Model-Driven Interoperability to enhance Product Data Quality

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Abstract. Data quality presents a major issue to reduce product cost and improve time-to-market for the vaccine industry. In fact, the molecular definition of vaccine product must be well formalized in the supply chain perimeter to be always compliant with the regulatory approved definition of the product.
To ensure product data quality, we study in this paper the concepts of model-driven interoperability and we highlight their capabilities to connect some models related to heterogeneous information systems. Therefore, to deal with product complexity and the diversity of its definitions inside the supply chain perimeter, we propose in this work a five steps approach based on MDI concepts. The proposed architecture deals with some specific product data identified as critical in our context and allows ensuring their quality in the Enterprise Resource Planning (ERP), as the main production information system in the vaccine industry. When deployed, our work provides some interesting results at Sanofi Pasteur France company.

Keywords: Model-Driven Interoperability, Product data quality, Reference frames, Vaccine supply chain.

1 Introduction

Data quality is widely considered as a critical problem inside industry. According to [1, 2], more than 52 % of audited enterprises confirm that they suffer from problems related to the lack of data quality. From a research perspective, data quality refers to many research domains. In fact, the quality of data definition between heterogeneous systems is related to the ontology concepts. Furthermore, the quality of data producing is related to enterprise modeling concepts. Also, the quality of data coding and treatment is related to software engineering, and data exchange is related to interoperability concepts. Basing on some diverse concepts related to these research domains, we propose in this paper an approach to ensure product data quality in the perimeter of vaccine supply chain.

We present in the next session some approaches dealing with data quality inside an independent information system as well as between heterogeneous systems. In the third section, we present some related works about the application of a Model-Driven Interoperability approaches. Furthermore, we explain in the fourth section our approach to ensure product data quality in the supply chain perimeter of vaccine industry. Next, we discuss in the fifth section some results reached with the deployment of our architecture. We present finally some conclusions and perspectives.

2 The data quality challenge

2.1 The vaccine supply chain

The specificity of vaccine industry dominates in the particular definition of its product, the vaccine [3]. At the production stage, we can only control the manufacturing process and not the product itself. Indeed, the biological aspect of the active substances in vaccines differs from product in the chemical industry (i.e. pharmaceutical industry) by a very complex structure. The biological production consists of a mixture of molecular substances not always well identified. This specificity makes the control procedures, already different from one product to another, both delicate and complex.

To produce and market a new vaccine, it is necessary to prove to health authorities (WHO http://www.who.int/, FDA in the USA http://www.fda.gov/, etc) the utility of the vaccine [4, 5]. This passes by the submission of "Marketing Authorization (MA) Request" to the Health Authorities of destination countries. The MA contains all information collected during the process of research and development. Once the product is approved, it can be manufactured and distributed inside this country.

When product data evolves in interaction with several information systems, their conformity with the regulatory definition is rapidly altered. In fact, according to each business context, product data can be adapted to some local objectives as: manufacturing more for the producer, selling more for the business units, breaking the release of more products until the verification of all product quality dimensions, etc. The consequences of data quality deficiency can be detected when some component batches reach their shelf life before their integration in final products composition. Some adapted solutions are required to ensure product data quality in such context.

2.2 Research about data quality

In an industrial context, the product quality objective is approached via the proposition of some local standards as procedures for quality control or international standards as guidelines to follow in a quality insurance perspective. However, dealing with data quality still less structured and considered as an interesting research activity

to address. Actually, data quality has been addressed in different areas, including statistics, management, and computer science [6].

From a computer science point of view, data quality is defined as follows: data has quality if it satisfies the requirements of its intended use [7]. To reach the quality objective, many data quality dimensions are proposed such as: accuracy, opportunity, pertinence, exhaustively, etc. and some measurement rules are defined to evaluate them [8-11].

Seen at the perimeter of an information system, proposed data quality approaches cover especially some structured data at a database level. [7, 12] propose some research issues dealing with data quality such as: the data profiling concepts, the extend of Entity-Relationship model to integrate data quality parameters, the expansion of relational model to capture some quality attributes, the definition of some quality parameters, the definition of data quality algebra, etc.

