Why the Top Medical Device Manufacturers Depend on Cockpit Enterprise

Bringing Safer Products to Market Faster

INTRODUCTION

Cognition® software solutions enable the creation of process-driven templates which guide users towards compliant development and documentation practices in the highly regulated life sciences industries. By taking a structured data approach to compliance, the solutions enable medical device and pharmaceutical product development teams to create an environment that guides users through required tasks in a systematic and consistent manner. This ensures a common approach is used for product development, design control, reporting, and submission documentation.

Cognition offers three industry solutions, Compass®, Cockpit® Enterprise, and Lighthouse™. These solutions are built on a two-level technology stack starting with the Knowledge Center Core Platform. It goes beyond just storing data and excels at modeling the relationships between data - this translates into enhanced traceability and data integrity. Built on the Knowledge Center Core Platform's environment, the Cockpit Framework is the engine that powers intelligent product development and reporting. Together, they provide the foundation for Compass, Cockpit Enterprise, and Lighthouse. This paper focuses on Cockpit Enterprise.

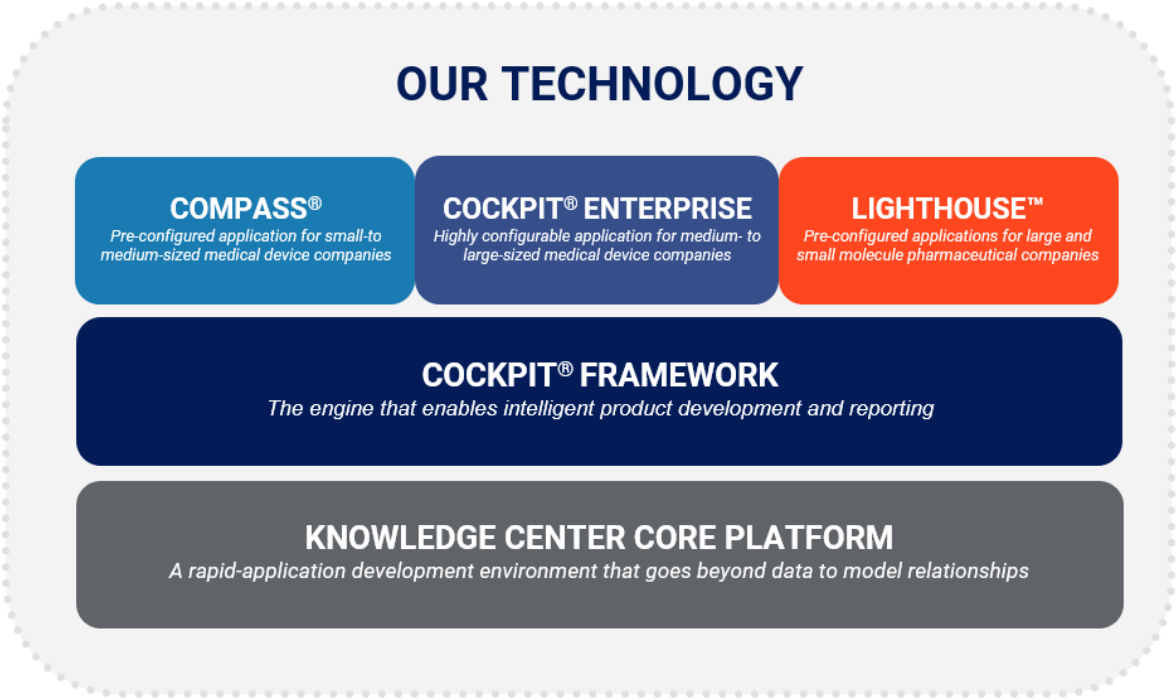

Figure 1: Our Solutions for A Structured Data Approach to Compliance

COCKPIT ENTERPRISE

Cockpit Enterprise is the software application for medium to large medical device product development teams that integrates risk management, requirements management, test management data, and more, in a unified environment. Cockpit Enterprise is highly configurable and can be personalized to meet a company's needs. It has a rich development framework that allows organizations to implement their Standard Operating Procedures (SOPs) and Work Instructions (WIs) in a controlled and auditable environment. Ultimately, Cockpit Enterprise helps medical device manufacturers of Class II and Class III devices author, review, and approve the documents required for regulatory submissions and audits.

Cockpit Enterprise is best suited for mature organizations that have established standard operating procedures and can dedicate the necessary resources to configuring and deploying the system.

