LIFE SCIENCES

LICENSE FOR DHF CHANGE

Manage design process activities and ensure completion of design control deliverables across enterprise regulated value streams

LICENSE FOR DHF CHANGE

License for DHF Change manages new product development design projects, activities and content with creation of the device design history file (DHF) to satisfy regulatory standards and good manufacturing practices for design control.

INDUSTRY CHALLENGES

All companies are faced with ever-shrinking product lifecycles in order to timely satisfy the diverging needs of global markets. This has resulted in an increase number of concurrent product development programs, which necessitates adoption of concurrent engineering methods. However, this also increases complexity due to the parallel activity of various functional teams. Coordinating the various functional teams to prevent overloaded resources and bottlenecks is critical for optimizing cycle time. This becomes even more challenging in the life sciences industry where compliance with government regulations is mandatory.

SOLUTION HIGHLIGHTS

License for DHF Change uniquely accomplishes zero delays by linking product development data to design project execution. In effect, design project management becomes data-driven by being linked with the product portfolio and the design content that regulatory agencies demand. When the two processes are disconnected with different technologies, there are multiple design projects being tracked, but they are not grounded in the reality of the product data that is created. Additionally, with disconnected processes it is not clear if the design content needed for regulatory agencies is being produced to ensure an on-time product launch.

License for DHF Change dramatically increases productivity globally by executing design projects and programs with real-time design information updates via automated synchronization of design artifacts to the DHF. This automated synchronization allows the design project or program manager to focus on high-value activities rather than tracking down design status. With **License for DHF Change**, companies can provide global teams with the accurate, real-time design information they need to keep design projects on track in response to ever-shrinking product lifecycles. **License for DHF Change** provides management with real-time visibility into a design project's status in terms of overall schedule, phases, gates, and resources.

License for DHF Change is implemented in the medical device industry, which places a priority on design quality. Poor design quality can literally be a matter of life and death in its worst case. Because of the risks involved in the development of novel medical devices, due diligence is of the upmost importance in terms of quality control measures. These competing priorities—quality and time-to-market— must be well managed through a careful process in order to reduce the risks inherent in the medical device industry.

For a complete and systematic QMS approach, audits are conducted. After audits are planned, findings are classified and follow-up is assigned to the responsible person. Upon completion of follow-up actions, a final report is issued and routed for complete closure.
License for DHF Change links all artifacts, records, analysis, documentation, and validation results. These artifacts are easily traceable and retrievable for internal or external audits providing added value for engineering, manufacturing and quality teams working on new product programs.

Key features and capabilities include:

Data-driven DHF Management

The DHF is one of the most important sets of documents created during the lifespan of a product. Essentially, the DHF is the central hub for collecting all information that medical device regulators care about. The DHF has all the relationships between the Design Control documents and it is how an organization demonstrates traceability of Design Controls throughout the entire development process. Design projects can be associated to product releases and the DHF so content can be easily navigated. License for DHF Change assures DHF context completeness via visual cues that communicate which deliverables are included in the DHF and its approver signatures.

License for DHF Change automatically tracks the activities and deliverables to generate the resulting DHF in accordance to U.S. FDA regulation 21 CFR 820.30(j). Design project deliverables can be viewed according to a number of configurable criteria to show only those deliverables that are most important. As a deliverable is promoted through its lifecycle, the system automatically updates the task status. After the tasks are completed, design project folders store and categorize the deliverables for access controls and increased visibility. The DHF provides dynamic links to related documents and data for improved visibility into related business processes, assigns design activities to team members, email task assignments with details of tasks, and configures preferences for task reminder.

Design project managers can display a consolidated summary view of the product DHF for all related design projects, signatures of approvers of its content and related records (such as Parts) to the design project. Baselines can be set up to display "DHF Snapshots," which capture the status of the design history file at specific times in the design project lifecycle. Design project leaders can easily view and compare multiple snapshots to the baseline.

Design Input to Design Output Traceability

The "Design Input to Design Output Traceability" view of License for DHF Change ensures that all requirements created with ENOVIA's Requirements Manager are satisfied and connects design project deliverables within the product. Visual cues identify outdated deliverables that are not synchronized with the DHF. These can be easily updated to ensure only the most up-to-date document is used in the DHF. It accurately communicates where and how the requirement or market opportunity is satisfied by a specific DHF section and improves the quality of audits.

Business Process Standardization

A flexible template capability helps standardize and automate global processes for creating and managing the DHF. The design project template consists of a work breakdown structure defined with phases, gates, milestones, and tasks with dependencies and responsible roles. Pre-configured process scheduling templates can define activity dependencies and slack time, task constraint dates and types, mandatory or optional use of tasks, documents that are needed with deliverables and design project role assignments.

Design project templates can also include design history file folder structures for storing content, questionnaires, documents, and deliverable templates and create a Product Design History File Index comprised on data from all supporting design projects.

Keep Design Projects on Track and Respond to Ever-Shrinking Product Lifecycles

License for DHF Change can define a multi-level design project hierarchy and schedule with phases, milestones and dependencies. Multiple schedule baselines can be created to compare and measure design performance. Design project experiments allow design project leaders to create alternate schedules without affecting the approved baseline schedule. The schedule alternatives can then be compared and merged with the approved baseline schedule to create a new baseline.

