. Implementation of Article 57(2), Second subparagraph of Regulation (EC) No 726/2004. Available at: www.ema.europa.eu/docs/en_GB/document_library/Presentation/2012/05/WC500126849.pdf
3. J Finkle. 'Planning for Successful IDMP Implementation', Regulatory Rapporteur, Vol 11, No 14, October 2014.
4. V Balasubramanian. 'An Architectural Approach to IDMP', DIA EDM/ERS Conference 2014, September 2014.
5. V Balasubramanian. 'IDMP as a Business Driver for Master Data Management', DIA eRegulatory and Intelligence Conference 2015, May 2015.
6. J W Ross, P Weill, D C Robertson. 'Enterprise Architecture as Strategy', Harvard Business School Press, 2006.
7. IBM. 'IBM Master Data Management: An MDM Overview'. Available at: www-01.ibm.com/software/data/master-data-management/overview.html (accessed 30 March 2015).
8. R Ramanathan, K Raja. 'Service-Driven Approaches to Architecture and Enterprise Integration', IGI Global, 2013.
9. Microsoft. 'The Microsoft Modern Data Warehouse'. Available at: http://download.microsoft.com/download/C/2/D/C2D2D5FA-768A-49AD-8957-1A434C6C8126/The_Microsoft_Modern_Data_Warehouse_White_Paper.pdf (accessed 17 May 2015)
10. A Sherlock. 'Regulatory Information Management as a Strategic Asset', PharmExec.com. Available at: www.pharmexec.com/regulatory-information-management-strategic-asset?rel=canonical (accessed 17 May 2015).