Enable Your CMC Drug Development Digital Transformation Strategy with a Structured Content and Data Management (SCDM) Guided Workflow System

CASE STUDY: HOW A LEADING BIOPHARMA ENABLED ITS DIGITAL TRANSFORMATION STRATEGY WITH COMPASS BIO



COGNITION®
NAVIGATING PRODUCT DEVELOPMENT

BACKGROUND AND THE CUSTOMER

The development of new drugs is a complex, multi-faceted process of generating data and building knowledge throughout the multi-year development process; it demands continuous, rigorous analysis and evaluation to ensure safety, efficacy, and regulatory compliance. Biopharma R&D and drug development organizations require workflow and data management systems configured to align with their specific internal requirements, along with external quality and regulatory requirements to effectively manage and navigate the full product development process.

Throughout product development for both small molecules and large molecules/biologics, the drug discovery and development process generates massive amounts of critically important data that needs to be captured, processed, analyzed, made available to various teams, and exported to create a wide variety of reports throughout the product development lifecycle.

Our customer is one of the most innovative and largest biopharmaceutical companies in the world, dedicated for over 100 years to trying to understand and address the serious health problems of today and unlock the potential medicines of tomorrow. This Biopharma company currently employs more than 100,000 people across many sites around the world.

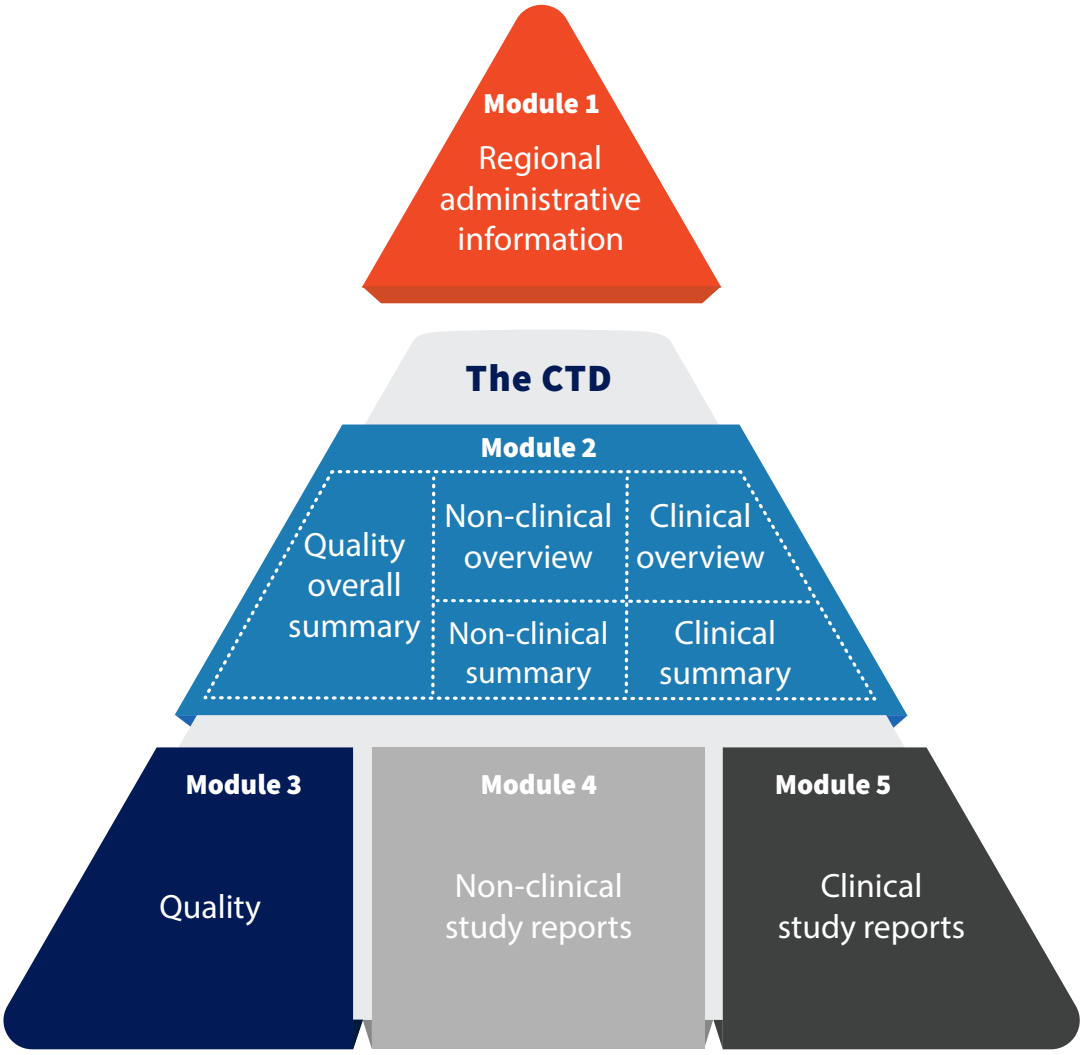
Driven by the downsizing, resizing, and reorganization that the biopharma R&D industry was facing at the time, our customer was transitioning away from having separate divisions and teams working on small molecule drug development versus large molecule/biologics drug development to a new model where both existed under the strategic umbrella of one global team.

