

IT GxP Compliance Programme - B2B and Supply Chain Integration Specialist (SME)

Our customer

Our customer is a best in class B2B (Business to Business) integration solution provider, responsible for the cost effective and rapid setup of business-critical supply chains using Electronic Data Interchange (EDI) to enable the management of transactions. Its broad range of blue chip clients includes global pharmaceutical and Life Science organisations.

The project

As part of its strategy and growth, our customer wanted to increase its capabilities to support these global pharmaceutical organisations. To do this they understood they needed to implement changes in order to meet with GxP best practice and adherence to GAMP® guidelines.

GXPi were commissioned to support with assessing this and then establishing an action plan to implement the necessary changes. Our customer expected to win new business as a result of this project.

“At the 11th hour in a contract negotiation with a major Life Sciences company for an EMEA based project, the requirement for FDA Part 11 / GxP compliance became apparent following the acquisition of a Pharmaceutical company.”

Stephen Holdship
Consulting Director, Crossgate

What we did

Our approach with this project was to structure an implementation plan that would satisfy the needs of the customer’s pharmaceutical clients whilst not compromising or over-burdening those parts of the business where such controls were not necessary. In order to do this we developed a programme that assessed what needed to be changed in order to achieve GxP compliance and a process by which this could be best aligned and delivered alongside the core customer business:

- Conduct a GxP audit and gap analysis of the existing the quality system, software development lifecycle (SDLC) and validation testing of software and systems
- Map all existing processes and documentation against the regulatory requirements and GxP best practice models (including ISPE GAMP® compliance) of the pharmaceutical industry in order to help the customer understand where change was needed in order to meet its business objectives

- Structure an action plan to modify existing processes and Quality Systems to meet GxP best practice
- Represent the customer during quality audits by pharmaceutical clients

We also provided GxP compliance training across the business in order to help with the roll-out of new processes and the culture change necessary to achieve compliance. With our extensive consultant network we were able to support the Quality Manager to help establish the changes to Quality Systems. Our approach ensured the sustainable transfer of knowledge from our consultants to the customer.

The GXPi difference

With our extensive experience of Quality Systems, regulatory compliance and validation of software and business systems, we were able to tailor a support package to meet with the needs of our customer. In this case that meant working very closely with our customer to develop and implement a strategy that ensured adequate GxP compliance with the needs of its pharmaceutical customers whilst not compromising the other existing areas of business in other vertical markets.

Our approach was pragmatic, risk-based and completely transparent. We used our own tried and tested GXPi templates and tools to reduce time and cost of implementation. We delivered a Quality Policy and Validation Master Plan. Our consultant team was able to mobilise very quickly and align the existing customer business with the requirements of its pharmaceutical client. GXPi was able to present the action plan in a way that helped secure new business opportunities by delivering the necessary changes and helping to generate confidence with the end customer.

“After the first session with GXPi, I was very impressed with their understanding of exactly how and what our business needed to do to achieve compliance, following which they were able to quickly mobilize a team to start helping us. Working with the Formpipe team, we were able to complete a full gap analysis of our current project delivery processes and prepare an action plan to introduce the necessary changes.”

Stephen Holdship
Consulting Director, Crossgate

Results

The Project was very successful. Our customer secured three new projects with top 20 pharma organisations. The payback was less than one year.

Item	Objective	Responsibilities	Documents Required
1.	Establish QMS	A documented set of processes and controls will ensure that there are fully qualified people in place for the development of critical systems.	Documents Required: System Development SOP, including on current status, using refs 2-12 from this list as sections. Other relevant GxP as mentioned below.
2.	Establish Requirements	Ensure that our requirements are a deliverable or verifiable by the customer.	Build on our own SWM template, but include numbered requirements. To be used by MFR's. Template High Level and Functional Risk Assessment templates (if not provided by customer). Build on Current SWM Template (which in effect already includes in 'Project Quality Plan').
3.	Quality Planning	Define how the QMS will be implemented for each critical product, application or sub-system as part of the overall project plan.	Partly addressed via GXPi audit. Create software development follow their own QMS for Client projects.
4.	Assessment of sub-systems	Ensure that all sub-systems are assessed for compliance with the relevant GxP requirements.	Development Process SOP, and templates for Software Design Specifications (May be split into core product and configuration).
5.	Product Qualification	Ensure the system meets the relevant requirements.	For each of 7. Ensure common Specifications (tailored specifically for each of the components) to enable installation and operation.

Software Supplier Responsibilities

“The challenge I gave GXPi was that the changes must not compromise the non-pharma business which still accounts for the majority of our global customers. GXPi achieved this and facilitated the ability to modify our project procedures to fully embrace GxP. Throughout our engagement, I have been very impressed with their pragmatism and drive to get on and make things happen.”

Stephen Holdship
Consulting Director, Crossgate

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