Quality Through Design

QUALITY THROUGH DESIGN

Specialising in the effective design and support of Pharmaceutical Quality Systems

Achieving business excellence on a strong compliance base

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EXECUTIVE SUMMARY

Quality Through Design provides a full spectrum of support to pharmaceutical companies. With the aim to go beyond compliance by creating or supporting a value adding Pharmaceutical Quality System (PQS).

How we add value is achieved by firstly listening to you.

Despite the fundamental requirements of a PQS being well established in most territories, it is clear that the PQS has to account for your specific business in order to ensure value is created. We seek to understand your challenges and opportunities and tailor a solution that is right for you.

The value may be through collaborative design or simply by providing a level of service that is both competitive and flexible as a contingency for your existing business and Quality teams.

Quality Through Design Ltd can help you achieve and surpass your goals

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SUPPLY CHAIN ASSURANCE

AUDITS; ONGOING QUALITY RISK MANAGEMENT

It is of vital importance that companies assure themselves of the quality of supplied materials and services. Crucially, the application of Quality Risk Management in determining the inherent level of risk (as well as the specific risk from your companies use of the material or service) is vital to ensuring the right level of assessment and oversight.

Quality Through Design can contribute to the design of your Supplier Quality Approval programme or support its application.

APPROACH

BACKGROUND ASSESSMENT

The first step in our process is to establish the criticality and inherent associated risk with the supplied material or service.

This enables us to establish Critical Quality Attributes (CQAs) which form the basis of the audit planning.

COMPLIANCE OVERLAY

Once we understand your needs, we can overlay the compliance framework (e.g. US FDA CFR, EU GMP) and begin the preparatory phase. This would include preparatory meetings with the auditee and advanced review of documentation with the aim of refining the scope of the agenda.

This phase would culminate in a targeted agenda to maximise the time available on site and to anticipate any audit restrictions in advance.

ON SITE AUDIT

On site we use our experience of auditing in a range of environments and across a range of activities and supplied materials combined with the CQAs that are important to you.

From the opening to the close of the audit, we conduct ourselves with the utmost professionalism and ensure the auditee is treated courteously and with respect. Importantly we apply our experience to understand non-conformances that may be uncovered and ensure they are put into a context that enables you to establish the true extent of the risk and the resultant impact.

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Prior to close out, the non-conformances would be agreed with the auditee and the context we provide would enable us either to assess their proposed Corrective and Preventive Actions or for you to be able to follow up without our support.

REPORT

The reporting of audits contains sufficient narrative to both understand the capability of the audited site and to provide the basis for scope setting of subsequent audits.

We will provide advice on important topics such as areas to focus on next time and potential area of weakness that can supplement the report and lead to more targeted supplier oversight.

WHY WORK WITH US?

Our team of auditors include auditors that have achieved eligibility to act as 'Qualified Persons' in the European Union which has afforded them the opportunity to design and assess Pharmaceutical Quality Systems (PQS) across the globe. Their knowledge of Good current Practices (including GMP, GCP etc) extends across numerous territories.

In addition to these skills, our auditors have all had their own PQS inspected by leading regulatory agencies and so understand what is needed from first hand experience.

In some cases, such as for audits supporting submissions within an EU regulatory procedure, a Qualified Person audit will be well received by Health Authority assessors.

Most importantly they all understand risk and how it can present itself in pharmaceutical operations. They are therefore best placed to determine how suppliers, as an extension of your PQS, can impact the overall state of compliance.

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AUDIT AND CONSULTANCY SERVICES

AUDITS PROCESS

The audit process as delivered by Quality Through Design Ltd consists of the following stages and associated deliverables:

Stage	Additional Detail	Deliverable	Considerations
Preparation	Assigned auditor will: confirm standards to apply in the audit, participate in a call with auditee, clarify any restrictions (e.g. such as restrictions on access or viewing activities)	* Completion of agenda and pre-audit documentation request	* Audit agenda will utilise Quality Through Design's template unless specifically instructed otherwise. Should pre-audit documentation be only partially provided or not at all; this will be communicated to the client.
Conduct	Assigned auditor will conduct audit to the agenda. Audit conduct will be respectful of the auditee. Non-compliances will be noted during the audit and explained at the time of discovery. Initial **classification of findings will be conveyed at the closing meeting. Final classification of findings will not be conveyed until agreed with the client.	Basis for an audit report	**classifications will be conveyed to the client in sufficient detail (in the initial post audit follow up) to enable agreement and confirmation of finding classification in accordance with client SOPs

