Why Medical Device Companies Choose Compass for a Structured Approach to Product Development

Bring Safer Products to Market Faster with Change Once, Update Everywhere Functionality

INTRODUCTION

Cognition® offers SaaS solutions to support customers of highly regulated industries fulfill their documentation requirements. Cognition's solutions use process-driven templates and personalized data-centric working tables to enable the creation of critical content to support product definition, design, risk, testing, and beyond for customers in medical device, pharmaceuticals, and other related industries. By building the design and development documentation within a structured database, consistency of documentation and process, data integrity, and centralization are all fully implemented. Major compliance areas are supported by guiding users through the regulated process in a systematic and consistent manner. This ensures a common approach is used for product development, design control, reporting, and submission documentation.

Cognition offers two industry solutions, one for medical devices and one for pharmaceutical. These solutions are built on a complex database that is accessible to users at two levels: a pre-configured out-of-the-box product or a more flexible version enabling customer configuration to align to specific procedures. Both Compass®/Compass® PRO for medical devices and Compass® BIO for pharmaceuticals excel at going beyond storage of data to modeling of relationships and interconnectivity. This enables the creation of complex traces, assurance of data integrity, ability to create reports, and most importantly reuse of data across projects / products or within a single document. Intelligent and comprehensive product development starts with data management and is efficiently applied with the ability to re-use the same data throughout, minimizing errors due to replication or basic human error. This paper focuses on the medical device industry and the out-of-the-box offering of Compass, as well as the configurable offering, Compass PRO.

COMPASS/COMPASS PRO

Compass and Compass PRO (collectively known as Compass) are pre-configured, out-of-the-box, SaaS solutions purpose-built to connect data across all functional areas of medical device product development, leveraging regulations such as 21 CFR 820.30 and MDR as well as standards ISO 13485, IEC 62366, and ISO 14971 as the foundation of the software design. It enables compliant product development by ensuring the process of authoring, reviewing, and releasing is enforced via workflows and built-in document templates. It provides a personalized data-centric working environment that is flexible for more complex projects, enabling each team member to work with the critical information in a table that is structured for their preferences. While allowing data, regardless of where and how it is created, to be compiled into compliant documents per corporate templates or procedures. It provides an adaptable set of document templates for

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the entire product design control process from user needs to validation, with a focus on risk, requirement, and test management. Saving time and resources, it maintains documentation and supports submissions as well as provides automatic generation of the master trace matrices and documents for the Design History File (DHF), Technical Documentation Records, or audit support.

COMPASS FUNCTIONALITY

Figure 1: Built-in Functionality

WHAT SETS COMPASS APART

PROCESS-BASED, OUT-OF-THE-BOX FUNCTIONALITY

Compass can work for your business without requiring dedicated administration personnel devoted to configuration or customization, thus allowing you to focus on product development rather than administrative tasks. Compass offers pre-configured document templates specific to medical device product development using our guided compliance approach. Data-centric working tables are also available for teams used to flexible data entry, enabling filtering and table organization in a personalized format, optimizing individual work. This data is integrated automatically into the same templated documents, enabling each team member to work in the space that is most productive to their expected tasks or outputs. This means your product development process is documented in a submission-ready format, while making data entry efficient.

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"With Compass we are confident in the consistency of our projects. We know our submissions will be a consistent package across our geographies."
- Combination Products Company

STRUCTURED DATA

Structured data contains specific information, each with a unique identifier. For structured data to be valuable, it may be used in multiple locations, exist over time, be reusable, be connected to child/parent/peers, and enable action at a distance. Given the unique ID setup, if you need to update the central property, the update will be pulled or pushed through to all locations that use it. This is exactly how Compass treats your product development data.

Structured data has many benefits, including:

- Establishing a single source of truth
- Increasing compliance
- Reducing errors
- Reducing time-to-market
- Improving data integrity
- Reducing resource costs
- Reducing IT Burden
- Increasing report quality
- Preparing for the future

"Compass is like a skeleton - providing us the structure we need for medical device development and leaving us to populate the content into the right boxes. This allows us to focus on the content rather than the structure of the data."
- Biomedical Company

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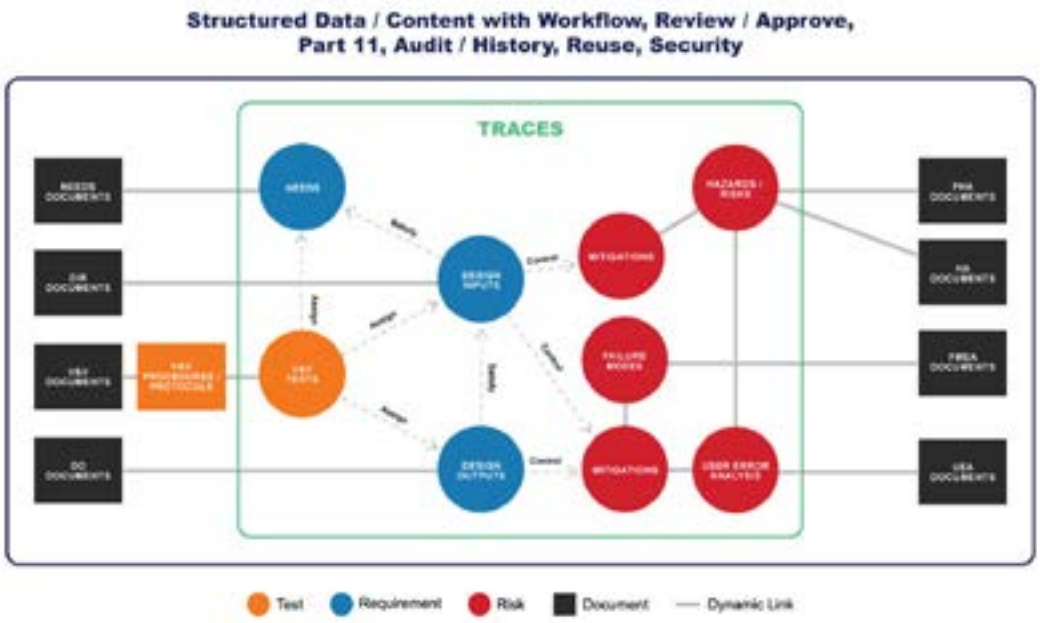

