GCP Compliance Audit - Clinical Supplies Distributor, East Europe (SME)

Our customer

Our customer is a clinical supplies distribution specialist operating in Eastern Europe.

The project

Our customer wanted to expand its GCP compliance capabilities from the domestic market it had been serving in order to support the growth of multinational pharmaceutical sponsor companies wishing to utilise its services.
Our customer requested that an audit of its current operations be carried out in order to establish a Gap Analysis with EU GCP requirements for the supply and distribution of investigational medicinal products and associated clinical material.
The purpose of this was to enable our customer to identify what changes would be necessary in order to bring its operation in line with EU GCP and 'best practice' that its clients (sponsor companies) would expect.

The scope of the compliance audit covered:

- Gap Analysis of existing the Quality Management System against EU GCP and GDP regulations and best practice
- Facility audit (following material flow from receipt through storage, labelling and shipping)
- Focus on critical elements such as Quarantine / Release, Controlled Drugs storage and Receipt and Destruction of returned material
- Assessing how electronic and paper records were managed and stored

What we did

We selected a team of consultants to work on this project that were able to understand and advise on the main compliance areas of the assignment; GCP, GDP and the overall Quality System. Using this blend of knowledge we were able to provide the customer with an assessment and action plan that dealt with their entire improvement program.

This was achieved as follows:

- We structured the overall audit and gap analysis process with a high level of interactivity with our customer's team in order to help explain the regulatory drivers and their impact upon the existing operation
- We spent time listening and understanding to what our customer's immediate, medium-term and long-term business objectives were and therefore what changes to existing Quality Systems and compliance would be needed in order to help achieve these
- We carefully explained the main compliance issues in each area of the business, recommended the priorities and suggested the best approach to deal with them
- We used our own GXPi methodology and templates to develop a detailed action plan that identified the compliance issues for each area of the existing business, provide a remediation action and assign a priority to each of these tasks.

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The GXPi difference

We listened carefully to our customer, mobilised a talented, experienced team quickly and worked in a completely integrated way with our customer. By using this approach, we were able to deliver the support as a blend of audit assessment, coaching and education in order to deliver maximum benefit to our customer.

The use of our own well-established audit methodologies and tools meant that the overall assessment of the business was completed in a very short timeframe with limited resource and low cost.

Because we invested time in understanding and appreciating our customer's business we were able to establish a realistic and achievable action plan that was sympathetic to customer resource constraints and existing commitments.

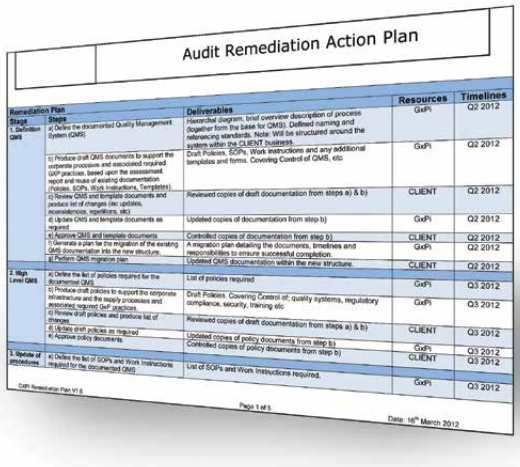
"We engaged with GXPi as we needed a consulting business that had experts in EU GCP regulations and practical experience of implementing quality systems to help us complete a gap analysis of our clinical trials logistics business in the Ukraine. Their team reacted very quickly and carried out an audit process that helped us understand what we needed to do to achieve the GCP compliance goals of our business. We have been very satisfied with the service GXPi has provided to us and we continue to use them as our Quality and Compliance support partner."

Oksana Maksimova -
QA Manager, Clinical Trials Logistics

Results

As a result of this successful project, our customer was able to expand its GCP compliance to new markets, including securing new contracts with new EU customers. The audit and subsequent action plan provided a return on investment (ROI) of less than 6 months.

We continued to provide quality and compliance support as an integrated part of the customer quality team.


Audit Remediation Action Plan

Remediation Plan		Deliverables	Resources	Timelines
Stage	Steps			
1. Definition QMS	a) Define the documented Quality Management System (QMS)	Hierarchal diagram, brief overview description of process (together form the base for QMS). Defined naming and referencing standards. Note: Will be structured around the systems within the CLIENT business	GxPi	Q2 2012
	b) Produce draft QMS documents to support the corporate processes and associated required GXP practices, based upon the assessment report and reuse of existing documentation (Policies, SOPs, Work Instructions, Templates)	Draft Policies, SOPs, Work Instructions and any additional templates and forms. Covering Control of QMS, etc	GxPi	Q2 2012
	c) Review QMS and template documents and produce list of changes (inc updates, inconsistencies, repetitions, etc)	Reviewed copies of draft documentation from steps a) & b)	CLIENT	Q2 2012
	d) Update QMS and template documents as required	Updated copies of documentation from step b)	GxPi	Q2 2012
	e) Approve QMS and template documents	Controlled copies of documentation from step b)	CLIENT	Q2 2012
	f) Generate a plan for the migration of the existing QMS documentation into the new structure.	A migration plan detailing the documents, timelines and responsibilities to ensure successful completion.	GxPi	Q2 2012
	g) Perform QMS migration plan	Updated QMS documentation within the new structure.	CLIENT	Q2 2012
2. High Level QMS	a) Define the list of policies required for the documented QMS	List of policies required	GxPi	Q3 2012
	b) Produce draft policies to support the corporate infrastructure and the supply processes and associated required GxP practices.	Draft Policies Covering Control of, quality systems, regulatory compliance, security, training etc	GxPi	Q3 2012
	c) Review draft policies and produce list of changes	Reviewed copies of draft documentation from steps a) & b)	CLIENT	Q3 2012
	d) Update draft policies as required	Updated copies of policy documents from step b)	GxPi	Q3 2012
	e) Approve policy documents	Controlled copies of policy documents from step b)	CLIENT	Q3 2012
3. Update of procedures	a) Define the list of SOPs and Work Instructions required for the documented QMS	List of SOPs and Work Instructions required.	GxPi	Q3 2012

Compliance Audit Remediation Plan

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