Smaller medical device organizations requiring preconfigured guidance on how to bring their products to market with less risk should explore Cognition's Compass product offering. Pharmaceutical companies requiring specific, functional capabilities to support electronic reporting of their small and large molecule products should explore Cognition's Lighthouse product offering. Both solutions offer guided compliance that is fully functional out of the box.

CORE CAPABILITIES OF COCKPIT ENTERPRISE

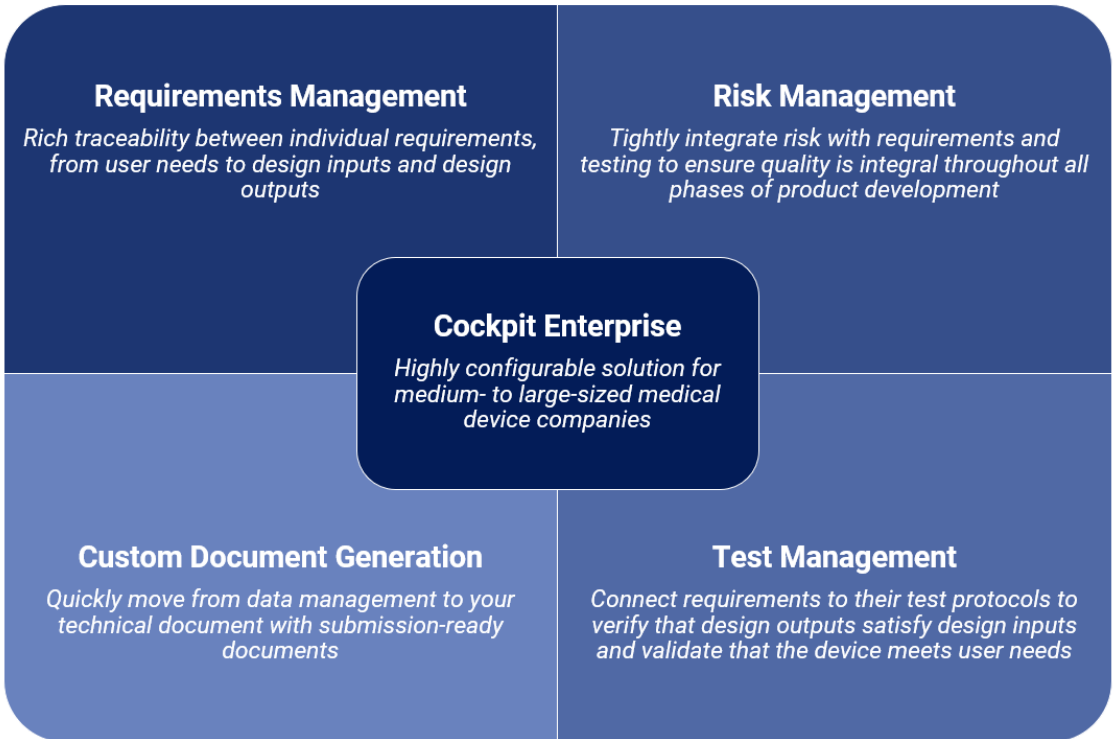

Figure 2: Core Capabilities of Cockpit Enterprise

KEY FEATURES OF COCKPIT ENTERPRISE

Cockpit Enterprise has many individual features that support product development teams in their endeavor to develop safe and effective products. This list below represents the most valued features as reported by Cognition's customers.

1. TRACEABILITY

Fundamental to Cockpit Enterprise, traceability is accomplished through a controlled process that enables your organization's standard operating procedures to be executed. This ensures the integrity of the linkages being made between items, and unlocks the ability to do meaningful impact analysis and automated report generation. Trace matrices are created as data items are linked and enable constant monitoring of the project status and whether all inputs are met by appropriate outputs and the project status overall.

