

Risk Management Requirements Implementation in ISO 9001:2015 clauses

| 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) |
| 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 |
| 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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[Actions to Address Risks and Opportunities Procedure](#)

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