

Risk Management Requirements Implementation in ISO 9001:2015 clauses



Risk Management Requirements Implementation

Clauses of ISO 9001:2015	Object of Control (<i>what is managed</i>)	Subject of Control (<i>who manages</i>)	Regulatory document (<i>recommended</i>)
01 General (0.1.c)	Scope of the QMS	Senior Management	Not Provided
0.3.3 Risk- Based Thinking	All QMS Processes	Senior Management	Quality Policy
4.4 QMS and its Processes (4.4.1.f)	All QMS Processes	Process Owners	System QSP (which regulates the performance of QMS processes)

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6.1 Actions to address risks and opportunities	All QMS Processes	Senior Management + Process Owners	New QSP 'Actions to address risks and opportunities'
8.3.3 Design and development inputs (8.3.3.e)	'Design and Development' Process	Owner of 'Design and Development' Process	'Actions to address risks and opportunities' QSP

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8.5.5 Post Delivery Activity (8.5.5.b)	Products in use	'Design and Development' process owner	'Design and Development' QSP
9.3 Management Review (cl.9.3.2.e)	QMS Processes	Senior Management (Directors)	'Management Review' QSP
10.2 Nonconformity and corrective action	Nonconformities	Process owners	'Corrective action' QSP

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