At a supply chain perimeter, the data quality problem is defined between heterogeneous information systems evolving in different business contexts. [12] propose "the context interchange architecture" to integrate and make use of heterogeneous information sources with the definition of "Wrapping" and "Mediation" concepts. [6] propose "the Total Data Quality Management" as a comparative analysis methodology to evaluate data quality. Also, they propose the "Complete Data Quality Management" as a methodology to evaluate the correspondence between different data states and defined business processes. Recently, [13] proposes a "data quality project" concept with the definition of some measurable criteria to reach a predefined business target.

2.3 Data quality in vaccine industry passes by interoperability concepts

During the past few years, vaccine production technologies have developed with more sophisticated tests and more strict regulations to define procedures and best practices. The definition of vaccine product in the R&D stage is structured in a Common Technical Documents format (CTD) as a standard model and format imposed by the health authorities to submit Marketing Authorizations (MA). The CTD format consists on a classification of related paper documents through some predefined sections. When the MA is approved, these documents are scanned to be archived next.

Throughout the production process, many business activities interact to manufacture and control product components. In this stage, the same product is defined in several information systems according to each local business specifications. Product definition can appear as printed procedures, a standard working instructions or electronic documents. The interaction between different business activities in the production stage is traditionally done by paper documents to preserve the traceability, especially of manufactured batches. Some electronic documents are forwarded in electronic formats (generally Excel).

The complexity of product definition in the R&D stage is reflected, through different business activities in the production stage, by some heterogeneous and disconnected information systems. Many barriers resist constituting a transverse view of the vaccine product at the production stage. Defined business processes are disconnected through business activities.

In this specific context of vaccine supply chain perimeter, the challenge to ensure product data quality remains unreachable with proposed approaches. In fact, at the information system level the data quality problem is approached in terms of data structuring. To address data quality dilemma through several information systems, proposed approaches are generally oriented to the definition of some quality indicators and propose some methodologies to assess them. These approaches are more suitable when data quality is addresses from a strategic or a tactic point of view. From an operational level, more adapted solutions are requested to deals with product data quality in the supply chain perimeter of vaccine industry. The integrity of product data is rapidly altered as well as information systems evolve.

For the specific context of vaccine industry, many information systems develop in the supply chain perimeter. The Enterprise Resource Planning (ERP) is considered as the main system supporting product definition as well as some business activities. The ERP system interacts with many information systems in this perimeter and develops a bidirectional data exchange (Fig 1).

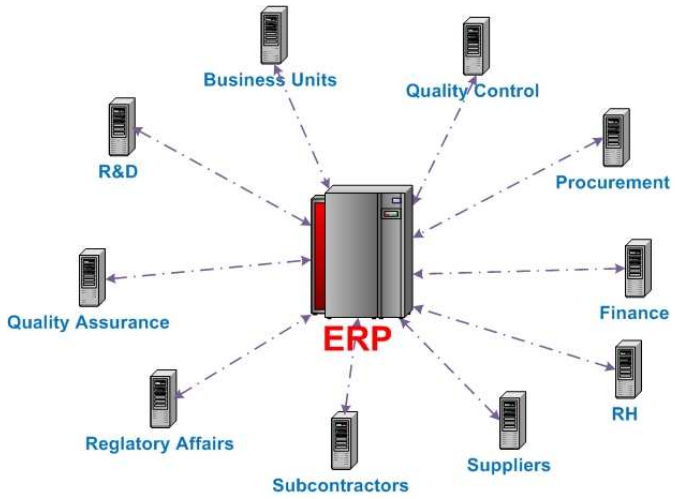

Fig. 1. The interaction with the ERP system in vaccine supply chain

When business opportunities expand, the product definition evolves to be aligned with the new defined business strategy. The preservation of the quality of product data definition in the ERP becomes a big challenge when the interaction between information systems is performed according to different business positions and priorities. To approach the data quality problem, the concepts of interoperability between heterogeneous information systems may bring some issues in the supply chain perimeter to connect the different occurrences of product data evolving in these systems and establish some communication ways between them.

The different barriers presented previously constitute some barriers for interoperability. According to [14], we identify three types of barriers:

- Conceptual barriers: They are concerned with the syntactic and semantic differences of product information to be exchanged through different business activities.

