



X-docs  
by Formpipe

## Bluefish Pharmaceuticals and Formpipe Life Science introducing innovation and simplicity to quality and compliance management



Founded in Sweden, and with operations in 12 European countries, Bluefish Pharmaceuticals has become one of the world's most progressive generic pharmaceuticals companies. With a clear corporate vision of making quality medicines accessible to all, Bluefish Pharmaceuticals offers an impressive product portfolio consisting of a broad range of high quality generics for all major therapeutic areas.

By focusing on innovation and simplicity, and driving cost efficiency in all stages, the company has created a strong and vibrant brand that offers quality pharmaceuticals at prices affordable to all.

### Evaluating Operations

With a clear mandate to deliver value, drive efficiency at every opportunity and a dedication to continuously improve processes across the company, Bluefish Pharmaceuticals embarked upon an initiative to assess its methods of quality assurance and compliance management.

While the existing quality and compliance measures were sufficient, the company realised there was an opportunity to improve efficiency in both time spent and cost allocated. The current process relied upon a manual, paper-based approach, which proved to be admin intensive and time consuming. It required a dedicated, full-time member of staff to manually manage documents and the associated workflows. While the approach met industry standards, Berit Lindholm, chief executive officer at Bluefish Pharmaceuticals, wanted to explore opportunities to enhance the company's efficiencies:

*"The number of hours the team spent on ensuring we maintained our compliant status was quite intensive. With the goal to improve efficiency across all of our company procedures, I decided it best to explore solutions that were not only time saving, but cost effective."*

### Looking for a new solution

Keen to implement a more robust way of managing quality assurance and demonstrating their compliant status, Bluefish Pharmaceuticals researched the market to find a new solution. Several software vendors were shortlisted, and each provided demonstrations of their products. There were several options available; from off-the-shelf systems to fully customised platforms that would be built around the unique needs of the Bluefish business. The latter, however, would incur significant costs and require more resources in comparison, which would not properly align with the company's goal to improve cost efficiency and also delay implementation.

What Bluefish needed was a middle ground. Time was of the essence; the company required a system that would not only be effective but would be implemented quickly too. A system that would offer the best of both worlds: a pre-configured, easy to deploy, electronic quality management system that could be tailored as and when the need arose.

Bluefish approached the process with an open mind. Where some businesses would insist that a system be built around their exact processes, Bluefish recognised the value a pre-validated system could offer, as Lindholm highlights:

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*“We are a small, virtual business, so it was vital for us to enlist the help of a provider that not only understood the challenges that come with operating a business of this scale, but also offer the necessary support and resources to stand up a new system.”*

After appropriate scrutiny and due diligence, Bluefish selected the pre-configured, SharePoint based, enterprise EQMS, X-docs, by Formpipe Life Science utilising the Docs, Train and Forms modules. The latter consisted of pre-configured processes to manage Deviations, Change Controls and CAPAs.

The EQMS met all of the company’s specified needs in relation to providing users with a platform to:

- Manage GxP controlled documentation and maintain the necessary framework to satisfy auditors.
- Meet the rigorous audit demands for training records in support of employees performing regulated actions.
- Simplify the job of monitoring and reporting on progress of activity including CAPA, change control, deviations and audits.

The contract with Formpipe Life Science was signed in May 2016. Describing the selection process, Lindholm comments:

*“We reviewed many options, but X-docs met our needs best. Formpipe’s values of professionalism, honesty, transparency and taking a collaborative and consultative approach to projects aligned nicely with our company and thus, made them a great choice as a trusted partner.*

*“It was clear from the demonstration, and positive customer referrals, that X-docs would help us on our journey to continuously improve our quality processes and relieve some much-needed pressure on administration personnel.”*

## Benefitting from improved quality assurance and compliance management

Implementation of X-docs and X-forms began in September 2016 and took under three months to complete. Phase 1 of the project included URS, validation report completion, testing, negotiating the SLA and approvals. The second phase – the implementation of X-train – involved migrating documents from Excel, defining new processes, and writing job descriptions. This phase was completed in partnership with the project and HR teams at Bluefish.

“As one might imagine, going from a paper-based approach to adopting a digital platform presents its set of challenges in terms of transitioning the employee base,” said Lindholm. “Formpipe helped us with this transition period every step of the way and made themselves available to provide assistance when needed. We were very pleased with their dedication to not only deliver a stable system for us, but providing quality support along the way.”

With quality assurance process management transformed, Bluefish has noted several benefits. Firstly, the firm has reduced manual administration by an estimated two thirds. This represents a significant cost saving for the value-driven business. With X-docs in place, Bluefish has full visibility over its entire quality-based workflows. The system assigns actions via push notifications and alerts, which facilitates a sense of ownership and allows for vital tasks to be handled in a swift manner.

The automated reporting, sophisticated search functionality, and audit trail insights are providing a level of transparency that surpasses the capabilities of previous methods. For processes like SOPs, Bluefish can now establish which members of staff are qualified to perform certain tasks, and which ones aren’t in a matter of seconds.

## Looking to the future

Bluefish’s dedication to continuously improve their business has the company exploring more modules with Formpipe Life Science and potential upgrades in the future.

Summarising her view of the project, Lindholm concludes: “Our experience with Formpipe has been fantastic, as they’ve turned, what could have been a cumbersome process, into an easy transition period for our company. I’d be confident in recommending Formpipe to any small business like ours who’s looking for an off-the-shelf solution that delivers exceptional quality and support. Although the change curve can be intimidating, with Formpipe, it’s worth taking the step to streamlining processes and providing your employees the opportunity to work more efficiently.

With Formpipe, Bluefish has stronger foundations in place to continue its mission of making quality pharmaceuticals accessible to more people.”



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