



ISO 14971 Gap Analysis Checklist

| Clause | Title | Item | <input checked="" type="checkbox"/> | Comments/Questions |
|--------|-------------------------------------|---|-------------------------------------|--|
| 3.2 | Risk Management process | Procedure describing the risk management process | | Does the procedure map to the elements in the standard? |
| 3.3 | Management Responsibilities | a. Policy for determining acceptable risk. | | Can policy be used to determine acceptable risk? |
| | | b. Provision of adequate resources. | | May be part of general quality management system |
| | | c. Procedure for assigning staff to risk management work. | | May be part of general quality management system |
| | | d. Procedure(s) for review of risk management | | Does management review effectiveness at defined intervals? |
| 3.4 | Qualification of personnel | Training records for risk management training, tools training, etc. | | May be part of general quality management system |
| 3.5 | Risk Management Plan | a. Procedure for plan development. | | May be part of overall risk management procedure. |
| | | b. Description of device. | | Is there a clear and thorough statement of intended use? |
| | | c. Verification plan. | | Does it tie into design verification and validation activities? |
| | | d. Allocation of responsibilities. | | Is there a clear delineation of who is responsible for what? |
| | | e. Summary of review activities. | | Who does the review? When? |
| | | f. Evidence of risk acceptability criteria. | | Do the criteria derive from the policy on determining acceptable risk? |
| 3.6 | Risk Management File | Evidence of file structure for all risk management activities. | | Are all risk management records readily retrievable from a file or file index? |
| 4.1 | Risk Analysis Procedure | Procedure for risk analysis. | | May be part of overall risk management procedure. |
| 4.2 | Intended use/intended purpose, etc. | Record of safety issue analysis. | | Is Annex A used? Is it modified for the specific products? |
| 4.3 | Hazard Identification | Record of hazard analysis | | How is this done? Use of expert group? Outside sources? Product history? Are hazardous conditions identified? |
| 4.4 | Risk estimation | Definition of methods used for estimating risks. | | Are there qualitative scales for probability and severity used? If so, are people trained in their use? How are risks handled where probability cannot be defined? |



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|--------|---|--|---|---|
| 5.0 | Risk evaluation | Record of risk evaluation activities | | Are risks that need to be controlled identified for further action? |
| 6.1 | Risk reduction | Procedure for risk control activities | | May be part of overall risk management procedure. |
| 6.2 | Option analysis | Record of risk control option analysis (including risk-benefit analysis, if appropriate). | | Has the hierarchy been explicitly considered? |
| 6.3 | Implementation of risk control measures | Design inputs from risk management activities | | What verification activities are performed? Note that this may happen outside the design stage. |
| 6.4 | Residual risk evaluation | Evidence, e.g., from design verification activities. | | Are risks appropriately reevaluated (after implementation of risk controls)? Note that this may need to continue post-production. |
| 6.5 | Risk-Benefit Analysis | Evidence as necessary...see 6.2. | | Who is involved? Have they quantified risks and benefits? If not, who makes these decisions? |
| 6.6 | Other generated hazards | Record of review of all risk controls for impact on new hazards. | | Has the impact of risk control measures been evaluated? |
| 6.7 | Completeness of the risk evaluation | Record of review by a manager | | Are all identified hazards and their consequences dealt with? |
| 7 | Overall risk evaluation | Records of related meetings, analysis, etc. | | How is this accomplished? By consensus? Is senior management involved? |
| 8 | Risk management report | a. Procedure for generating a Risk Management report b. Summary of risk management activities c. Traceability of hazards to residual risks d. Clearances | | May be part of overall risk management procedure. |
| | | | | |
| | | | | Is the traceability matrix complete? |
| | | | | Does it have sign-off by a senior manager? |
| 9 | Post-production information | a. Procedures for linking information into risk management review: <ul style="list-style-type: none"> • Manufacturing • CAPA • Servicing • Purchasing • etc. b. Records implementing procedures | | What criteria are used to determine whether the risk analysis must be revisited? Who is involved? Are the outputs of prior risk management activities tied into the CAPA process? |

Note: Items in **bold** are critical elements that should be present even at the very beginning of implementation