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SOLIDWORKS ENTERPRISE PDM FOR MEDICAL DEVICE MANUFACTURERS

Overview

In evaluating all the essential criteria for selecting a system of record for your electronic CAD and engineering documents, you will find that SolidWorks® Enterprise PDM has been designed and developed to help companies in the medical field comply with the guidelines and requirements of the FDA's 21 CFR Part 11 rule regarding the management of these documents.

Compliance with
FDA 21 CFR Part 11

SOLIDWORKS

Extend the Value of SolidWorks with SolidWorks Enterprise PDM

It is clear that the SolidWorks mechanical design and simulation solutions give medical device manufacturers a decided advantage in delivering more innovative products to market in a reliable and time-efficient manner.

Today, the medical devices engineering business is driven by a need to manage information digitally. Ensuring the authenticity, integrity, confidentiality, traceability and security of the electronic data pertaining to engineering information is becoming required for most medical devices companies wanting to meet and comply with US FDA CFR 21 Part 11 regulation.

Incorporating SolidWorks Enterprise PDM into your computing environment raises the operational efficiency of your product development team, by enabling key constituents in the process to work more knowledgably and efficiently. SolidWorks mechanical design and data management applications combine to ensure the quality and integrity of your CAD data throughout the product development lifecycle. This is an absolute requirement for FDA regulated companies that must validate the integrity of all documents of record that are subject to audit.

Integrated SolidWorks assembly analysis, eDrawings® communication, and SolidWorks PDM software help Berchtold Corporation to validate design performance quickly, and utilize design data efficiently across engineering and business functions

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Electronic Signatures

Moreover, SolidWorks Enterprise PDM supports the electronic signature and records management requirements of 21 CFR Part 11, significantly reducing the risk, time, and effort associated with adhering to these FDA regulations. Every design change along with the review and approval events throughout the product development process are electronically recorded, providing a fully accountable audit trail.

The modular design of SolidWorks Enterprise PDM allows you to introduce its capabilities in a multi-phase implementation methodology, each phase with a clear set of defined goals and business value contributions.

Phase I - Product Data Management (PDM)

Medical device manufacturers have traditionally utilized paper copies of design drawings as documents of record when preparing a Design History File (DHF) or Device Master Record (DMR) for records archival, which introduces non-value-added, manual steps to the overall development process. An FDA compliance audit may uncover the fact that you are unable to trace the paper artifact back to the correct versions of the electronic CAD files from which it was derived. Cost cutting, time saving, and risk mitigation initiatives are driving companies to generate more of their design data electronically, greatly increasing the potential value of a completely electronic records management solution. The first and most critical phase in the pursuit of full electronic records management compliance for 21 CFR Part 11 relative to your engineering design data is to establish a reliable and systematic methodology to ensure the integrity of your engineering documents of record.

SolidWorks Enterprise PDM allows you to gain control of the large number of CAD files and associated engineering information that you have scattered throughout your network by centralizing the storage of all files, guaranteeing that one and only one copy of each file is recognized as the authoritative version. This is known as a single version of the truth.

In addition to information centralization, all dependencies between files are automatically managed, ensuring that assembly and part models, as well as drawings, can be reliably and accurately regenerated upon retrieval. These basic capabilities eliminate the significant IT overhead costs of maintaining a manual or internally developed process, while enhancing the productivity of the engineering community by reliably managing complex file relationships.

Other benefits medical device manufacturers realize by implementing SolidWorks Enterprise PDM include:

- Improved integrity of the SolidWorks model file configurations, significantly reducing the likelihood of distributing misinformation to downstream users (purchasing, manufacturing, quality, etc.) where the cost of change and rework are much higher.
- Promotion of design reuse by maintaining a central design repository where property based searching and powerful visualization tools allow you to view and interrogate previous design models, which reduces cost.
- Enabling designers to make well-informed decisions when implementing change by providing immediate response to where-used queries to determine the impact that change may impose on other products.
- Fostering collaboration of physically dispersed product development teams by maintaining a logically centralized design center with secure, distributed file vaults to optimize file access performance over a wide area network.

Phase II – New Product Introduction (NPI) and Engineering Change
Centralized the storage, configuration management, and distribution of the CAD documents provides the foundation for the next phase of the implementation, and that is to effectively manage the processes by which a company introduces new products and controls the new product introduction process.

A company's ability to reliably track and report on the steps and documented artifacts by which they developed a product is an essential element to withstanding the scrutiny of an FDA audit. SolidWorks Enterprise PDM includes a simple, flexible, and powerful workflow capability that allows each company to model their auditable processes in a simple, state-based lifecycle model. This approach to managing your NPI and Engineering Change processes ensures that you can quickly build an auditable source for authorized approvals at each required step/state in a document's lifecycle. Access to documents can be determined by their state in the process, ensuring that documents are changed or viewed by the right people at the right time.

The completion of the first two deployment phases eliminates the need for you to consider an investment in a more costly enterprise PLM solution, while providing the foundation for a more comprehensive electronic records management solution.

Phase III - CAD Document System of Record - Electronic Signature
Only when a company has centralized the management of their electronic CAD documents and institutionalized the process for NPI and Engineering Change should they consider taking the step to make Enterprise PDM the system of record for their product design data.

In addition to managing all design documentation, SolidWorks Enterprise PDM maintains a complete audit trail to facilitate FDA compliance.

At this stage of the evolution, the most significant cost savings can be realized, transitioning from a costly, time consuming, paper-based records management process to a more efficient electronic records management process for all CAD documents. Time savings are not only realized by the personnel previously responsible for generating, distributing, approving, collecting, filing, and archiving paper reproductions of the electronic CAD drawings, but also by everyone involved in identification, retrieval, and presentation of those documents to support an audit.