These internal organizational changes, and new strategy, provided the opportunity for new approaches and ways of thinking that were focused on how the product development teams could start dealing with the large amounts of data required more effectively and efficiently and how teams could utilize the data better across the organization, all while navigating the “new norm” of having to do more with significantly fewer personnel resources available.

At the same time, throughout the drug discovery and drug development industry, modeling, digital twins, AI, and machine learning were also emerging areas to consider as successes were coming out of other industries, which stimulated biopharma researchers to start thinking about how they could apply these new tools within their teams to mine the valuable data they were already generating.

While drug development leaders at our customer were researching data management software solutions, they learned about some specific successes that their Medical Devices division already had in using a product development SaaS application tool developed by Cognition Corporation. In an effort to explore potentially better data management solutions for their own large molecule/biologics drug development process, the team contacted Cognition to discuss their specific challenges and to learn more about Cognition's capabilities.

THE CHALLENGES



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

The Chemistry, Manufacturing, and Controls (CMC) Module 3 component of the Common Technical Document (CTD) required for pharmaceutical regulatory submissions involves extensive documentation, including drug substance and drug product information, manufacturing processes, analytical methods, stability studies, and more. Managing the manual transcription and compilation of this documentation consisting of text annotations, images, data, tables, et cetera from various sources while ensuring accuracy, consistency, clarity, and coherence across different sections of the report can be very challenging and can often result in data integrity errors, risks, and delays in submission approvals.

Vast amounts of data were generated and collected in silos from the Biopharma company's R&D teams around the world, making it difficult for teams to access, share, and discuss information and to develop the required accurate data tables and reports needed in a reasonable amount of time. This impeded collaboration and led to overall drug development process inefficiencies. While the FDA and other health agency regulatory filings for small molecules were large in size at the time, they were still significantly smaller in size and less complex than the regulatory filings required for large molecules/biologics. Therefore, the magnitude and impact of the challenges the Biopharma company was facing were growing significantly as they managed their drug development pipeline and their growing number of biologics in development.

Drug development data processing and the manual creation of the required complex data tables and reports had become a major bottleneck for our customer, just as for many other biopharma companies. Creating the complex data tables essential for reports and regulatory filings required a significant amount of time and resources to complete; therefore, a high-priority goal for our customer was to find ways to reduce the time and resources needed so their researchers could do more science—especially considering they had many potential small and large molecule assets progressing through their development pipeline in parallel.

