



X-docs  
by Formpipe

# Formpipe Life Science's X-docs™ transforms document management process for leading pharmaceutical development organization CoreRx®

**CoreRx®, a contract development and manufacturing organization (CDMO), with a focus on early phase drug development, turned to Formpipe Life Science for a solution to its document management needs following a period of rapid growth. Within the first year of implementation, Formpipe's X-docs platform has enhanced efficiency and traceability, improved training and streamlined the audit process, as well as reduced the number and associated cost of deviations. Due to its success, CoreRx has already incorporated additional software from Formpipe's portfolio within its business.**

## Challenge

Over recent years, CoreRx has gone from strength-to-strength. Its proven track record of delivering comprehensive drug development services has helped propel the company to the top of its game. With 30 percent year-on-year growth recorded for the past three years, the organization has recently significantly upscaled its operations, expanding its manufacturing footprint from 7,000 to 35,000 square feet in 2012, and added two new buildings currently under construction to ensure it is able to meet the demands of its growing client base. In line with this, it has also seen staff numbers rise from 20 to 80.

While this exponential growth is testament to the team's hard work and proof of the quality of service being continually delivered to clients, the expansion has not been without its challenges. Delivering safe, effective, and innovative drug products, on time, and on budget is at the heart of CoreRx's business, and if it was to continue to do this, it was crucial to evaluate current processes and ensure they were fit-for-purpose moving forward.

Performing effective and safe document management, and having fast and controlled access is essential in the pharmaceutical industry, not only from a regulatory standpoint but also in terms of organizational efficiency. For CoreRx, it was clear that its current document management process, which was entirely paper-based, would not withstand the rapidly evolving needs of its business.

At 20 employees and operating in a 35,000 square foot facility, CoreRx had four Standard Operating Procedures (SOP) manuals; one master set in document control and three satellite sets that it had to maintain. It realized that as the team grew, if it continued with a paper-based system, the SOPs, test methods, and controlled documents that people need access to when they are performing a procedure, would not be available. It required an electronic document management solution which would ensure that everyone had access to the procedures and tests they needed, where and when they needed them.

Auditing and traceability was also a challenge. Paper-based documents were sometimes misplaced in circulation, and with an increasing work force, this problem would only increase. Training of changing work practices, and introduction training for employees not yet trained, is a vital part of SOP management and this was also proving difficult for CoreRx. As staff numbers

were increasing, CoreRx expected a corresponding rise in the number of deviations as a result of personnel not having access to, or not being trained correctly on, the latest SOPs and equipments manuals. These deviations took many forms which ranged from incorrect drug testing of incoming materials and out of specification drug batches, to equipment not being calibrated within specifications. The cost of eradicating these type of errors was significant for CoreRx. Having identified the need for an electronic document management system, CoreRx required a scalable, off-the-shelf-solution which could be implemented quickly and efficiently, and expand with the business as it continues to grow.

## Solution

To streamline the document management process, boost efficiency and consistency, and improve training across the company, CoreRx implemented Formpipe's X-docs electronic quality management system (EQMS). The platform provides CoreRx with the ideal solution to address all of its document management needs including, 21 CFR part 11 compliance for electronic signatures and audit trail, and improved access to SOPs within its expanding workforce across three locations. The system also offers the capability to notify all users when SOPs are updated and creates an auditable task for each user to read and attest they understand the SOP.

As well as the management of SOPs, the X-docs solution is able to accommodate different types of document libraries and workflows, meaning all staff now have access to any document they need wherever they are within the workplace, whether that be a policy, procedure, work instruction, equipment manual, or material safety data sheet (MSDS). CoreRx has also been able to expand the system to bring in computer validations and a number of other controlled documents related to projects. Because the company now has the ability to create specific project files in different directories, the team can set-up permissions depending on requirements. For example, they are able to grant an auditor permission to review certain information, such as approved documents within the scope of the audit, without seeing unapproved documents, or documents pertaining to other customers. Furthermore, the usability of X-docs means that new employees can be added to the software quickly, and are able to browse the system after just a few minutes of simple instruction. With a rapidly expanding team, this saves both time and cost for CoreRx.

In line with CoreRx's need for an off-the-shelf solution which could be integrated within its business in a short timeframe, Formpipe was able to implement X-docs in four weeks, allowing CoreRx to completely migrate its paper-based system to a fully functional X-docs electronic environment in only three months. Importantly for CoreRx, the unique software also has the ability to expand with its business as its needs change, supporting the company's long term plans. In fact, since the initial implementation in 2014, X-docs' flexibility has meant that Formpipe has been able to cost-effectively support CoreRx in expanding the use of the solution to solve other challenges within the business.