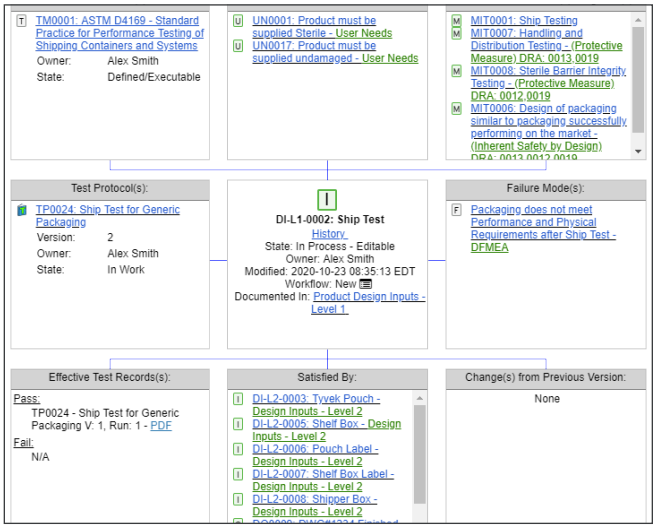

Figure 3: Individual Requirement Trace

2. DESIGN CHANGE IMPACT ANALYSIS

With fully traced data items, impact analysis becomes second nature. The effect of changes on upstream and downstream data connections can be easily viewed before making a change. Cockpit Enterprise enables you to view traceability from a system level, such as a trace matrix between all design inputs, design outputs, and test procedures. Or you can zoom in to a single data item such as a system requirement and see everything that it is connected to, including upstream user inputs, downstream subsystem requirements, risk controls, and verification tests being performed.

3. HISTORY TRACKING

Every data-entry activity in Cockpit Enterprise is recorded and timestamped to create a fully auditable log of change history. See who made the changes, what they changed, and when they made them.

4. ASSET LIBRARIES

Cockpit Enterprise allows for the creation of controlled, pre-approved asset libraries, such as a harms library with defined severity scores. Asset libraries can be connected to multiple projects so that the same database is used. This eliminates errors due to recreation or mis-alignment across projects.

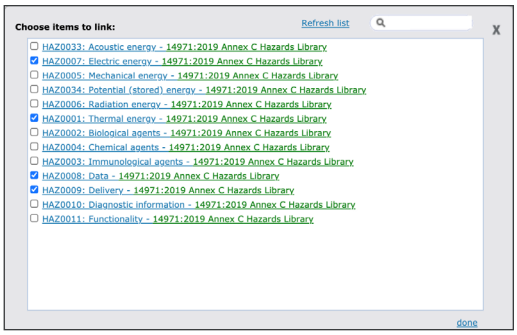

Figure 4: Hazards Library

5. CUSTOM DOCUMENT TEMPLATES

In Cockpit Enterprise, creating custom, reusable document templates that match your standard operating procedures and requirements for notified bodies is standard functionality. Document templates save an enormous amount of time by providing a structured framework in which to work and are configured to automatically pull in data from the project as it is being created. All document content is updated automatically as any data in Cockpit Enterprise is updated. There is no need for any manual updates to get the desired outcome.

6. DOCUMENT REVIEWS

Document reviews can be performed right in the system to avoid long cycles of exporting, reviewing, and requesting changes. In Cockpit Enterprise's document review feature you can suggest changes, review the change, approve it, and implement it all prior to exporting the document to the document control system. Individual items (risks, requirements, and tests) can also be reviewed in the system with the same functionality as document reviews.

7. CUSTOM REPORT GENERATION

Similar to impact analysis, project reports can be generated to show a wide range of critical information. Reports can show information about data items, such as all requirements that do not have a defined target value. Additionally, reports can show information about relationships, for example, all requirements that do not have a test protocol linked to them. Dashboards can be created to visually show status as a visual snapshot, instantly-up-to-date with no manual tracking necessary.

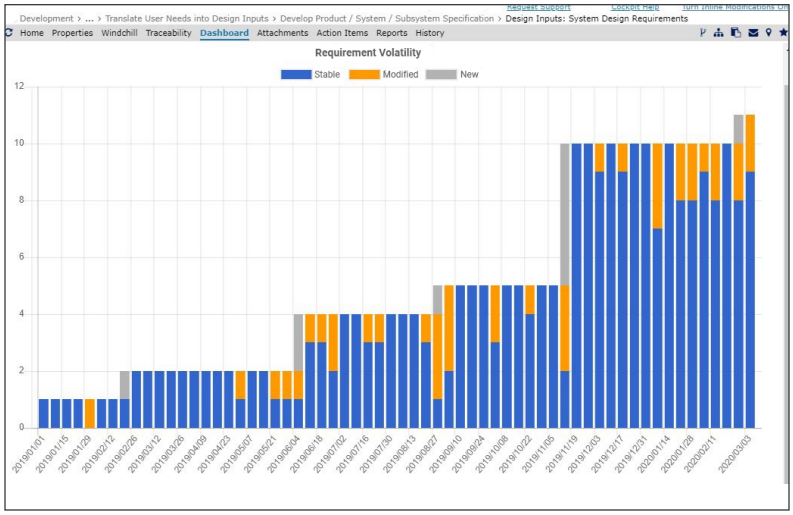

Figure 5: Requirement Volatility Report

8. DOCUMENT EXPORTS

Exporting documents is straightforward and fast in Cockpit Enterprise. Export in either Word or PDF, and include a cover page, headers, footers, and watermarks as required. Documents export submission-ready with no post-processing required.