Additionally, documenting, interpreting, reporting, and verifying the accuracy of the tremendous amounts of data from a variety of sources was extremely labor-intensive and time-consuming. Most of the data was stored in Excel, Word, or home-grown databases developed by researchers on laboratory desktop PCs, which was a big challenge for both in-project and cross-project analyses because massive amounts of data had to be manually integrated and verified before the data could be utilized, interpreted, and transferred into the needed reports.

While data accuracy and verification of the huge amounts of data generated throughout the product development process were historically always a major challenge encountered in biopharma, the potential impact of these critical activities had to be dealt with head-on when our customer had a large molecule/biologics regulatory filing (BLA) negatively impacted by errors in the manual transcription of data that were found by an agency reviewing the reports. These issues caused the filing to be delayed several months while the Biopharma company rereviewed the raw data (which was correct), identified the source of the manual transcription/aggregation errors, communicated the situation to the agency, and corrected the filings. While the issues with the original regulatory filing did occur during the same time the organization had downsized its personnel across the organization, ultimately the manual verification of the data had compromised the accuracy and integrity of the filing and the same thing could impact other future filings, reinforcing to the Biopharma company that improved processes and solutions for data accuracy were high priority must-haves going forward.

Finally, during this same timeframe, ICH guidelines were continuing to evolve with a vision of some commonality and harmonization around requirements for different global regulatory filings. Instead of using data only once for a limited purpose, such as one report developed for a specific regulatory agency, a goal was emerging around a way of being able to share and reuse data for any number of analyses and reports throughout the product development lifecycle. If this could be achieved, then a company could put a report or regulatory filing together that would address the majority of the data that was required by all the different agencies instead of having to rewrite regulatory filings each time they were needed. All of this resulted in the Biopharma company creating a list of must-have capabilities.

Must-Have Capabilities Desired

- A solution developed with a data backbone and software application tools that can capture the specific types of analytical and process data, workflows, analyses, and output needed by a biopharma company (for example, to document the wide variety of data needed to compile CMC Module 3 reports).
- Digital data management platform that can scale with the massive volumes of often complex data generated throughout the drug development product lifecycle.
- Ability to automatically generate complex tables from large amounts of data and automate a variety of types of reports “on demand.”
- Ideally, include Structured Content and Data Management (SCDM) capabilities, and not just Structured Content Authoring (for example, narrative content) capabilities.
- Scalable, highly integratable software that is compatible with a biopharma company’s internal proprietary software and their existing commercially available data management software systems, without requiring significant support from their IT teams.
- Out-of-the-box SaaS to eliminate the need for expensive customization and ongoing, time-consuming and expensive validation and revalidation. Ideally, there is a portfolio of software application solutions that could be configured and integrated together as needed.
- Software must fit within the existing IT structure. This includes ensuring it is compatible with what they already have within their overall IT systems and that it will be easy to maintain and support in both the short and long term.
- The ability to automatically transcribe and aggregate large data sets, which ensures data integrity and chain of custody while not requiring manual data transcription and extensive data integrity verification.

- Data governance must ensure high quality and traceability throughout the data life cycle; data access should be controlled according to system user roles whereby data is accessible only with permission for specific data types and sets.
- Integrate Quality by Design (QbD) from drug discovery through manufacturing.