Figure 2: A Single Source of Truth with Structured Data

INDUSTRY-LEADING RISK MANAGEMENT

Compass provides medical device companies an advantage with its risk-focused approach that places high emphasis on the value of tightly integrating risk management in the design control process with requirements and tests. Compass supports the risk management process defined in ISO 14971 and has the ability to embed global and/or regional regulations and standards to guide users through the risk analysis process. The templates in Compass ensure process consistency and enable stepping users through the process to produce comprehensive and useful assessments. Risk becomes an active part of the development process with integration with requirements and testing, not just a paperwork exercise to “check the box”.

Compass guides you through the process of creating a:

- Risk Management Plan
- Preliminary Hazard Analysis
- Use Error Analysis
- Design FMEA
- Design Risk Analysis
- Benefit Risk Analysis

Figure 3: Fully Integrated Risk Management

Unlike other risk management tools, Compass not only manages individual risk data points, like hazards, hazardous situations, and harms, but it also maps out the sequence of events that can ultimately lead to a patient being harmed. While the individual risk data points can be stored in a library and reused, it is this

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unique sequence of events that must be mitigated. Data sharing across supporting tools creates a seamless risk management system where sequences originating in both normal and fault conditions can be assessed in a single risk analysis.

To best control risk, risk control measures must be implemented into the design. In Compass, risk management and requirements management are tightly integrated. In concert with test management, this enables real-time assessment of the impact of every change across every function.

For more on our approach to Risk Management in Compass, click here.

"Our post-market surveillance identified a particular rate of harm that was actually higher than what was currently documented in our Hazard Analysis. With Cognition, we were able to make that update and have it applied instantly to not only the hazard analysis document, but also to the risk index value in three dFMEAs, and five design verification protocols."
- Interventional Medical Device Company

TRACEABILITY

Traces are used for a variety of reasons, from audit support, to proving that outputs align to inputs, to ensuring that all user needs are covered, and that testing is complete. By creating traces as data is added, copy-paste errors are eliminated, and time to build large trace tables becomes inconsequential. Compass builds best practice trace matrices via pre-configured templates, enabling connections to be established as data is added and automatically creating output documents and views. Changes in data content are instantly available across the entire project so that information is up-to-date without hunting for cross-references. Changes can be assessed for impact analysis at all connection points with easy visualization of the relationships. Compass trace matrices can be adapted to an organization's SOPs and can be exported for reporting purposes.

Figure 4: 9-Box Requirement Trace

For more on our unique trace functionality, click here.

"Compass is very credible for consistency because it allows you to trace everything. The functional traceability allowed us to present to the FDA our device satisfying the requirements."
- Biomedical Company

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WHY DEPEND ON COMPASS

A UNIFYING SOLUTION

Compass does what Excel and Word cannot, it unifies your data into one system, which enables you to focus on developing and not on maintaining or updating data and relationships. When you allow risks, requirements, and tests to exist and work together you promote quality as an integral part of the product development process.

"The capability to have all the requirements, risks, and tests in one place and in order is what drew us to Compass. We view Compass as a big container that is our project and within that container there is everything we have designed about that project or device and we can be confident that the data is properly structured and updated."
- Biomedical Company

DATA INTEGRITY

As a database driven system the Compass provides a "single-source of truth" for every data item. As an example, if a requirement is changed in the product requirements document, it is automatically updated in the master trace, verification protocol, subsystem requirements document, and anywhere else that requirements may be referenced. Compass simplifies the process of managing large quantities of design-related data, reducing the likelihood of human error, and thereby improving data consistency and accuracy of the data. If you update in one place it will update throughout, ensuring alignment across all documents and reports.

"If you have to make a change you are not going to make a mistake with Compass. You are not going to miss it like you may in Excel. You can see everything that is affected by the change."
- Combination Products Company

AN EXTENSION OF YOUR TEAM

Cognition takes a customer-first approach to supporting and engaging with our customers. When you choose Cognition you are getting more than a SaaS solution for product development, you are getting a team of developers, engineers, and industry-focused experts who are here to support and guide you beyond the sale. We take pride in being an extension of our customers' teams and working alongside them to help get to market faster.

"I was very impressed with the support and engagement we received from Cognition starting with our first phone call. It was very apparent that they would be there for us beyond the sale. Once, we met Cognition team members and saw the Compass software, choosing Compass was a no-brainer."
- Consumer Products Company

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THE BOTTOM LINE

Medical device product development can be complicated and error-prone. Errors cost time and money. Choosing Compass as a solution for your product development data will enable you to confidently get to market faster. With Compass you know your data is structured, connected, and accurate allowing you and your team to focus on development rather than data management.

For more information on Compass features and use cases, click here.

"Compass saves us time. With Compass it is easy to create an overview trace that would be burdensome to create and nearly impossible to manage changes for using excel. When I make a change, I am confident that Compass will update the data throughout so I do not have to take time to confirm and can instead focus on creating the content."
- Biomedical 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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