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## About CoreRx

CoreRx is a contract development and manufacturing organization providing customized pre-formulation services, formulation development, manufacturing, packaging and analytical services to the pharmaceutical and biotechnology industry. The company is renowned for reliably expediting early development activities to speed potential drugs to clinical trials while applying stage-specific scientific knowledge and experience. From first-in-man drug development to full cGMP manufacturing support, CoreRx combines 200+ years of combined pharmaceutical development expertise to produce safe, effective, and innovative drug products, on time, and on budget.



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## Business Impact

A year on from its implementation, CoreRx is already harnessing the many benefits of having a centralized electronic document management system. Currently hosting over 1,200 publications, the platform has delivered a myriad of cost and time savings, and efficiencies. As well as reduced storage requirements and staff costs, all documents are now created and maintained via the system meaning training, safety and compliance have all been improved. To give an example, CoreRx has estimated that on training alone, if the business had remained with a paper-based system, it would have taken a team of five staff to maintain the training program for its current team of 80. Having all SOPs within a central system that all employees have access to, while also having the ability to notify users when SOPs or work instructions change and task them to read and confirm their understanding of the new document, means that X-docs has eliminated the need for CoreRx to hire additional staff.

CoreRx has also noted a substantial decrease in the expected number of deviations and associated costs. Assuming the increase of deviations were in line with its business growth, CoreRx expected to see an increase in 42 deviations this year by continuing with its paper-based system. Using X-docs, the number of deviations actually decreased; CoreRx is attributing this decrease in deviations to employees having access to the correct, up-to-date procedure documentation whenever they need it. With a single deviation costing around \$1,600 just to write up, not including any product loss, CoreRx has estimated that X-docs has saved the company \$67,200 this year (based on 42 expected deviations that did not occur).

In terms of the quality assurance (QA) organization, it is essential for CoreRx that this function runs lean while remaining credible. A paper-based system for this group would be unmanageable and going paper-less has been a huge time and cost saver in its document control function. Before X-docs, the QA department processed 70 batch records in a year. After implementing the system, and given the organization's growth, the QA department is projected to process 250 batch records this year, a feat that would not have been achievable previously with the same staff level and without X-docs.

Additionally, prior to implementing the system the person responsible for document control would have to update three different manuals every time a company's SOP was updated. Now, it's a case of simply pressing the publish button to give every employee immediate access to current versions. The time saving here is considerable and means the company does not need multiple team members dedicated to making sure all the QA binders have the most current versions of all controlled documents.

For the company's validation department, using X-docs means that when they start a document they have a compliant IQ/OQ template available. This cuts down on the time it takes to write a validation because it prompts the author to input all the correct information.

Looking at the solution from an auditor's perspective, they can now be given access to all published directories and non-confidential files, so they can quickly browse SOPs, policies, equipment files and publications. CoreRx has created a traceability matrix, matching its SOPs to the corresponding provision in the 21 CFR Part 210/211 regulations, so that the organization can show auditors that it has controlled processes in place for each of the GMP regulations and can demonstrate to them several important factors - transparency into CoreRx's business practices, a controlled business process environment and strict adherence to all GMP regulations.

Kyle Brinkman, Director QA at CoreRx summarizes the decision to select X-docs in this manner:

*"Having carried out extensive market research, Formpipe's X-docs was an obvious choice for us. We required an out-of-the-box electronic document management solution with a short period of development and implementation. By working closely with the Formpipe team we were able to integrate the solution within our business within just three months and create a scalable platform which we can build on and adapt to meet our ever-changing business needs. The interface is simple and user-friendly meaning the team was able to get up and running quickly, and we gained business benefits almost immediately, including enhanced efficiency and traceability, improved training and compliance, and a streamlined audit process."*

## Future Outlook

As an expanding company with an aggressive growth strategy over the next two years, CoreRx's business is ever-changing and in its aim to remain at the top of its game, needs to continually raise the bar on the way it operates. As well as continuing to provide improved efficiencies and document control, the scalability and flexibility of the X-docs platform means that it has the ability to adapt in line with CoreRx's business requirements. In fact, since its implementation, CoreRx has incorporated a number of additional software solutions from Formpipe's portfolio within the initial platform, and is also currently in the process of implementing the company's X-forms solution, in a bid to achieve even more efficiencies.

## Benefits Summary

- Off-the-shelf, user-friendly solution which was developed and implemented within the business quickly and efficiently
- Expandability and scalability means the new platform can be adapted to meet the changing needs of the organization
- Effective and safe document management with fast and controlled access, boosting traceability and compliance, and improving organizational efficiency