

# x-docs™ QMS Module to Manage Vital Documents for the Drug Development Process - Quotient Bioresearch

## Our customer

Quotient is a leading provider of early stage and specialist drug development services to pharmaceutical, biotechnology and medical device clients worldwide. Their services are regulated under GCP, GLP and GMP regulations by the MHRA throughout the drug development lifecycle.

## The project

Quotient needed to ensure compliance with US FDA 21 CFR part 11 requirements for Electronic Records and Electronic Signatures. They required a detailed and full audit history for each document, and the ability to store a compliant electronic signature with the document during approval stages. They also wanted to configure their document workflows and permissions to mirror existing

processes, as well as sharing published documents in a secure environment across multiple geographic locations, some of which had 'common' documents with corporate and some of which had specific 'local' documents. Finally, they specified that anyone should be able to initiate a change request on any document, whether they were a document Consumer or Contributor.

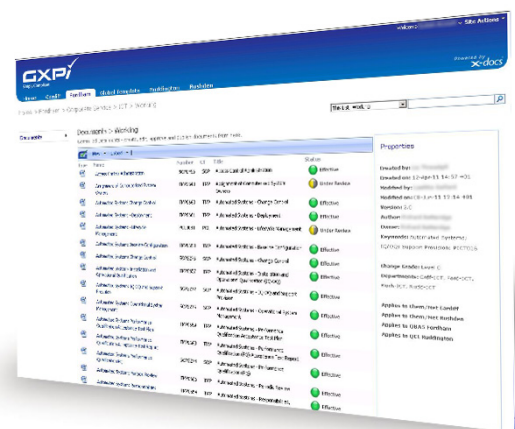
**“We chose GxPi and x-docs™ because the team seemed to understand a lot of our problems with controlled documents, particularly where we had documents that were going to be shared across multiple sites and access would be based on permissions.”**

Quality Manager, Quotient Bioresearch

## What we did

When we started the process, we invested time in educating the Quotient team around what was possible with SharePoint and using Out of the Box functionality of **x-docs™** to establish their exact business use cases. Even at this stage they had not completely decided what solution (**x-docs™** or a competitors) they wanted. Our extensive consulting background enabled us to capture their baseline requirements, and set up a test area for them to work in and review the actual functionality. **x-docs™** had most of the features they required and, as they had made a corporate IT decision that SharePoint was their desired platform, some of the competition dropped away.

We then helped them to compile a detailed User Requirement Specification, whilst we then started to write a detailed design specification for the new features they wanted and a configuration specification to build their specific hierarchy of sites. As it happened, we had to bring a new business they acquired on-line sooner than expected; we had to quickly migrate documents from this business into a hosted environment whilst their configuration and testing for their on-premise version was completed. After the build and testing we trained the key User group and administrators and delivered a User Manual specific for their system. Because we were with them from the education phase both the GxPi and Quotient project teams worked in a very collaborative and trusting way.



x-docs™ 'Working Library' screen for Contributors

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## The GxPi difference

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We were able to tailor a configured solution based on **x-docs™** to suit Quotient's requirements with the flexibility to add further features, modules and users in the future. We addressed the concerns of Users, who did not like using their existing software; we have always been led by the need to simplify complicated processes in software with the User in mind and we sought input from some Ergonomics Consultants to make the user Experience as simple as possible (given the limitations of keeping SharePoint as the core platform). We also had to be creative within budgetary constraints, whilst making the solution flexible enough to grow with Quotient. Finally we had to fit into the existing ICT structure (in particular their virtualised environment and their licensing requirements) so having a highly experienced IT team was critical.

**“After talking with GxPi, we realised that they not only had the skills to deliver the compliance aspects of the document management system, but as Microsoft Gold Partners, they had the technical skills to configure our build. We knew we wanted some new code functions and features building, and also some specialised webparts and they were able to quickly understand what we wanted and why. They had developed some useful tools to deploy, build, assign permissions and test quite a complicated site hierarchy. We were also pleased to see that they had other solutions on SharePoint for compliant training management and Digital Signatures that we could integrate at a later stage.”**

Group ICT Manager, Quotient Bioresearch

## Results

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The system was installed on Quotient's servers in November 2010 for them to start their validation effort. **x-docs™** now allows Quotient to manage their controlled documents across four geographic locations on a Microsoft SharePoint platform. It has been configured to their specific needs and rolled out to over four hundred users. **x-docs™** was a great help when, earlier in 2010, Quotient acquired a new business and they were able to migrate the existing documents straight on to the hosted system being used for their configuration set up, making for a highly efficient, effective and timely changeover. Quotient were using the hosted version of the **x-docs™** product for configuration and testing, which meant that their documents were migrated and stored securely in GxPi's validated data centre.

**“We really liked the simple user interface and the integration with our existing working tools.”**

Quality Manager, Quotient Bioresearch

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