- Technological barriers: These barriers refer to the incompatibility of information technologies (architectures, platforms, infrastructures…)
- Organizational barriers: They relate to the definition of responsibility, authority, etc.

All these barriers are well identified in the vaccine industry and especially in our particular context of Sanofi Pasteur Company.

The European projects ATHENA [15, 16] and INTEROP [17, 18] provide more specifications about interoperability concepts and identify at least four abstraction level of interoperability between systems as well inter than intra-organizations :

- The business level: refers to some organizational interoperability issues to work together partners from different business activities with different business culture, legislations, and especially priorities.
- The process level: refers to different issues to make various processes work together. This connection is requested first in our context between some processes already defined in different business contexts. The purpose to connect processes in a networked enterprise between companies still a long term objective in vaccine industry.
- The application and service levels: refer to issues to indentify, compose and make function together various applications.
- The data level: refers to issues to connect different data models developed in different machines with different platforms and deploying different operating systems.

In addition to these interoperability levels, further dimensions must be addressed such as the knowledge dimensions (not always capitalized to be modeled and structured in information systems) and the semantic dimension to preserve the coherence between defined interoperability levels.

To perform communication at these different interoperability levels, the ISO 14258 [19] proposes three basic ways to connect models together in order to establish interoperation:

- The integration: refers to the existence and the use of a common format for all models related to the systems in interoperation.
- The unification: refers to the existence and the use of a common format but only at a meta-model level related to the systems in interoperation. This meta-model is not an executable entity as it is in the integrated approach but provides a mean for semantic equivalence to allow mapping between models.
- The federation: refers to the impossibility of defining a common format for all systems in interoperation. This means that they must share an ontology.

Due to the diversity of systems evolving in the supply chain perimeter of vaccine industry and the need to ensure product data quality inside, the federation approach are requested to develop an interoperability framework. Some organizational barriers prevent the deployment of such initiatives due to the magnitude of such project, the maturity of participants and especially the complexity and the permanent evolution of the reality of such industry.

We choose in our work to reduce our objective to some specific product data, identified as the most critical in the supply chain perimeter. Therefore, we have to identify for each system different models that impact data throughout different interoperability levels and we choose to explore the model driven engineering

interoperability concepts to reflect the business, functional and architectural specifications of each systems at the product data level in order to ensure product data quality. We aim with this work to translate vaccine interoperability problem from a federated to an unified interoperability approach.

We present in the following section some specifications of the model-driven interoperability concepts and we detail in the fourth section our approach to ensure product data quality.

3 The emergence of the Model-Driven Interoperability concepts

The evolution of MDA concepts go back to 2001 [20] with the fist specification proposed by the OMG. The interest in the MDA evolves with the proposition of the full specifications in 2003 by [21] and marks the new approaches for software engineering. In addition, the MDA concepts are developed to deal with model problems in technologies for interoperability [22]. The Athena project [16] proposes a complete model-driven interoperability framework. [23] present an interoperability framework for model-driven engineering of enterprise software applications. This framework provides the concepts for software engineering to support interoperability between enterprise business systems.

To solve problems in the parameterization process of ERP systems, [24] present a model-driven approach to deal with the standard model proposed by the ERP when it does not match the enterprise requirements.

Moreover, [25] are interested in model transformation process. They present a transformation framework to convert an enterprise model defined in GRAI language to an activity based UML model at the same CIM abstraction level of the MDA framework. [26] present also a transformation framework from CIM to PIM abstraction level to ensure interoperability.

The data quality problem is not widely addressed via MDA approaches. [27] propose an event management framework to improve information quality. [28] present an approach to structure the quality requirements to build dependent information systems. [29] highlight the need of preserving and improving the quality of data models through the transformation process and propose a state of the art about modeling related languages, tools, modeling processes, quality insurance techniques, etc.

Basing on model-driven interoperability concepts, we develop in the following section our approach for product data quality in the specific context of vaccine industry.

4 MDI for Data quality

We propose a five steps approach to ensure product data quality in the vaccine supply chain perimeter.