License for DHF Change provides bi-directional integration to Microsoft Project for design project managers that prefer using a Microsoft Project user interface for editing schedule information. Tasks can be copied from design projects or from design project templates, including copying partial task structures.

Key Benefits:

- Aggregate regulatory content into a traceable Design History File (DHF) to confidently handle future audits and submissions.
- Ensure how the DHF satisfies each requirement and market opportunity.
- Coordinate design project scope, schedule, and resources, to deliver the product portfolio within business constraints.
- Govern the design project "invisibly" with in-context task management.
- Reveal design project and compliance risks based on real-time information.

Minimize Resource Conflicts and Bottlenecks through Flexible Work Calendars

The work week, working hours and holidays vary across the globe. License for DHF Change provides the ability to create flexible work calendars based on organizational and regional factors. Exceptions can be created on a calendar. Exceptions can be for holidays or for work days and can recur on daily/weekly/monthly/annual basis. A practical use of exceptions is for handling production cutovers that require extra work on a weekend of longer than usual hours for a set period. The same use of exceptions may be required if development or production is behind schedule. The company may choose to implement mandatory overtime temporarily.

Focus on High-Value Activities with Design Project Meeting Traceability

Design project or program managers can capture meeting details to maintain artifacts for historical references. Managers can define meetings and track who was invited and who actually attended. Agenda topics can be added to meetings with time durations allocated for each topic and associated document attachments for discussion. Issues that need further follow up and recorded decisions are stored as an outcome of the meeting. Users can manage a company's processes with a phase gate review process. Project leaders can define criteria to schedule the gate review meeting date and capture the gate meeting details such as list of attendees, topics and artifacts, and final decisions.

Real-time Issue / Risk Management

Issues can be captured, tracked, and closed in the context of a design project. Issues are identified, classified and assigned to design project members for resolution. Risk management enables design project teams to identify, quantify, analyze, and mitigate design project risks. During the analysis process, risks need to be assessed and quantified in two dimensions. These two dimensions are impact and probability with ranges from 1-5. These dimension values help minimize these potential negative impacts by determining each risk priority and clarifying which design project risks need mitigation.

'My Calendar' for Improved Team Collaboration

The "My Calendar" view helps teams manage their assignments by providing a consolidated view of Design project WBS Tasks, Risks, Issues, Meetings and Route Tasks. The user assignments can be visualized in daily, weekly and monthly views based on task due date and start date. From these views, users can directly access assignment details.

Design Project Intelligence

Users can add feeds on design projects and tasks within a 3DDashboard. With these widgets, the users can monitor design project related information in context of other sources of information and from there decide the course of actions to be taken. The available widgets are "My Design projects" and "My Tasks", which monitor design projects that the user is involved in as well as assigned tasks. Tagging services allow users to quickly filter widgets and tables content based on already defined tags and to enrich design project information with their own tags. Visual cues are used to monitor tasks that are late or upcoming for proactive and intelligent decision making with real time data.

Design Project Access

The 3DEXPERIENCE® platform security model provides a common, consistent access model across all DS solutions. This applies to design project data as access can now be defined not only for individual users, but also as a combination of organizations and collaborative spaces. Access can not only be defined on a design project itself but also on individual objects within design projects. For example, a given WBS phase can be made visible for a supplier for review or authoring.The richness of the security model allows scaling from very simple SMB scenarios to OEM/Suppliers extended enterprise access needs. All design project content and deliverables are managed and stored securely within controlled folder and subfolder structures. Within a design project, each folder and file maintains additional levels of security.

Lifecycle controls establish folder content baselines as a means of measuring design project performance and historical references. Team members can establish a single environment for managing and sharing all design project information — not just documents. By subscribing to folder and document events, members can become informed immediately as changes and additions occur. Reports provide a consolidated list of design project-related content from either the work breakdown structure or from the folder structure.

Collaboration & Approvals

Users can benefit from a wide range of capabilities for global enterprise collaboration. Those capabilities include the ability to manage and organize shared documents and structured product data. They also enable the creation of digital workspaces for virtual teams to work together. Users can easily raise issues, organize meetings and track decisions. Any object lifecycle modifications can be formally approved using routes defined by end-users or from standard route templates.

Microsoft Integration

Users can create and access **3D**EXPERIENCE data from the most popular Microsoft applications: Word®, Excel®, PowerPoint®, Outlook®, Windows Explorer, and Windows Desktop Search. This capability enables enterprise-level collaboration while not disrupting the established productivity of end-users. With product content being managed in **3D**EXPERIENCE rather than on users' PCs, organizations are able to create, manage, and review product content more securely.

LICENSE TO CURE FOR MEDICAL DEVICES

High consumer expectations for better healthcare and advances in technology that improve quality of life are creating favorable market conditions for medical device companies. *License for DHF Change* is part of *License to Cure for Medical Device* a Dassault Systèmes Industry Solution Experience based on the **3D**EXPERIENCE® platform that allows companies to eliminate scattered processes and data and to "embed" regulations as an asset, optimizing quality and compliance and reducing cost and time to market.

This end-to-end solution supports all aspects of a medical device company's quality system and regulatory compliance ISO-regulated design controls. To learn more, please visit www.3ds.com/license-to-cure-for-medical -device

Our **3D**EXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

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