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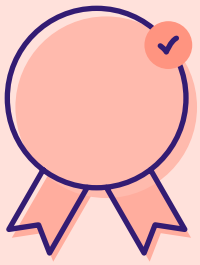

ISO 14971 compliance checklist

ISO 14971 lays out the core risk management considerations for a medical device organization. It is not an auditable standard which you can get accreditation for, nor is it mandatory to bring your medical device to market. Nevertheless, ISO 14971 offers a useful, comprehensive and industry-trusted framework for embedding GMP into your organization and properly managing the risks connected to your medical device design, development and manufacture. Use this checklist to ensure you meet and apply the demands of the standard.

4. General requirements for risk management

Item number	Requirement	Complete?
4.1	**Risk management process**	
	Has the organization ensured the availability of a risk management procedure as part of the design and development of its medical device?	☐
	Does the risk management process extend into the post-production phase (including sterilization, packaging, and labeling where appropriate)?	☐
	Is production and post-production information and data collected and reviewed as part of the risk management process?	☐
	Does the organization's quality management system integrate the risk management process?	☐
4.2	**Management responsibilities**	
	Are top management involved in the overall guidance and effectiveness review of the risk management process?	☐
	Are adequate resources provided for effective risk management activities?	☐
	Are competent individuals trained in the risk management techniques with which they are involved?	☐
	Has top management established a policy for determining acceptable risks and risk levels?	☐
	Does top management participate in periodic review of risk management activities to rectify any weaknesses, implement improvements, and adapt to changes?	☐

4.3	**Qualification of personnel**	
	Are only competent people with the necessary knowledge and experience performing risk management tasks: construction, production, intended use determination, application of medical device?	☐
	Are representatives from various disciplines or functions involved in risk management activity to ensure balanced input?	☐
	Are records to provide objective evidence of competence and training maintained?	☐
	Are personnel records properly maintained with confidentiality and security and without duplication?	☐
4.4	**Risk management plan**	
	Is a properly organized, maintained plan for continual risk management in place?	☐
	Does the plan encourage objective and comprehensive evaluation of risks?	☐
	Is a procedure in place for the development and continued development of the plan?	☐
	Does the plan contain a thorough description of the pertaining device, including a clear thorough statement of intended use?	☐
	Does the plan define a scope to establish the baseline on which risk management activities are built, and involve identification of the medical device and the phases of its lifecycle?	☐
	Does the plan clearly allocate responsibilities and authorities to the respective individuals to ensure accountability?	☐
	Are risk management activities carried out under the plan frequently reviewed by management as an essential responsibility?	☐
	Are the criteria for risk acceptability defined before beginning risk analysis for effective risk management?	☐
	Are the evaluation methods and criteria for acceptability of the overall residual risk decided?	☐
	Is verification activity planned, ensuring that essential resources are available when required?	☐

	Does the plan align with the device's design verification and validation activities?	
	Do risk acceptability criteria in the plan derive from your policy of determining acceptable levels of device risk?	☐
	Are the methods for collection and review of production and post-production information to act as input into the risk management process properly defined?	☐
	Is a record of changes kept to facilitate audit and review of the risk management process for each particular device?	☐
4.5	**Risk management file**	
	Is the location of all records and other documents applicable to risk management activity properly recorded and maintained, with ready retrieval from a file or file index?	☐
	Is the traceability of records and other documents maintained to help in auditing activities and completion of risk management activities?	☐
	Does the risk management file fully demonstrate that the risk management process is applied to each identified hazard?	☐
	Are identified hazards, or any step-in risk management process such as unspecified or ineffective risk control measures, appropriately controlled?	☐

5. Risk analysis

Item number	Requirement	Complete?
5.1	**Risk analysis process**	
	Where applicable, have you checked the available information on risk analysis for a similar medical device on the market?	☐
	Has the organization systematically assessed the previous work for applicability to your current risk analysis?	☐
	Have you ensured that a basic minimum data set is available for traceability, management reviews and audits?	☐