4.1 The definition of some critical data

As announced previously, to ensure data quality, we choose to target a reduced number of product data, identified as the most shared and the mainly critical in the vaccine supply chain perimeter. As examples of these data, we identify the *manufacturing site*, the *shelf life*, the *storage conditions* and the *batch size* of one manufactured component in a given product. These data are identified as critical because they present an important impact in regulation respect, planning stability, production processes, etc. Each data is impacted by the evolution of one or many information systems in our perimeter. When these systems evaluate, it is very difficult to maintain the quality of critical product data. Therefore, in the next step we will analyze the specificities of each critical product data throughout its lifecycle to provide a large visibility about data evolution capabilities.

4.2 The appropriation of critical product data

We analyze in this step the lifecycle of each critical data in order to structure the potential impact of each business service as well as their systems. As an example, we present in the following figure (Fig 2) the evolution of the data "component storage condition" throughout its lifecycle.

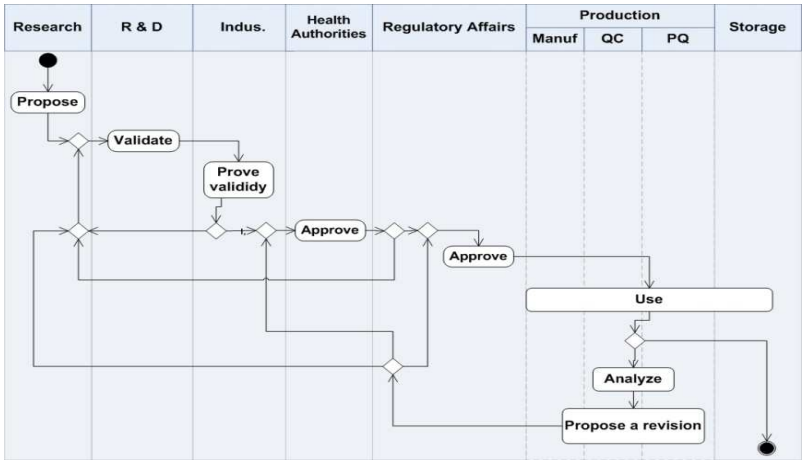

Fig. 2. The evolution of storage condition product data throughout its lifecycle

This UML activity diagram illustrates the interaction of each supply chain service with this critical data.

4.3 The deployment of MDA concepts

4.3.1 The analysis of supply chain perimeter

According to the description of the vaccine supply chain presented previously, many business activities should interact to define a common validated occurrence of one critical product data to be updated in one information system. Each member of our supply chain develops for their core activities some models that can be aligned through each interoperability level. These models are not always formalized and can be structured in just some procedures, best practices, guidelines and may be some specific knowledge related to the expertise level of some collaborators. To identify models impacting these critical data, we choose to start our analysis from a discussion with supply chain actors about the following question: "what we have to check if we want to update such product data in such business domain?"

This analysis method allows us to understand the specificities of our supply chain around a transverse view of our critical product data. As example, if we analyze the regulatory affairs impact on each critical data, we can identify these specificities at each interoperability level:

- At the business level: some best practices and specific knowledge to consider when modifying critical product data, in particular: the specifications of Marketing Authorizations, destinations countries or the latest approved authorization license.
- At the process level: some regulatory process models defined to perform product data modification. It is about the identification of modification types, the notification for concerned destination countries, the management of engendered modification lead-times, the date and the period of the activation of the new data value, etc.
- At the application level: some coherence rules to verify the functional structuring of different module as the attribution of data utility flag to inform about the use possibility of data (verified or not-verified).
- At the data level: some integrity constraints defined to maintain data consistency in the databases.

To deal with all constraints expressed at these interoperability levels in order to ensure product data quality, we propose following an original approach based on Model-Driven Architectures (MDA) concepts.