Why Cognition®/Compass® BIO Was Selected

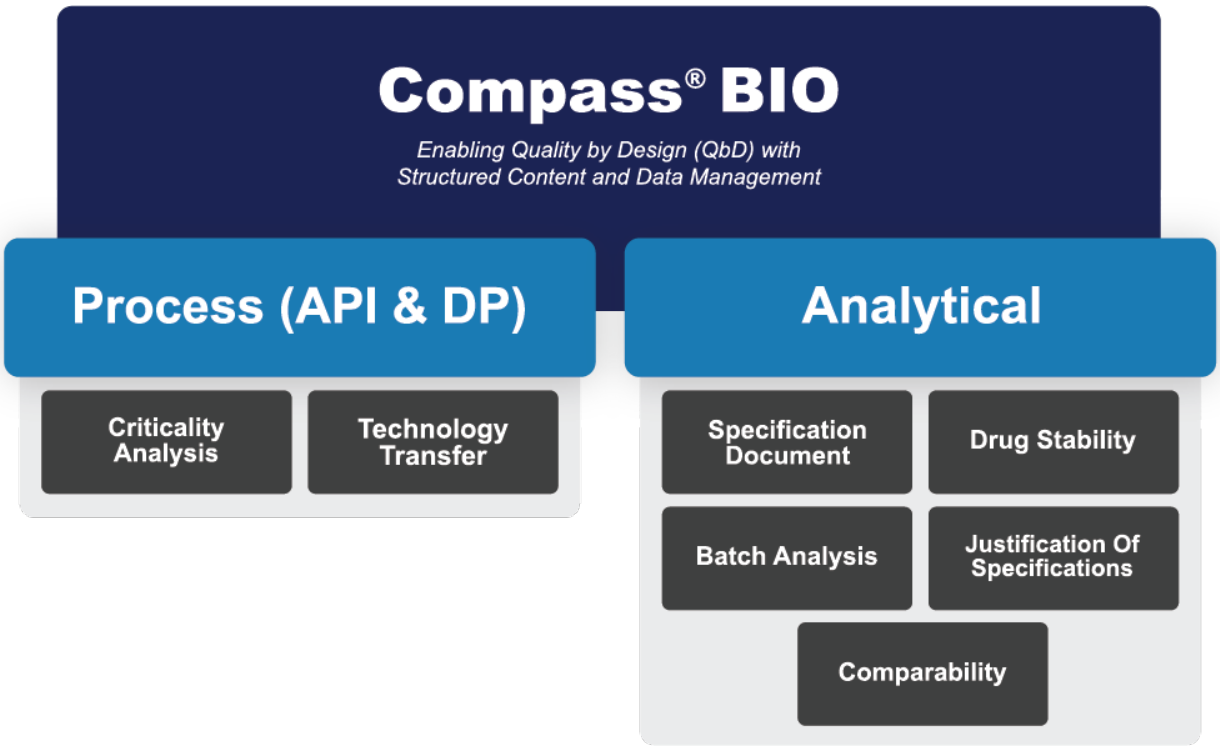
To identify the optimal solution for their product development digital transformation needs, the Biopharma company performed a comprehensive market assessment, based on their specific requirements, and spoke to several potential software vendors. While the preference was for an out-of-the-box product to provide a maximum of built-in functionalities, facilitate deployment, and ensure future maintenance, custom development project solutions were also considered

As the Biopharma company compared the potential options available, they quickly recognized that Cognition's Structured Content and Data Management (SCDM) approach not only checked all their boxes, but it was also the only viable solution that included all their must-have desired requirements.

Compass BIO is a suite of software applications for generating drug development e-reports for biologics and small molecules that have been developed to be used individually or combined.

Compass BIO enables the creation of structured analytical and process data reports with a data-driven, tabular organization of all relevant information. This streamlines rapid report generation using reusable project templates, applicable throughout the entire product development lifecycle.

The analytical data software suite of applications can include Specification Documents, Batch Analysis Reporting, Drug Stability Reporting, Comparability Reporting, Justification of Specification Reporting, and other capabilities. The process data software suite of applications capabilities can include Criticality Analysis, Process/Recipe, Tech Transfer, and other capabilities.