In order to comply with the electronic signature requirements of 21 CFR Part 11, SolidWorks Enterprise PDM allows the application administrator to require users to provide their username and password to access the system and a second password (double electronic signature) upon promoting a document from one state to the next. This electronic signature is forever coupled to the document, providing the required authenticated approval information essential for an audit.

SolidWorks Enterprise PDM is easily integrated with your Microsoft® Active Directory or LDAP directory service. This leverages the many authentication features (such as password aging and denial of service) provided by these services, eliminating the confusion and administrative cost of maintaining redundant security models.

Phase IV - Electronic Records Management – Office Documents

In addition to the tight integration with SolidWorks and other CAD applications, SolidWorks Enterprise PDM is capable of storing, processing, distributing, viewing, and printing files in over 300 formats, including email messages, Office documents, PDF fileS, and graphics images such as TIF, GIF, JPG ,and more. This makes SolidWorks Enterprise PDM a sensible choice as the system of record for any other engineering or design related files that are required elements of your DHF or DMR.

Low Training Requirements

The native Explorer-based interface provides every user with a familiar Windows® look-and-feel, removing the user adoption barrier introduced by more complex enterprise applications. Users can simply store their Office documents to the secure SolidWorks Enterprise PDM Vault directly from the native menus of their favorite applications.

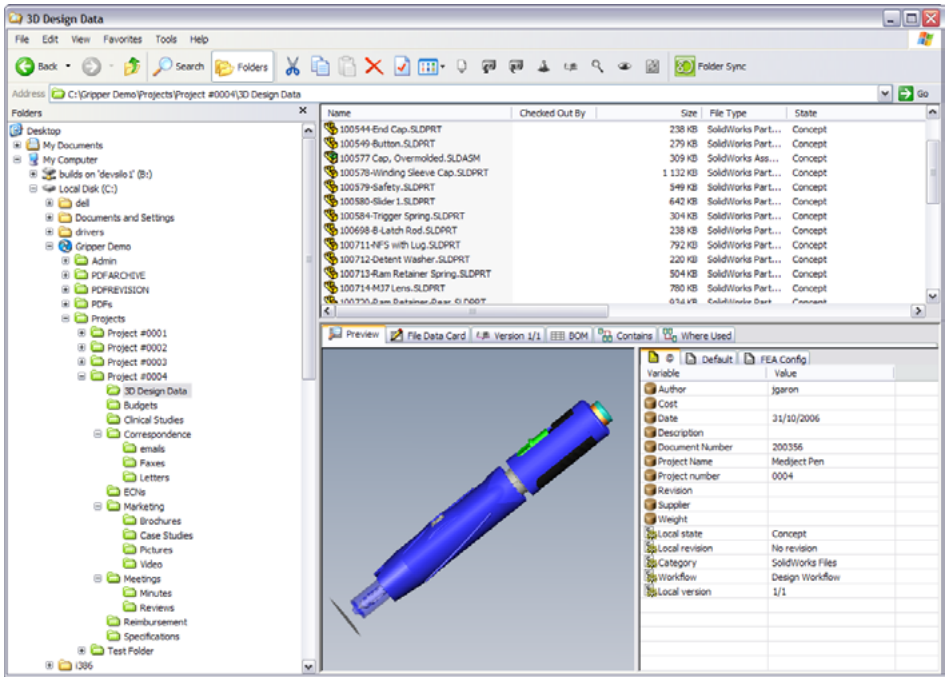
Workflow

Once the document has been submitted to the Vault, it is automatically attached to a routing process that you have designated based on its type. Participants in the process are conveniently notified by email when their review and approval is requested. All activities in the process are logged and made available in easily accessible history reports that meet the auditing requirements of 21 CFR Part 11.

With SolidWorks Enterprise PDM, you can document the reasons for making design decisions, including analysis and test results, and can track revisions generated at each step of the process.

Audit

Conducting an audit becomes efficient and accurate when using SolidWorks Enterprise PDM. All document records can be categorized and assigned a set of additional properties, allow for quick finding and immediate viewing of documents of interest. If desired, the retrieved documents can be printed directly from the client without the need for the authoring application to reside on your local workstation. In addition, upon retrieval of a specific document, its audit history is only one click away.



SolidWorks Enterprise PDM manages design revisions and automatically captures the history of all revisions

Summary

SolidWorks® Enterprise PDM is designed and developed to help companies in the medical field comply with the guidelines and requirements of the FDA's 21 CFR Part 11 rule regarding the management of engineering electronic documents.

Additional benefits include:

- Reliable PDM application ensures the integrity of SolidWorks file dependencies.
- Native Windows client interface is seamlessly integrated into SolidWorks, allowing designers to work comfortably and productively.
- Simple, state-based lifecycle model for essential business processes is quick to deploy and provides all essential audit requirements to comply with 21 CFR Part 11.
- Integration of security policies with Active Directory or LDAP leverages the comprehensive authentication services they provide, and eliminates the administrative overhead of maintaining redundant security models.
- Electronic signature features meet all requirements for signature manifestations as defined in 21 CFR Part 11.
- Comprehensive support for hundreds of Windows file formats enables companies to extend use to non-CAD eletronic documents, eliminating the need to license and administer multiple records management applications.
- Layered licensing makes Enterprise PDM cost-effective for all classes of users.

You will find more ideas and help on the SolidWorks website at **www.solidworks.com.**

The SolidWorks eNewsletter, press releases, and information on seminars, trade shows, and User Groups, are available at **http://www.solidworks.com/sw/183_ENU_HTML.htm.**

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