4.3.2 The application of the MDA Framework

Our approach aims at its perspective to develop a new software application devoted to manage product data and ensure their quality in the perimeter of vaccine supply chain. This approach deals with all the information (models, best practices, constraints, etc.) identified through the different interoperability levels to structure them through the three abstraction levels of MDA [21, 30, 31]

The conceptual model related to the deployment of MDA consists in:

- The use of the appropriation model identified in the second step (section 4.2) as a high abstraction level of a Computer Independent Model (CIM). This model would has to be transformed to a new CIM model (CIM2CIM transformation), expressed at the supply chain context by the integration of

additional constraints expressed from business and process models already defined at each supply chain service

- Afterward, the second CIM model has to be transformed in a functional and architectural Platform Independent Model (PIM). However, we are unable with this first release of our work to constitute and merge business models from different services to feed the transformation process from the first CIM model to the second one. This is due to the lack of visibility and coherence between the different business strategies of all the partners in the vaccine supply chain. Therefore, we propose to transform manually the first CIM model to a PIM Model with the integration of different business models capitalized from all supply chain systems as constraints.
- The deployment of the MDA Framework [32] allows to integrate process and application models and constraints to generate a Platform Specific Model (PSM). This PSM model should reflect all the specificities of supply chain systems and presents a common approved view of product data model. In the perspective to develop a new application, this PSM model should be transformed to obtain the code. However, we propose in our particular context to make use of this PSM when it is expressed in the same platform than the information system where we need to ensure data quality. Data quality is achieved when we compare the generated new model with the exiting one.

We present in the following figure (Fig 3) these model transformation steps through the different MDA abstraction levels.

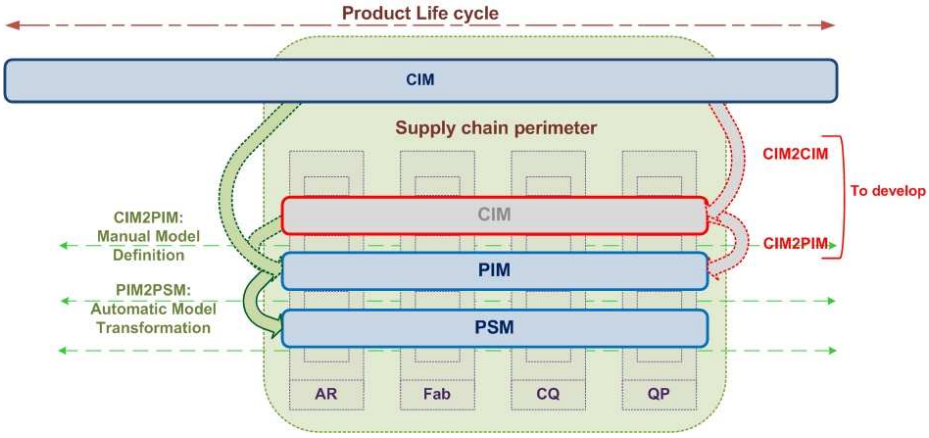

Fig. 3. The application of MDA concepts

We present following some technical information about the PIM to PSM transformation process.

4.3.3 PIM to PSM transformation

The PIM model is manually defined in the UML language. It is about an iterative process that we update frequently to modify or integrate additional constraints from

different systems in our supply chain perimeter. These constraints are usually related to the specificities of some products or some irregular processes.
The new generated PSM model is to be expresses in relational language. We provide for using this model to confront it with the one of the Enterprise Resource Planning (ERP) system and ensure critical product data quality inside.
The choice of UML and the SQL meta-model is directly related to the technical transformation Framework. In this work, we explore two Frameworks:

- The ATL Framework is explored first to implement the UML and SQL meta-models from the ISO/IEC 9075:1992 proposed in [31] using the Kernel MetaMetaModel (KM3) language [33].
- The KerMeta Framework is explored secondly to implement the same UML and SQL meta-models from the ISO/IEC 9075:1992 using the KerMeta metamodeling language [34].

Due to the lack of stability using these metamodels with these frameworks, we prefer to support the transformation process with the ATL Framework using the proposed UML and SQL metamodels. The SQL model resulting in the ecore file (XMI format) is edited to reconstitute the logical model of the database.

The application of our architecture to ensure critical product data quality in the Enterprise Resource Planning (ERP) system passes by the mapping of the new generated PSM model and a specific data model defined as an abstraction of the ERP data model at the perimeter of these critical data. In the mapping process, we aim to feed existent application models with all entities needed to maintain data quality under a global vision of product data in the vaccine supply chain. To structure the mapping process, we propose following the concept of “reference model” as a framework to capitalize all necessary information needed to ensure product data value.

