

# Implementation of 'hosted' **x-docs™** EDMS QMS Module - Food and Drug Analytical Services Ltd. (FDAS)

## Our customer

FDAS is an independent contract testing laboratory serving the pharmaceutical, biopharmaceutical, veterinary and nutraceuticals sectors and primarily offers routine QC and stability testing from their cGMP laboratory.

## The project

The company required a validated electronic document management system (EDMS) with the Quality Management System (QMS) module to ensure that all of their manufacturing and testing procedures were stored and managed in compliance with Good Manufacturing Practice (GMP) and the US FDA 21 CFR Part 11 regulation on Electronic Records and Electronic Signatures. A solution was needed that would keep

records created separated for each of FDAS's customers. FDAS looked to GxPi to implement a system that was regulatory compliant, ensured quick and easy secure access to records and offered their clients and regulatory authorities a view of all product data. They also had a variety of different customers that needed access to their own data without being able to see other's data, while FDAS needed access to all.

**"As our company communicates with approximately 70 different clients at any one time, it is essential that we have a document management system that is reliable and easy to use."**

Larissa Taylor, Technical Director at FDAS

## What we did

We quickly established the storage hierarchy that FDAS wanted to configure, and built that environment in our qualified hosting centre. This meant that we could walk them through a document lifecycle, confirm that was what they wanted, and then test and validate that configuration whilst documenting the tests. We released the environment to FDAS after giving them formal training and allowed them access to undertake User Acceptance Testing (UAT) with our support. We also helped them migrate their existing documents into the **x-docs™** environment ready for 'go-live'. GxPi's consultancy services team also provided GMP and IT compliance expertise to FDAS. This unique combination of skills meant that GxPi left FDAS with an understanding of how the system would operate and the potential risks and benefits to using it. Finally, during an MHRA audit, GxPi provided their IT Quality Manager to act part of the FDAS quality team to answer questions on **x-docs™**.



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## The GxPi difference

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We understood exactly that FDAS needed a simple to use, quick to set up, compliant QMS, to manage their quality documents in a validated electronic environment. We took a great deal of care in validating and managing the build of our products and this greatly reduced the risk of implementation, amount of work that FDAS needed to do, and greatly increased their confidence in our product.

**“During our investigations of EDMS solutions on the market we found that many systems lacked the rigorous security and validation procedures required by the pharmaceutical industry. We selected GxPi’s **x-docs™** to improve laboratory efficiency and comply with regulatory requirements in a cost-effective way. The consultancy services offered by the company have added further value, enabling us to achieve efficient compliant processes.”**

Larissa Taylor, Technical Director at FDAS

## Results

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We implemented the entire project in 6 weeks and since ‘go-live’ there have been no reported findings around the **x-docs™** QMS platform or use, from the initial and subsequent MHRA audits. Our solution was delivered to FDAS within very tight implementation and monthly budget constraints.

GxPi’s **x-docs™** hosted (QMS) module was easy for the users

to learn how to use, ensured regulatory compliance and was implemented and validated quickly. The system is GMP compliant, enabling FDAS to manage quality documentation, templates and workflows, versions and revisions and create a full audit trail of all their GMP documents. The hosted solution gives FDAS all of the IT security, support and management of an ‘in-house’ supported enterprise solution without the associated costs.

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