> *"Cognition has developed a novel solution around what biopharma drug developers do every day, and they have designed Compass BIO to align to the product development process in a way that provides an excellent structure for accurately managing the incredible amounts of data biopharma companies need to generate. Its software application capabilities provide a great foundation to build product development workflows and automated report generation,"*
> *said Senior Executive, Biopharma Co.*

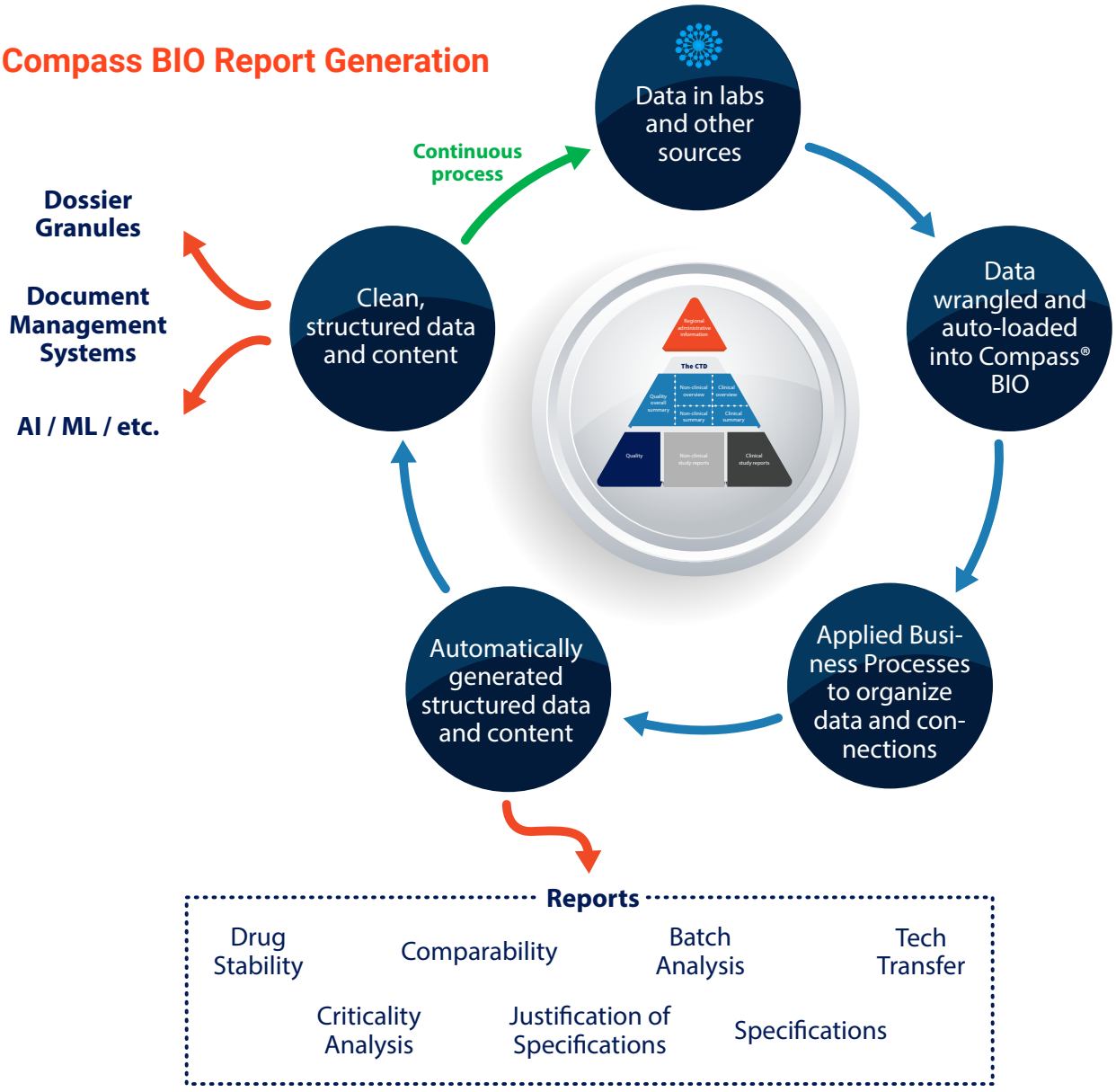
Our customer knew that evaluating, implementing, and investing in a new software system needed to be a stepwise approach so that they could prove to their colleagues (including research, development, IT, and senior leadership teams) that the product was working as desired, it was adding value, and it was cost-effective for both their short-term and longer-term needs. They also knew from prior experiences that the likelihood of larger future investments in the proposed solution would expand even further if they could get buy-in from other cross-functional teams.