4.4 The reference model

As exposed previously, when we deal with data quality, we address some quality dimensions to analyze and enhance. To ensure the quality of critical product data in the ERP system, we choose to address the following data quality dimensions:

- The accuracy of the data value.
- The validity of the data value in the ERP system.
- The conformity of data value to its definition source as well as to its definition in the vaccine supply chain perimeter.
- The coherence of data value according to production process.

We can consider that the others data quality dimensions are already satisfied when product data are already defined and structured in the ERP system.

To reach selected quality dimension, we propose to define a Reference Model as a framework to structure:

- The product data value to define.
- Some formal rules to structure all rules needed to update a product data value in the ERP system: procedures to update such product data in the ERP system.

- Some informal rules defined from the mapping of the new PSM model, generated through the MDA framework, and the one from the ERP system. As example of informal rules, we can identify those related to the mapping process as correspondence, aggregation, of interpretation; those related to the semantic correspondence between data values ("Between +2°C and +8°C" Ξ "Between + 2°C / + 8°C" Ξ "5±3°C" Ξ "T2"), etc.

Using these defined informal rules, product data value is defined for all product components independently. To be conforming to the definition and the structuring of product data in the ERP system, several coherence rules need to be defined. In fact some components enter in the composition of several final products. The figure 4 illustrates a simple presentation of a multilevel bill of materials (BOM). Each manufactured product components is presented by a state (S1 to S6) and the link between two successive states presents a BOM level. Therefore, the first product state is presented by S1 and the last, i.e. the final product, is presented by S6. The definition of a common component data value in the ERP is very recurrent and must be coherent with the structuring of the entire product and especially with the specifications of product destination country.

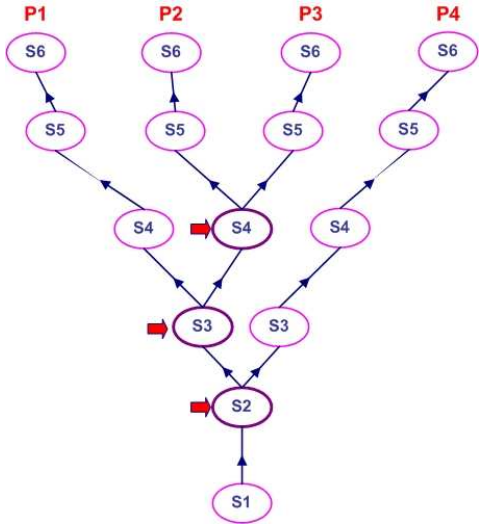

Fig. 4. Component reuse

As example, the component S3 enters in the composition of the three final products: P1, P2 and P3. The critical data definition for the product state S3 in these three products must be identical; otherwise, we must duplicate the definition of this product state and check different BOMs.

We present in the following figure (Fig 4) an overview about the interaction of the Reference Models with the defined architecture in order to structure the mapping process between different data model and ensure product data quality in the ERP system.