	An audit outcome (approved/ not approved) will not be conveyed until discussion with the client.		
Initial post audit follow up	Assigned auditor will summarise audit findings and suggest potential outcome to the client	Email or teleconference (1 hour) within 5 working days of the audit completion	N/A
Audit report (client review)	Assigned auditor will generate audit report using Quality Through Design template unless otherwise instructed. Report shall contain sufficient narrative to provide the context of findings. Report shall contain documentation viewed and other pertinent details. Report shall be reviewed internally by Quality Through Design Report shall state focus areas for the next scheduled audit (if applicable) and the time frame for routine re-audit (as communicated by the client and based on pertinent SOPs)	Report in pdf format with 'Draft' watermark for initial client review within 20 working days of audit	Client review is based on the receipt and subsequent response to comments via email and annotations.
Audit report issuance (to auditee)	Assigned auditor will provide a pdf of the report signed by the auditor. Auditor will communicate the expectation for CAPA generation and response. Instruction to direct CAPA	Endorsed report in PDF format	***Should the client wish to convey the outcome of the audit, the auditor will not convey the outcome

	responses simultaneously to the client and the auditor will be conveyed. The time frame for CAPA proposal will be agreed between the client and the auditor (and communicated to the auditee). ***Auditor will communicate the outcome of the audit		
CAPA follow up	Assigned auditor shall track the provision of CAPA from the auditee (via email reminders) and, upon receipt of the CAPA, review the suitability. Auditor and client shall review CAPA by email	Auditor will review CAPA and propose outcome to client within 5 working days	Client review is based on the receipt and subsequent response to comments via email and annotations.
Audit Close			

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THE COMPLETE PACKAGE

In addition to the support of your Supply Chain Assurance programme, Quality Through Design can support all aspects of your PQS.

OPTIMISED QUALITY AND TECHNICAL AGREEMENT PROCESS

Quality and Technical Agreements are required for GxP compliance. They can also be valuable tools that give you a consistent extension of your PQS to your outsourced service and material providers whilst also allowing you to track the critical attributes of the relationship.

Importantly, Quality and Technical Agreements are a negotiation. Negotiation is hard to automate and technical agreement processes can become quite protracted with a large number of escalations, follow up calls and lag time.

Quality Through Design have designed a process that will allow any member of the Quality team to run the technical agreement process and efficiently manage and limit escalations to more senior team members. The process also contains measures to increase transparency of status tracking by utilising common applications such as Microsoft Excel™ and Microsoft Visio™.

The deliverables include templates, a critical attribute guide with narrative, a 'Quality and Technical agreement' playbook, and the configuration of tracking and visualisation tools.

PQS BASELINE AND MATURITY ASSESSMENTS

A well designed and compliant Quality System should have internal measures (e.g. self-inspections) and external measures (e.g. external audits) which can give a Quality leader a good indication of performance, gaps and opportunities for improvement. Quality Through Design recognise the strength of these measures but equally recognise the benefit for a more focussed external perspective.

An external perspective using up to date industry knowledge, lean and six sigma principles and experience across a range of PQS can be of real value. Whether it is on one site or across a range of sites, an external assessment can help deliver improvements in compliance and a reduction in operating costs.

These assessments are also designed to engage with cross functional business partners as Quality is at the heart of many processes and systems but it is often in collaboration with other stakeholders where the most can be achieved.

ADVANCED PQS DESIGN USING THE PRINCIPLES OF ICH Q10

Once a compliance framework is in place the business can start to look at working with the PQS to achieve maximum value. Quality Through Design can work with you to add other elements of a PQS discussed within ICH Q10 'Pharmaceutical Quality System'. Whether that is the basis for a Knowledge Management System or simply some additions to an existing process, Quality Through Design can help.

Once the business recognises the value that can be achieved by embracing the Pharmaceutical Quality System and realising some of the direct benefits to broader cross functional and business objectives; the PQS and the business will go from strength to strength.

NEXT STEPS

If you are interested in how Quality Through Design can help you and your team, simply contact us through the website. Alternatively, please feel free to call us and discuss how we can help you achieve and surpass your goals.

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Director

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www.qualitythroughdesign.co.uk