Therefore, a pilot project was funded and implemented, led by the CMC team, to focus efforts initially on the analytical (Drug Stability) and process (Criticality Analysis) areas of product development where key activities and outputs needed improvements. They also knew that the potential loss of the drug development team's prior institutional knowledge, related to achieving successful product development outcomes, was at risk due to ongoing layoffs, reorganizations, and changes in biopharma strategies. Utilizing guided workflows and standardized built-in templates throughout their process to ensure consistency would help ensure compliance with their company SOPs and regulatory requirements by maintaining comprehensive documentation and audit trails to support regulatory submissions, inspections, and compliance with guidelines such as GxP.

THE RESULTS

During the deployment of the pilot phase project, the Cognition team worked closely with the Biopharma company to optimally set up the software applications and configure the customer's desired internal SOPs and workflows into a solution that was flexible and adapted to their specific needs. Compass BIO is a Structured Content and Data Management (SCDM) system aligned with biopharma product development workflows with QbD best practices built in so that no custom software development is required, which makes the implementation rollout straightforward and efficient.

Compass BIO Report Generation



Throughout the pilot, the CMC project team received a wide variety of positive feedback and internal success metrics directly from various teams which they could communicate more broadly to their senior leadership teams to highlight the benefits and return on investment (ROI) of using Compass BIO. The results achieved ultimately resulted in the pilot project being expanded to additional Compass BIO software application modules and users across the organization.

As the successful pilot was progressing within the CMC team, the benefits also led to broader discussions with various teams in our Biopharma customer's Discovery through Development organization, as well as with the IT team, to look deeper into what other Compass BIO capabilities could add value to if the solution was rolled out across the organization.

From the Biopharma senior management's perspective,

> *"any investment in a new modular solution that we could implement that could be shared across the drug discovery and development organization, versus only used by one team, was better because you could split and share the costs between those groups using the resource, and from an IT perspective, there are fewer unique software systems to support."*

Improved Data Accuracy and Consistency

Cognition's Compass BIO suite of applications has improved process and product development quality and data integrity throughout our Biopharma customer's organization by eliminating manual errors resulting from passing spreadsheets, documents, tables, and other ad hoc data exchanges between various people and teams, which was previously the operational status quo in the organization.

While it can be difficult to acknowledge and accept, all manual efforts are ultimately risk factors in a process and people are prone to making unintentional mistakes; however, by increasing the use of automation in the process, the likelihood of these mistakes significantly decreases, enhancing the reliability and accuracy of information. Additionally, by having seamless connectivity with data sources, Compass BIO provides real-time data traceability and identification of any potential data quality issues upon import to mitigate risk in regulatory submissions.

As the Director of Data Analytics at our Biopharma customer said,

> *"There is inherent risk in manual transcription of 20,000 data points, even with strong procedural controls for manual data verification. With Cognition's Compass BIO, all data is pulled from LIMS and the data tables generate automatically. We have reduced the number of data touches and significantly improved our report integrity."*

Automate Submission Ready Reports

The ability to design and automatically deliver customized reports such as CMC Module 3 Reports facilitates information transfer, eliminates laborious and time-consuming manual creation of complex data tables, and streamlines the creation and distribution of reports.

Cognition's Compass BIO provides a virtual guided workflow system that also enables teams to use a single set of data tables and reports from source to regulatory submission. The Biopharma customer can now simplify CMC data analysis and reporting by quickly generating, organizing, and linking complex tables and reports from large datasets. This automation supports CMC Module 3 analytical and process reporting for their regulatory filings.