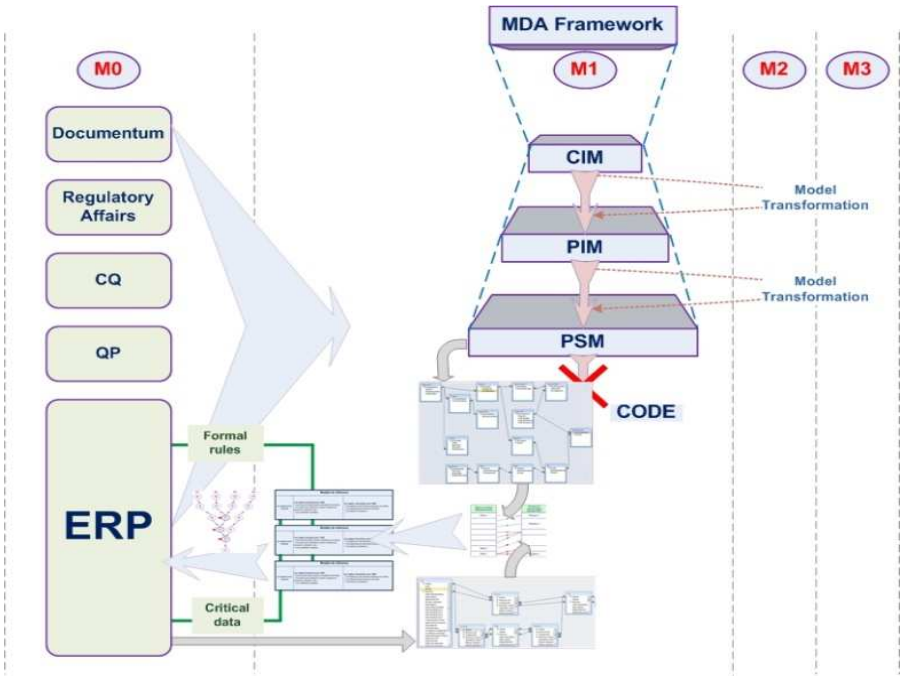

Fig. 5. The role of the reference models in proposed architecture.

Face to the huge volume of metadata generated throughout our architecture, we propose following some structuring issues.

4.5 The reference frames

During the previous fourth steps, a lot of metadata are generated when defining models, metamodels, reference models, etc. All these data need to be structured to ensure their traceability and especially to share them between the supply chain actors. Therefore, three levels of reference frames are defined:

- An enterprise reference frame is defined to structure the first Computer Independent Model (CIM) and share it at the enterprise level. All enterprise actors can review models to maintain their coherence and validity throughout product data lifecycle.
- A domain reference frame is defined at the perimeter of vaccine supply chain to structure the second CIM model as well as the Platform Independent Models (PIM). All supply chain actors can review defined models.
- An application reference frame is defined at the perimeter of the Enterprise Resource Planning (ERP) to structure the Platform Specific Model (PSM), the data model generated from the ERP, all models defined for the MDA Framework, the data reference models, etc. This application reference frame contain all information needed to ensure product data quality in the ERP system.

To ensure the structuring of metadata in these reference frames, different technologies [35] are proposed in the literature but not covered actually by this work.

6 Discussion

The complexity of vaccine industry and the need to propose some pragmatic solutions to enhance product data quality are the most important drivers to guide the different proposed steps of our approaches. Dealing with some critical data in the supply chain perimeter allows as to progress from a federated to an unified interoperability approach to deal with systems heterogeneity and ensure product data quality.

The proposed approach takes advantage from the evolution of model-driven engineering concepts to propose an interoperability framework in order to ensure product data quality. However, we have to deal with some difficulties:

- The proposition of a common business models at the second CIM level is not very easy. We are usually faced to some divergent directives related to the core business activities. Therefore, we choice to identify just some business constraints to integrate when we transform the first CIM model to a PIM model.
- The platform and the frameworks used to deploy MDA concepts suffer from an important lack of stability. The transformation process is enough hard to perform even when meta-models are well defined according to their description languages.
- The quality of the defined model at the PIM level drives the quality of generated model in the PSM level that also drives the quality of data in the ERP system. The permanent evolution of the PIM model to integrate additional constraints may generate divergent rules to drive product data quality. This lack of stability in the outcomes of our approach can limits their approval by the supply chain community.
- The shared models through the different reference frames are still difficult to understand for all supply chain actors. A personal accompaniment is requested to verify or enhance these models.
- The proposed mapping rules must be explained to validate the quality of product data, but not to suggest the evolution of the ERP data model.

When deployed, our approach allows us to verify the quality of three product line. Actually, we finish the verification of the quality of the identified critical product data (manufacturing site, storage condition, shelf life and batch size) for each manufactured component in only one product line. Additional efforts must be spent for the other product lines.

Conclusion

We present in this paper a Model-Driven Interoperability approach to ensure product data quality in the specific context of vaccine industry. Our approach is interested to

ensure the quality of some specific product data identified as the most critical in the vaccine supply chain perimeter.

The application of MDA concepts presents the core of the proposed approach. We aim to optimize the proposed models and exceed the lack of stability of available platforms by the integration of more modeling specificities coming from the recent standards such as the ISO/IEC 19763 devoted to Information technology and Metamodel framework for interoperability (MFI). This standard proposes some interesting connections with the Health Level Seven (HL7) SDO standard dedicated to deal with health care information.

In the other hand, we project to develop the MDI concepts to deal with other important problems in the vaccine industry especially for the regulatory planning.

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