Innovit Healthcare Insights

What's best to address your regulatory data submission challenges? PIM or PLM?

There's a mounting list of regulations aimed towards Unique Device Identification (UDI), intended to improve patient safety, supply chain efficiency and post-market surveillance. The benefits are numerous, but challenges continue for medical device suppliers on their long – and often painful - journey to tackle those UDI requirements.

For example, manufacturers are presented with the challenge of submitting UDI data to a myriad of country-specific regulatory agencies, each with their own set of variations. In addition to regulatory compliance imperatives, manufacturers are also expected to provide product data to distributors, GPOs and hospitals for commercial and supply chain needs. It is within this business landscape that manufacturers must assess whether they need to deploy their UDI submission solutions alongside their Product Lifecycle Management (PLM) or Product Information Management (PIM) systems.

Though PLM and PIM systems have completely different purposes, there is an incorrect assumption that both are equally suited to address regulatory submissions. Let's first take a quick look at both applications and help provide some clarity on their intended purpose, overlapping capabilities and functional differences.

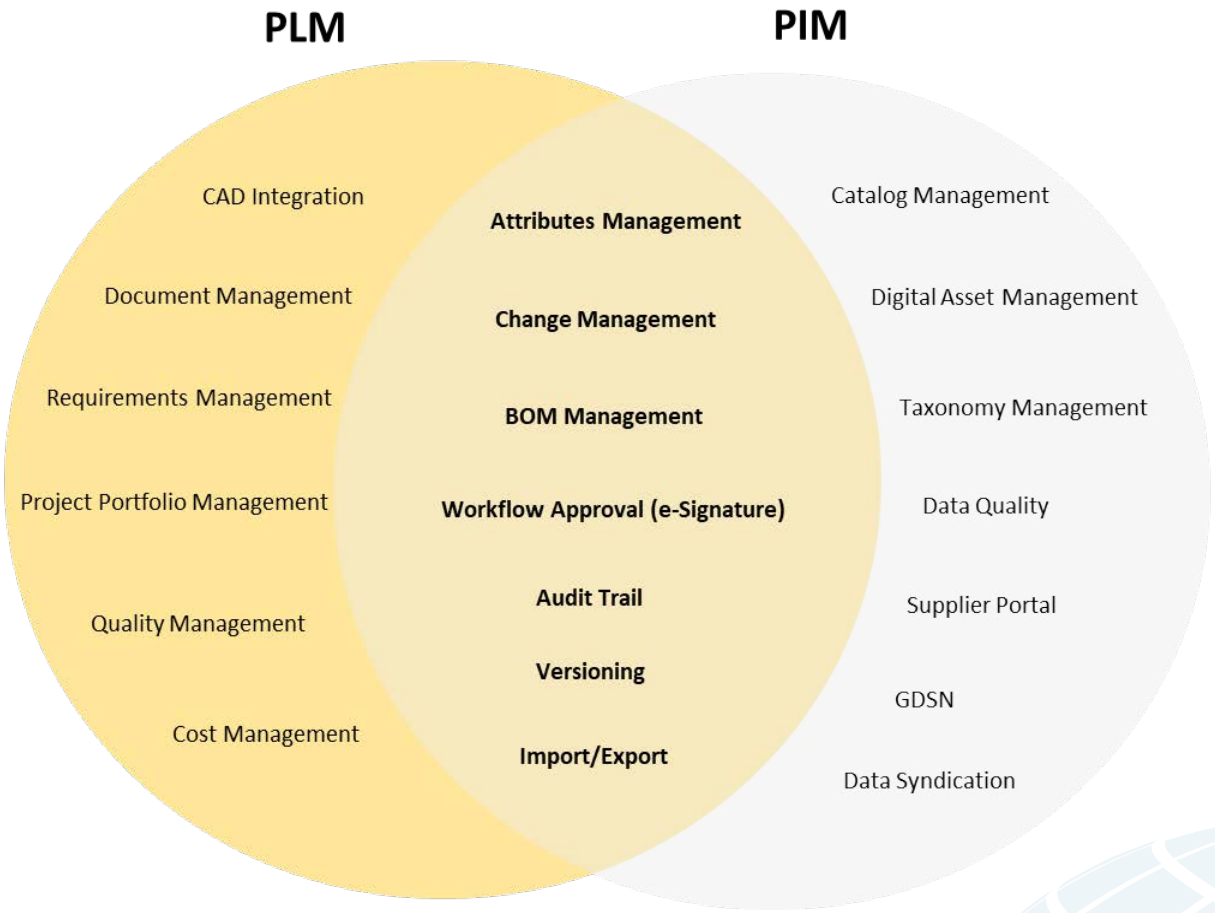
innovit

"Are PIM and PLM *equally* suited to address regulatory submissions?"

