

# Implementation of x-docs™ CAPA Module as a Hosted System - Renovo

## Our customer

Renovo is a biopharmaceutical product company and a leader in the discovery and development of drugs to reduce scarring, improve wound healing and enhance tissue regeneration. Renovo operate research facilities, a Quality Control (QC) laboratory operating to Good Manufacturing Practice (GMP), and a clinical trials unit supported by nurses and surgeons. The company are audited by the MHRA and FDA.

## The project

Renovo used a predominantly paper-based documentation system where documents were circulated for approval and stored in a central repository. The company decided to complement its quality management system with a system that would electronically track and manage its Corrective and Preventative Action management programme. Renovo wanted to be able to view and track the status of all of their open and closed CAPA forms. With this in mind, the company looked at several systems. They selected GxPi's CAPA Module because it offered greatest flexibility,

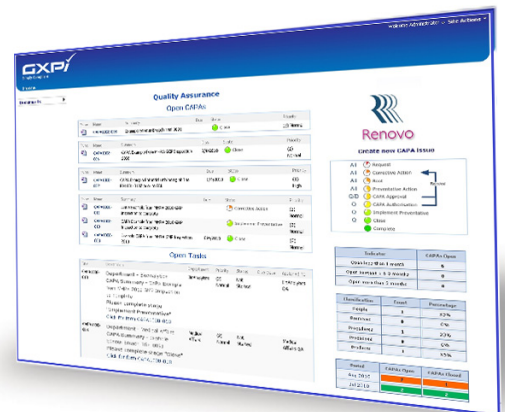
ease of configuration and it could be set-up and hosted in GxPi's qualified data centre in Nottingham with little impact on Renovo's limited IT resource. Since 2006, IT and QA compliance consultants from GxPi had supported Renovo providing expert advice on best industry practice for the development and validation of computer software. GxPi also had a long history of understanding compliance in the sector and were not just offering a simplifying technology, but understood Renovo's specific regulatory framework.

**“We were attracted to the GxPi's CAPA solution due to the flexibility of configuration that the CAPA Module offers. Our long-standing relationship with the company together with the professionalism and support of the consultancy services team was a further reason for our decision.”**

Steve Lomax, VP Quality Assurance, Renovo

## What we did

We quickly established the CAPA process that Renovo wanted to configure based on their paper system and it translated into a twelve stage linear CAPA process. We recommended that the number of steps could be reduced at this stage. We configured and set up a version 1.0 quickly into our hosting centre and after testing, Renovo determined that the number of stages should be reduced to eight as many of the intermediate steps were being performed by the same person. The speed of this 'real-time' configuration, review, sign off, build and test greatly reduced the cycle time of the project.



Quality Assurance Dashboard

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## The GxPi difference

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We understood Renovo needed a simple to use, quick to set up, hosted CAPA module. They were also working under tight timelines and restricted budgets. We took a lot of care in validating and managing the design and documentation of our core products and this greatly reduced the amount of work that Renovo needed to do. The decision by Renovo to select the CAPA Module, which is part of the **x-docs™** 'Forms Based Process' module, was based around the key requirement of being able to design and configure a CAPA workflow to best suit the company's needs. Renovo chose to use the CAPA Module in a hosted system environment to leverage all of the IT security, support, validation and management of an 'in-house' supported enterprise solution without them having to carry that cost directly.

**“We have been really impressed with the way the CAPA Module has integrated with existing processes. Within the system, we can manage, track and resolve quality issues effectively. This helps us to maintain regulatory compliance and also raises awareness across departments of their requirements to comply with regulatory standards of GMP and GCP activities.”**

Steve Lomax, VP Quality Assurance, Renovo

## Results

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Renovo used the CAPA Module as a hosted system to track, manage and resolve CAPAs within its organisation. The module assisted with monitoring the areas that generated the most issues. Since introducing the module, Renovo experienced greater visibility of CAPAs across all departments. In addition, the fact it was being used as a hosted system meant that it has caused minimal disruption to existing systems, the people using it and the established processes within Renovo.

Using the CAPA Module in a hosted environment removed the need for Renovo to carry out extensive installation and

operational qualification themselves, leaving more time to focus on User Acceptance Testing and performance qualification testing of the system. The validated private cloud environment meant that GxPi could spin up further environments quickly without any down time on their existing system.

GxPi are also responsible for managing the backup, restore, Microsoft licensing, Helpdesk support and routine maintenance activities of **x-docs™**, allowing our customer to focus on their core business.

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