Software Solutions for Life Sciences Product Development

Structured Data and Guided Compliance to Deliver Products to Market Faster with Less Risk

WHO IS COGNITION CORPORATION?

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 integrates our unique technology that generates 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.

KEY FUNCTIONALITY

Cognition software applications support the creation of reusable templates to guide users toward compliance in the highly regulated Life Sciences industry. Templates allow teams to take a stepwise approach to common product development, transfer, and reporting activities for pharmaceutical and medical device submissions. Corporate work instructions can be embedded into every template in the specific functional locations for all steps of prescribed activities. Corporate procedures, job aids, and standard operating procedures can also be either embedded in templates or linked to from templates. Comprehensive traces and reports present data and content in any format or style required to satisfy both internal technical reporting as well as formal regulatory submissions.

Cognition supports medical device product development and pharmaceutical Module 3 of the Common Technical Document (CTD) reporting for large corporations, medium-sized companies, and startups. There are no limits on the number of data items, reports, or connections in projects using Cognition software.

OUR PHILOSOPHY

At Cognition, we believe in a guided compliance approach using structured data to support specific, evidence-based product development. Our software solutions walk you through your compliance requirements so they are done right the first time and each time after that, allowing you to get to market faster with less risk.

WHY GUIDED COMPLIANCE?

- Develop products in a structured, streamlined way to get submissions right the first time
- Maintain a single source of truth: update once, and it is updated across the entire project
- Support traceability, even across the largest and most complex projects
- Free up valuable time and resources by putting the focus on development rather than administrative tasks
- Save time and money while increasing quality and reducing risk

PROBLEMS WITH UNSTRUCTURED DATA

Applications such as Word and Excel do not manage data in a structured way, and they do not allow for effective sharing of data and documents. Consequently, there is great difficulty in manually tracing relationships with content, and inaccuracies often occur from manual copying which results in poor data quality. Manually created documents using unstructured data are difficult to maintain, review, and reuse. Large risk documents are error-prone in Excel due to lack of controls with errors in traces, triggering massive manual verification or rework with a poor chain of evidence. This all results in project delays, increased audit risk, and exposure to 483s.

WHY STRUCTURED DATA?

Structured data improves data integrity with comprehensive data management including audit logs from project level down to individual item levels. It includes global ID management for intra- and inter-project linking with support for complete risk-based validation. Structured data provides instant access to all data within and across projects with automated generation of traces and technical documents. Content can be reused across projects in libraries that are readily available, which significantly reduces errors and time to market. Enforced processes and work instructions embedded within a templated framework create libraries of regulatory requirements, hazards, harms, and other data to ensure users follow appropriate regulations and standards, which results in increased compliance.

A STRONG FOUNDATION FOR SUCCESS

Cognition offers three solutions for the Life Sciences industry, Cockpit® Enterprise, Compass®,and Lighthouse™. These solutions are built on a two-level technology stack starting with the Knowledge Center Core Platform. This goes beyond just storing data and excels at modeling the relationships between data - which 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 Cockpit Enterprise, Compass, and Lighthouse.