PLM vs PIM Overview

	PLM	PIM
Primary Function	Enable the entire process of ideation, conceptualization, engineering and manufacturing of products including post-sale service and obsolescence	Enable centralized management of product and catalog data for purposes of tailoring, validating and distributing product information to various internal and external channels
Typical Users	Engineers R&D Quality Managers	Marketing Sales Supply Chain Data Stewards
Typical Product Lifecycle Phase	Concept, Design, Development, Pre-Production, Production	Production, Commercialization
Typical Data Sources	CAD Systems Usually source/author of product data	PLM ERP Suppliers Usually consumer of product data
Typical Target Systems	PIM Manufacturing Quality Management Cost Management Portfolio Management	eCommerce Channels Distributor Portals Supply Chain Applications ERP BI/Data Warehouse GDSN

PLM vs PIM Functionality Comparison



Product Lifecycle Managment

Product Lifecycle Management (PLM) is software–enabled for overseeing the entire lifecycle of a product. It includes everything from the idea, design and prototyping to product manufacturing, release, post-sale service and the disposal of products. It's about the business process involved with developing and releasing products and carries all the technical information of a product to date.

What it's ideal for:

If your organization is developing new products, then a PLM system helps to make the product development process more collaborative, transparent and efficient with shorter product development cycles.

What it doesn't do:

PLM systems seldom include marketing and sales information, nor supply chain data required for the GDSN. In addition, the system does not directly publish or distribute the product information to customer-facing websites, distributor portals or retailer-specific channels (GDSN and non-GDSN).

Product Information Management

Product Information Management (PIM) on the other hand, is a set of processes and tools that aggregate product master data into a single repository. It allows the data to be transformed, personalized and syndicated. The result yields an accurate view of product data that can be highly tailored to the needs of each distribution channel, trading partner and target market. PIM systems can personalize, validate and publish data as required by the target systems and publishing via GDSN.

What it's ideal for:

For businesses that host complex product content or contain a high number of SKUs, PIM is key. If your company is collecting product data from multiple sources and needs to enrich, personalize, validate and publish content to various channels, trading partners and systems, then PIM is the right solution for you.

What it doesn't do:

PIM does not actively author or manage product requirements, engineering BOMs (e-BOMs), Engineering Change Orders (ECOs), Quality Issues, Portfolio Analysis, Cost Management and others. It is not directly integrated to CAD Systems.

Which is the Right Choice to Address Regulatory Data Challenges?

Most organizations have some measure of product data required for regulatory submission within their PLM system. Often deployed as a validated system, the PLM has key product functionality such as attribute extensibility, change management, workflow and audit trail already available within the application.

As a result, many companies continued along this path, adding more related attributes directly into the PLM system. Unfortunately, these same companies are hitting a wall – as this process is neither efficient nor scalable. Typical roadblocks may include:

- Additional countries are developing their own UDI regulations each with their own different requirements
- PLM applications are being extended to store more and more attributes that have no relevance to the product engineering and manufacturing process
- PLM applications are being extended/customized to store multi-lingual product data
- PLM applications are being extended/customized to publish data in different file formats and messaging protocols
- The core PLM users responsible for the design, engineering and manufacturing process are disrupted due to more rigid data modeling and validation requirements, regulatory related upgrade cycles and workflow processes

An alternative strategy is required, and many organizations are turning to **PIM solutions** for regulatory data submissions.

Unlike a PLM system, a PIM solution is designed precisely to handle the data variations required by different channels, trading partners and regulatory agencies. It is designed to maintain large volumes of product data including those that are target-market specific. Most PIM systems support multi-lingual data maintenance and they provide the ability to easily extend their data model to support new data requirements. It's also worth noting that important features such as change management, workflow, data validation, audit trail and e-signature are also part of most PIM solutions. Finally, PIM solutions provide much more flexibility for data publication in different file formats and messaging protocols since they are designed from the outset to enable data synchronization to multiple systems.

PLM and PIM are Complementary

When deployed correctly in a best-practice architecture, PLM and PIM are highly complementary. PLM can support its core focus of enabling the end-to-end product development and manufacturing processes and feed product data to the PIM system. The PIM application can enrich the data with additional attributes required for regulatory submission, supply chain, GDSN and other channels and allow the validation and syndication of product data from a single application. This approach not only allows PLM and PIM applications to be used for their core focus but also gives organizations the best platform to scale and adopt to expanding regulatory and commercial data requirements.

400 Concar Drive
San Mateo, CA 94402
USA

www.innovit.com

Tel: +1 512 730 3800
Fax: +1 888 478 4438

ABOUT INNOVIT

Innovit's globally certified product master data management solutions protect revenue streams, reduce supply chain costs, improve online product marketing effectiveness, and ensure regulatory compliance. Delivering the fastest time to value for a complete end-to-end solution, Innovit provides preconfigured modules that have out-of-the-box data validation, the broadest global coverage for data synchronization, and publication capabilities that offer maximum syndication advantage for omni-channel commerce. Operating since 2000, Innovit is based in San Francisco with offices in London, Sydney and Melbourne that service customers such as Johnson & Johnson, Kellogg's, 3M, B. Braun and Colgate Palmolive across diverse industries including healthcare, CPG and automotive aftermarket.