9. CHANGE REQUESTS

Cockpit Enterprise has strong change review capabilities that allow you to propose changes, analyze their impact, review, and approve them prior to implementation. When you are ready to make the changes official, you can implement them confidently with one click.

10. SEARCH

Cockpit Enterprise has a rich search feature that enables you to quickly find items across the entire ecosystem, which may include many individual projects. Search within specific data types, within specific attribute fields, or search universally for a word or phrase. Cockpit Enterprise doesn't just find words on the screen, it can return the individual data objects that you are searching for.

WHY ORGANIZATIONS CHOOSE COCKPIT ENTERPRISE

Top functioning medical device product development teams enjoy a wide range of value propositions by using Cockpit Enterprise. This list below represents some of the top values as reported by Cognition's customers.

1. ENTERPRISE LEVEL CONFIGURABILITY

Cockpit Enterprise's level of configurability enables organizations to design a system that is specific to their unique quality system and business needs. Among the possible types of configurations available, teams can choose to configure project templates, document templates, trace schemas, workflow processes, and integrations with other systems. This capability results in a robust system that allows for maximum efficiency and accuracy when developing new products.

"What has given us success is our ability to create and develop templates that precisely meet, requirement-for-requirement, our quality system - that's huge! We have configured Cockpit Enterprise based on the foundation of our global quality system, and our templates have been validated to meet our global work instructions."

- Minimally Invasive Medical Device Company

2. DATA INTEGRITY

Cockpit Enterprise is database driven, and provides a "single-source of truth" for every data item - if a requirement is changed in the product requirements document for example, it is automatically updated in the master trace, verification protocol, subsystem requirements document, and anywhere else that requirement may be referenced. This enables continuity throughout the entire development environment and ensures data integrity.

"Before we had Cockpit Enterprise, the problem we faced was that when I went to update document A, I really needed to update document B as well. So, you end up with a change process which attempts to get people to do this manually. In Cockpit Enterprise I no longer have to do that, changing document A automatically changes document B. In the old way the changes may never show up, which would end up in a potential CAPA situation."

- Interventional Medical Device Company

3. INDUSTRY-LEADING RISK MANAGEMENT

Cockpit Enterprise includes risk management capabilities that are unmatched in the industry. Cockpit Enterprise allows risk management to break free from the confines of isolated, 2-dimensional spreadsheets that require complex and time-consuming manual activities to confirm data integrity, align with SOPs, and perform reporting activities. Inter-connected data in Cockpit Enterprise enables medical device product development teams to perform multiple risk-management activities while simultaneously ensuring data continuity and integrity, not only in one activity but throughout the whole risk management process. Additionally, Cockpit Enterprise supports the use of data libraries containing pre-approved content to be used in the analyses, thereby helping users to remain aligned with company processes and procedures.

Cockpit Enterprise supports the establishment of a traceable connection between identified risk controls and the requirements which implement them in the product design, however, this alone does not complete the integration of risk management and design processes. Cockpit Enterprise also supports the identification of failures (design, process etc.) and use errors as contributions to the Sequence of Events of a risk.

In other regulatory preparation tools, risk management is not a native integration. Cockpit Enterprise, on the other hand, allows for a risk-first approach that places high emphasis on the value of tightly integrating risk management in the design control process with requirements and tests.

In Cockpit Enterprise, you can create templates that follow your standard operating procedures to successfully create a:

- Risk Management Plan
- Preliminary Hazard Analysis
- Use Error Analysis
- Design FMEA
- Process FMEA
- Overall Risk Analysis
- And More...