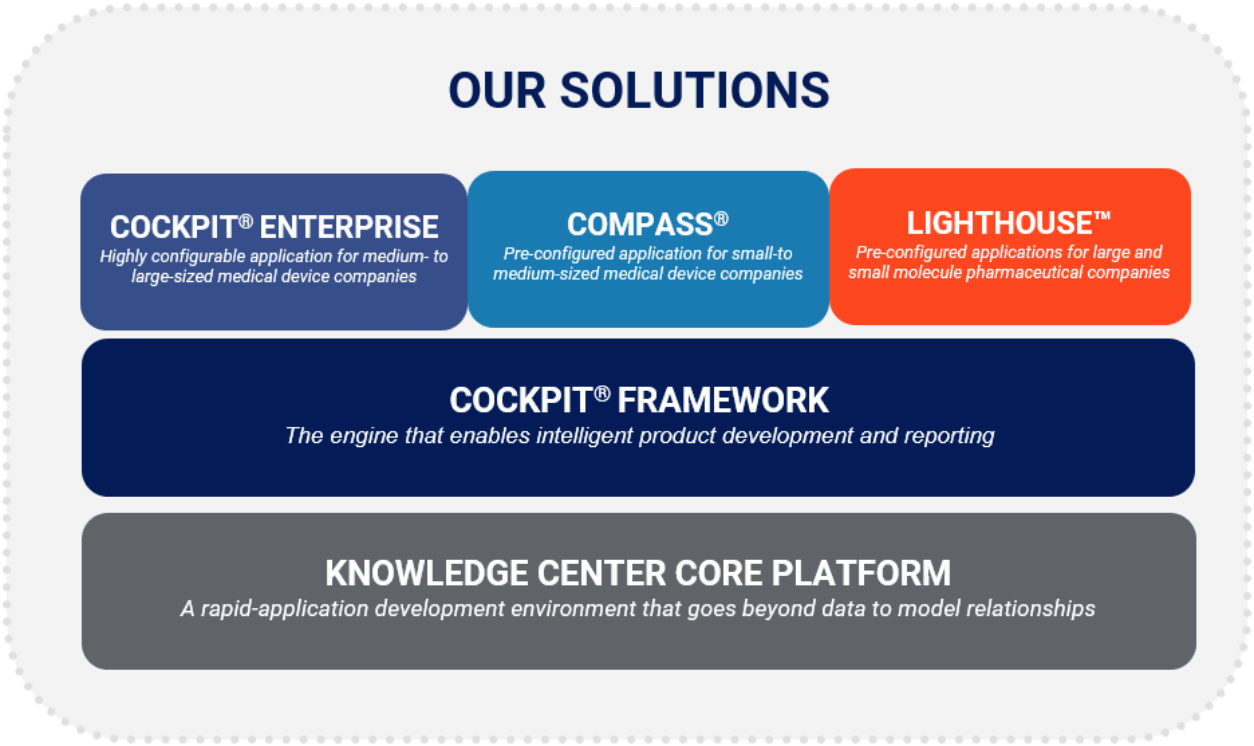

Figure 2: Cognition Solutions

WHAT IS THE KNOWLEDGE CENTER CORE PLATFORM?

The Knowledge Center Core Platform is the foundation on which our solutions are built. It is a rapid-application development environment built on a database, and the development environment on which the Cockpit Framework is based. The tight integration of the Cockpit Framework and the Knowledge Center Core Platform enables a single source of truth for all data. The Knowledge Center Core Platform's flexibility means the database design is not a static representation and is easily updated as the systems around the data evolve and are updated. The Knowledge Center Core Platform goes beyond storing data and excels at modeling the relationships between data; this translates into enhanced traceability and data integrity. As with any software application, security is crucial. The Knowledge Center Core Platform provides the mechanisms for extremely granular control of data access and enforces security based on the rules and logic the Cockpit Framework dictates to keep the system and your data secure.

WHAT IS THE COCKPIT FRAMEWORK?

The Cockpit Framework is built upon the Knowledge Center Core Platform. The Cockpit Framework provides all capabilities to support structured data and a systems engineering approach to product development and reporting. The framework creates the ability to have items such as parameters, requirements, hazards, etc. The Cockpit Framework powers our solutions for medical device and pharmaceutical development

WHAT IS COCKPIT ENTERPRISE?

Cockpit Enterprise is a SaaS solution for medium to large medical device product development teams that integrates requirements management, test management, risk 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.

WHO IS COCKPIT ENTERPRISE FOR?

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.

To learn more about our Cockpit Enterprise Solution, click here.

WHAT IS COMPASS?

Compass is a pre-configured out-of-the-box SaaS solution purpose-built to connect data across all functional areas of medical device product development, leveraging regulations such as 21 CFR 820.30 as well as standards ISO 13485 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 complex workflows and built-in document templates, and automates a complex workflow between those interconnections to ensure compliant development. It provides an adaptable set of document templates and workspace views for the entire product design control process from user needs to validation, with a focus on risk, requirement, and test management, from user needs to validation. 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.

WHO IS COMPASS FOR?

Compass is best suited for small- to medium-sized medical device companies looking for guidance on how to bring their products to market with less risk. Compass offers guided compliance that is fully functional out of the box.

To learn more about our Compass Solution, click here.

WHAT IS LIGHTHOUSE?

Lighthouse is built specifically for the pharmaceutical industry to automate the generation of large, complex data tables and report documents while providing workflow, audit history, and electronic signature capabilities, ensuring data integrity and protecting the chain of evidence for reporting. Lighthouse is used to create structured content for both internal reports and Dossier reports with seamless integration from source data to corporate document management systems. The Lighthouse solution is a suite of applications that support improved quality and efficiency of R&D and manufacturing-related report deliverables, primarily in CMC processes for Module 3. With Lighthouse, pharmaceutical companies can improve quality while reducing errors, time, and cost for regulatory submissions.

The Lighthouse application suite includes: Criticality, Tech Transfer, Recipe, Specification, Batch Analysis, Drug Stability, Justification of Specifications (JOS), and Comparability.

WHO IS LIGHTHOUSE FOR?

Lighthouse is for pharmaceutical and CXO companies and provides specific, functional capabilities to support electronic reporting of pharmaceutical products, both small molecule and large molecule. Lighthouse is used by manufacturing, quality, analytical, and regulatory teams.

To learn more about our Lighthouse Solution, click here.

FOR MORE INFORMATION

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