As a testament to the benefits that Compass BIO has provided them, our Biopharma customer's Senior Scientific Director has said,

> *"We have tamed the beast of Criticality Analysis with Compass BIO. It lets us import or create recipes or process definitions, identify CQAs, and create complex risk analysis for all products. Our large molecule API teams consider it a core application."*

Having central access to relevant product development information in a structured content and data management system has revolutionized how our Biopharma customer's teams work today. In the past, information was scattered across groups and geographies and people needed to spend an inordinate amount of time and resources trying to find and interpret key data, develop complex tables, and generate the various types of reports required.

Now, every group has access to critical information and a single set of data tables and reports for use by CMC development, lifecycle management, and regulatory teams. This new capability enables informed decision-making and saves a tremendous amount of time and, ultimately, money throughout the product development process. Additionally, from source to submission, the collected and stored data can also be tracked and verified all the way back to the beginning of the discovery workflow, through the drug development workflow, and through commercialization, providing a crucial historical record that can be accessed as needed.

Significant Efficiency Gains and Cost Savings

With Cognition's Compass BIO in place, our Biopharma customer has standardized their workflows and significantly increased their operational efficiency and reduced costs. Time-consuming paperwork is minimized, and teams across the organization involved in product development can easily find the critical information they need and generate the specific reports they desire when needed.

Rather than spending hours on tedious and repetitive manual tasks, the Biopharma company's teams now have more time to focus on critical scientific activities that require their skills and expertise. They no longer spend valuable time and efforts on manual data reporting, tedious verification of data for accuracy, and inefficient data management.

Initially, a return on investment calculation produced during the initial vendor selection process predicted that the ongoing cost savings would outweigh the investment of bringing in the Compass BIO software for the pilot project. What our Biopharma customer discovered was that the Compass BIO suite of software applications provided multiple efficiency gains on many fronts, eliminated redundancies in daily work, and decreased their overall ongoing operating costs.

A senior scientist in the Biopharma company's Informatics team provided feedback that

> *"we have eliminated the tedious process of data table verification for our Stability Reports. We have also reduced the time to create large stability reports from 40 days to less than 20 days (50% improvement). The Compass BIO Stability Reporting application is saving us the equivalent of 3 full-time equivalent resources every year."*

LOOKING AHEAD

Currently, Cognition's Compass BIO is the Structured Content and Data Management backbone for our Biopharma customer's continually growing and evolving drug development organization. It has become a vital part of the Biopharma's organization and is used by multiple teams that are part of the product development process.

The use of the Compass BIO suite of applications continues to effectively support their unique and proprietary product development processes and is an integral component in supporting their future growth and successes.

An added benefit that has positively impacted our Biopharma customer is that the digital transformation that Compass BIO provides has also improved communication and fostered more efficient and effective collaboration between teams throughout the organization.

To address future requirements, Cognition continues to develop its Compass BIO suite of applications to support the newest technologies and approaches in biopharma drug discovery and development. Continual investment in product development keeps the solution future-proof and provides new functionalities, ensuring that biopharma customers can benefit well beyond the initial deployment as the Compass BIO platform evolves.

Finally, not only is our Biopharma customer very happy with the positive impact and ROI Compass BIO has had on their product development organization, but their Compass BIO users also continue to recommend Cognition and its suite of applications to their industry colleagues at other companies.

ABOUT COGNITION

For more than 20 years, Cognition Corporation has designed product development solutions specifically for the life sciences industry. We are shifting the data management landscape for life sciences product development from a static, document-based approach to a dynamic, information-driven approach helping to streamline and alleviate the administrative burden of product development documentation.

For biopharma companies, Cognition's Compass BIO software suite of applications for CMC module 3 reports—specifically created for biopharma and CDMO companies—is an innovative, technically driven digital CMC software solution to help biopharma companies navigate, organize, and generate the complex data tables and reports required for data management of projects and regulatory submissions without requiring manual data transcription and extensive data integrity checking.

To learn more about all the benefits of Compass BIO or to request a demo, meet with us:
https://meetings.hubspot.com/david-cronin/compass-bio-intro-call

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