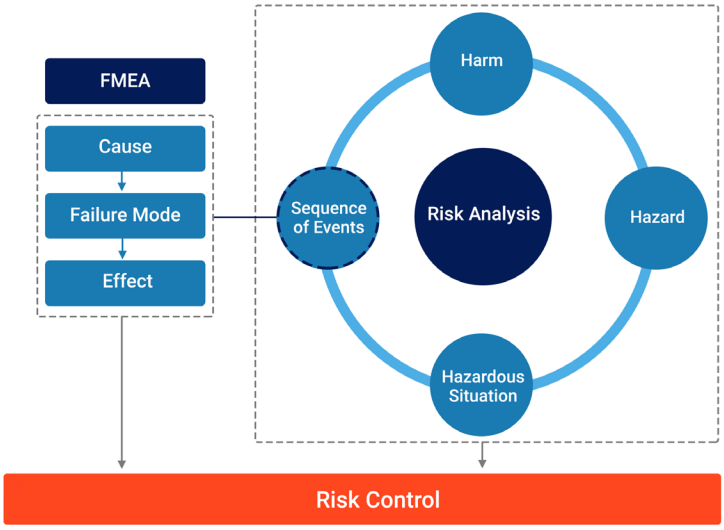

Figure 6: Seqeunce of Events

To learn more about our approach to risk management, see the article written by Cognition's Ben Higgitt, in MDDI Online, Complying with ISO 14971:2019.

"I have seen other tools that create a spreadsheet-like risk table in an attempt to check the box for risk management, but in my experience those risk capabilities are not data driven like in Cockpit Enterprise. A huge differentiator for Cockpit Enterprise is the ability to manage the Risk Chain."

- Orthopedic Medical Device Company

4. CROSS-FUNCTIONAL INTEGRATION

Cockpit Enterprise's unified data model allows for traceability of all data items, from user needs to design input requirements, design output documents, verification and validation tests, risk activities, and process requirements. This not only builds up a unified source of truth, but it enables cross-functional teams to collaborate effectively and develop the product in unison, with a full view of the entire development environment.

"Our Systems Engineering team owns the product development process and is at the center of it, but, by using Cockpit Enterprise we have allowed other groups to gain access to the electronic environment and make their contributions independently. For example, our Marketing team was able to log in and write their own user needs."

- Medical Diagnostics Company

5. DYNAMIC DOCUMENT AUTHORING THAT IS SUBMISSION READY

Cockpit Enterprise combines database style functionality with document authoring, reviewing, and approving. This enables teams to not only create rich traceability between data items - across risk, requirements, and test management - but to also create the document deliverables that are needed for regulatory submissions. By using configured templates, teams can work in a "data view" and automatically generate the "document view" without any extra work, resulting in time savings all within the same quality-enforced, structured data environment.

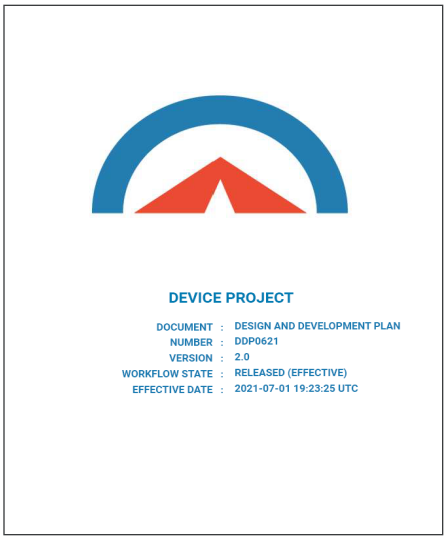

Figure 7: Document Deliverable

"With Cockpit Enterprise we manage our data, create our documents, review and approve them, then export them to our official system of record. For us, Cockpit Enterprise is an automated DHF document authoring tool."

- Implantable Medical Device Company

6. BEST-IN-CLASS CUSTOMER SUPPORT

Cognition has a proven track record of superior customer support. Cockpit Enterprise is supported by a team of developers, medical device engineers, systems engineers, and technology professionals who are dedicated to the success of our customers, and who are available at a moment's notice.

"I can't say enough good things about the team and the attention we get. The people at Cognition want us to do well and are extremely responsive to us. Cognition is an excellent software vendor partner."

- Medical Instrumentation Supply Company

THE BOTTOM LINE

Medical device development done right is hard; and without a structured data approach it is nearly impossible to do it right. The cost of doing it wrong is an unnecessary financial burden on medical device companies and has the potential to result in harm. Cockpit Enterprise provides an environment for product development with industry-leading functionality, based on two decades in the medical device industry, for bringing safe products to market faster and at considerably less cost.

"I'm a longtime medical device engineer, and your products are the best I have seen."

- Personal Care Consumer Product Company

ABOUT COGNITION

For more than 20 years, Cognition Corporation has designed its product development solutions specifically for the Life Sciences industry including medical device, pharmaceutical, laboratory equipment, and combination products. Cognition software uses a unique technology of generating structured data items, dynamic links between items, reusable templates, and structured documents and reports to support the generation of both internal technical reports and submission deliverables to global health authorities.

FOR MORE INFORMATION

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