

## ISO 9001:2015 ALIGNMENT BOOTCAMP

Day	Topics	Duration	Objectives	Case Studies & Workshops
1	<p><b>What is a Quality Management System and why should we want one</b></p> <p>This topic is a refresher of the main points covered in the Quality System Primer. It covers:</p> <ul style="list-style-type: none"> <li>• Overview of Quality Management systems relevant to the MTP sector: GLP, GMP, ISO 13485</li> <li>• Other models of Quality Management: TQM, CQI, 6-Sigma; HACCP</li> <li>• Reasons for quality systems</li> <li>• Benefits of quality system certification and of alignment with a quality system</li> </ul>	1 hour	<p>Describe how a quality system benefits their work</p> <p>Explain how ISO 9001 is a suitable QS framework for their need(s)</p> <p>Outline the process to implement a quality system</p>	<p><b>Pre-reading and pre-assessment</b> - What is a QMS (review of QS Primer).</p> <p><b>Workshop:</b> Participants will take it in turns to discuss where they see the value of a QMS and what they see as the challenges. This workshop integrates learnings from the QS Primer.</p>
	<p><b>A quick history of Quality Management Systems</b></p> <ul style="list-style-type: none"> <li>• Where, when and why did the focus on quality start</li> <li>• Edwards Deming – the father of Continuous Improvement “if you can’t describe what you’re doing as a process, you don’t know what you are doing”</li> <li>• Deming’s original 14 Quality Principle:</li> <li>• Common and Special Causes of Error</li> <li>• Total Quality Management vs the Quality Management Systems</li> <li>• The Plan-Do-Check-Act cycle of Continuous Improvement</li> <li>• The concept of the “process approach”: supplier, inputs, process, outputs, customer (SIPOC)</li> </ul>	2 .5hours	<p>Describe how Quality Management has changed and evolved over the last 60 years.</p> <p>Identify the influencers on the development and evolution of QMS.</p> <p>Discuss some of the key factors that contributed to the development and evolution of QMS</p>	<p>This module will consist of a series of videos. Following each, participants will be provided with a series of questions for them to discuss around the topic points and module objectives.</p>
	<p><b>Benefits of quality system certification and of alignment</b></p> <ul style="list-style-type: none"> <li>• What is the ISO 9001 Quality System model?</li> <li>• Building a quality culture</li> <li>• Key elements of ISO 9001</li> <li>• How companies can use ISO 9001 to improve productivity</li> <li>• Differences between ISO 9001:2015 and previous versions</li> </ul>	3 hours	<p>Understand the benefits of a ‘quality culture’ and how to build one.</p> <p>Describe the fundamentals of an ISO 9001:2015 aligned quality management system.</p>	<p><b>Workshop:</b> Prepare a plan for a single ‘Plan-Do-Check-Act’ cycle for a designated scenario such as responding to a customer complaint.</p>

Day	Topics	Duration	Objectives	Case Studies & Workshops
2	<b>The Application of Risk Based Thinking in an ISO 9001:2015 QMS.</b> <ul style="list-style-type: none"> <li>• Risk as the basis of planning and implementing a QMS.</li> <li>• How risk-based thinking reduced prescriptive requirements and eliminated the requirement for preventive action.</li> <li>• The need for formal risk management frameworks.</li> </ul>	3.5 hours	Understand the application of risk management in an ISO9001:2015 QMS Be able to conduct a risk assessment in accordance with the requirements.	<b>Workshop:</b> Conduct a high-level risk assessment for determining risks and opportunities for a given new business scenario using a provided template.
	<b>Purpose, structure and requirements of ISO 9001:2015</b> <b>Leadership</b> <ul style="list-style-type: none"> <li>• Who is Responsible for Quality?</li> <li>• How personal actions guide and sustain an organisation</li> <li>• How the QMS works to help an organisation meet customer expectations and improve productivity</li> </ul>	1 hours	Understand and develop strategies for meeting the ISO 9001:2015 requirements for Leadership and Commitment	<b>Workshop:</b> Devise a plan for how top management can ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation
	<b>Purpose, structure and requirements of ISO 9001:2015</b> <b>Resource Management</b> <ul style="list-style-type: none"> <li>• Identification &amp; provision of resources needed to implement the quality policy &amp; achieve its objectives and to satisfy customer requirements and expectation.</li> <li>• Specifically covering the ISO requirements for:               <ul style="list-style-type: none"> <li>– Human Resources (awareness, training and competence)</li> <li>– Infrastructure</li> <li>– Work environment</li> <li>– Organisational knowledge</li> <li>– Documentation and archiving</li> </ul> </li> </ul>	2.5 hours	Understand and develop strategies for meeting the ISO 9001:2015 requirements for resource management	<b>Workshop:</b> Critique of sample training plans and records for establishing required levels of competency  <b>Workshop:</b> Evaluate environmental risk factors in an industrial scenario
3	<b>Purpose, structure and requirements of ISO 9001:2015</b> <b>Operation</b> <ul style="list-style-type: none"> <li>• Planning and Control</li> <li>• Requirements for Products and Services</li> </ul>	3 hours	Understand, document and implement the ISO 9001:2015 requirements for designing,	<b>Workshop:</b> Prepare change control for a design change using template <b>Case study:</b> When things go wrong due to poor design control

Day	Topics	Duration	Objectives	Case Studies & Workshops
	<ul style="list-style-type: none"> <li>Design and development</li> <li>Verification and Validation activities in the Design and Development process</li> <li>Control of externally provided processes, products and services</li> <li>Provision of production and services</li> <li>Release of products and services</li> <li>Control of non-conforming outputs</li> </ul>		developing and delivering a product or service.	<p><b>Case Study:</b> purchasing controls model</p> <p><b>Workshop:</b> Assess requirements for validation activities for a provided manufacturing process</p> <p><b>Workshop:</b> Propose CAPA for a provided manufacturing issue</p>
	<p><b>Purpose, structure and requirements of ISO 9001:2015 requirements</b></p> <p><b>Performance Evaluation</b></p> <ul style="list-style-type: none"> <li>Monitoring and measurement of processes &amp; product</li> <li>Customer feedback</li> <li>Analysis of data</li> <li>The role of Internal Audits &amp; Management Reviews</li> </ul> <p><b>Improvement</b></p> <ul style="list-style-type: none"> <li>General requirements</li> <li>Control of nonconforming product</li> <li>Non-conformity and Corrective Action</li> <li>Continual Improvement</li> </ul>	3 hours	<p>Describe the ISO 9001:2015 requirements for monitoring, measurement, analysis and improvement</p> <p>Document operations and activities that meet the requirements of ISO 9001:2015 for monitoring, measurement, analysis and improvement</p>	<p><b>Workshop:</b> Prepare 'Points to Consider' for assessment of :</p> <ul style="list-style-type: none"> <li>Product conformity</li> <li>Process conformity</li> <li>Quality system effectiveness</li> </ul>
	<p><b>The Biggest QMS Obstacles and How to Avoid Them</b></p> <ul style="list-style-type: none"> <li>The importance of effective Document and Record Management</li> <li>Understanding of competing interests:             <ul style="list-style-type: none"> <li>Agility vs Standardised Process</li> <li>In house vs Outsourcing</li> <li>Compliance vs Quality</li> </ul> </li> <li>The important role of the QA Unit</li> </ul>	1 hour	<p>Start to apply a process of implementing a QMS that aligns with ISO 9001:2015</p> <p>Describe how to implement an effective QMS &amp; avoid obstacles</p> <p>Identify tools for planning &amp; conducting internal quality audits</p>	