	Have you clarified the scope of your risk analysis and if it verifies completeness?	☐
5.2	**Intended use/reasonably foreseeable misuse**	
	Does the documented intended use include elements like medical condition, patient population, part of the body or type of tissue interacted with, user profile, use environment and operating principle?	☐
	Has the intended user(s) been considered, and whether a lay user or trained professional will use the device?	☐
	Has the use of the medical device in situations that are not foreseen or intended by the manufacturer been considered to a reasonable degree?	☐
	Have future hazards due to potential uses of the medical device, and also reasonably foreseeable misuse, been considered and documented?	☐
5.3	**Identification of characteristics related to safety**	
	Have all characteristics that are qualitative or quantitative and can be related to the operating principle of the device, its intended use, and/or reasonably foreseeable misuse which could affect the safety of the medical device, been documented?	☐
	Have all characteristics been related to the performance of the medical device and to the sterility/measuring function, materials used for parts coming into contact with the patient, usage of radiation for diagnostics or therapeutics, or others?	☐
	Has it been considered whether the limitations of these characteristics, if exceeded, could affect the safety of the device?	☐
5.3	**Identification of hazards/hazardous situations**	
	Have anticipated hazards in both normal and faulty conditions based upon the intended use, reasonably foreseeable misuse, and characteristics related to the safety of the device been identified and documented?	☐
	Have hazardous situations been identified, with associated risks assessed?	☐
	Has the reasonably foreseeable sequence of events that can transform a hazard into a hazardous situation been documented?	☐

	Have typical hazards been listed, demonstrating the relationship with hazardous situations, foreseeable sequences of events, and associated possible harm?	☐
	Is the method of hazard analysis determined, considering whether an expert group, outside sources and product history are used?	☐
5.5	**Risk estimation**	
	Have both components of risk, probability of occurrence and severity of harm, been separately analyzed?	☐
	Is a systematic process in place, including qualitative scales, for categorizing the severity levels and the probability of occurrence of harm, with relevant information recorded within the risk management file and relevant personnel trained in the application of these qualitative scales?	☐
	Are systematic faults, or the sequence of events leading to hazardous situations, continually monitored?	☐
	Are the resulting hazardous situations separately listed, with focus on reducing the risks due to these situations?	☐
	Is quantitative data made available where possible for a new device development or security risk?	☐
	Have risks been evaluated and estimated in a qualitative way – and quantitative, if the data is available?	☐
	Is a mechanism in place for managing risks whose probability cannot be reasonably defined?	☐

6. Risk evaluation

Item number	Requirement	Complete?
	Has the acceptability of the risk of the medical device been defined?	☐
	Have estimated risks been evaluated by using the criteria for risk acceptability defined in the risk management plan?	☐
	Have risks been actively investigated to determine which require controls?	☐
	Are risks that need to be controlled identified for further action?	☐

4. General requirements for risk management

Item number	Requirement	Complete?
7.1	**Risk control option analysis**	
	Has the design and manufacture of the medical device been determined to be inherently safe, with protective measures such as alarms and barriers as appropriate?	☐
	Have risk mechanisms from ISO/IEC Guide 63:2019 been considered and followed?	☐
	Has information for safety, such as written warning or contra-indications and/or training to users or intended users, been provided?	☐
	Are procedures in place to ensure no risk is originating from contamination of components, residues of hazardous substances used in the manufacturing process, or mix-up of parts?	☐
	Are protective measures, such as visual inspection steps in the manufacturing process, applied as appropriate?	☐
	Has a benefit-risk analysis been conducted to determine if the benefit of the medical device to the patient outweighs the residual risk?	☐
	Has the hierarchy of risk control options been explicitly considered?	☐
7.2	**Implementation of risk control measures**	
	Has first verification been conducted to ensure that the risk control measure is implemented in the final design of the medical device or in the manufacturing process?	☐
	Has second verification been conducted to ensure risk control measures as implemented are actually reducing the relevant risks?	☐
	Has the effectiveness of the risk control measures been validated, using a validation study to establish a convincing residual risk evaluation?	☐
	Has the effectiveness of the risk control measures been verified by various testing methods, such as usability testing (IEC 62366-1), testing according to the test standard, clinical investigation of medical devices (ISO 14155), or clinical performance studies for in vitro diagnostic medical devices (ISO 20916)?	☐

	Have verification activities been documented, considering that these activities might happen outside the design stage?	☐
7.3	**Residual risk evaluation**	
	Have the implemented risk control measures made the relevant risk acceptable?	☐
	If the risk is exceeding the acceptability criteria established in the risk management plan, have additional risk control measures been investigated, planned and implemented?	☐
	Are additional risk control measures continually investigated until residual risk does not exceed acceptability criteria?	☐
	Are risks appropriately re-evaluated after implementation of risk controls?	☐
7.4	**Benefit-risk analysis**	
	Has device evaluation proven that the risk does not exceed the criteria for risk acceptability and that the benefit of the device outweighs the risk?	☐
	Does benefit-risk analysis activity exclude economic or business considerations?	☐
	Are properly delineated roles and responsibilities in place for the conducting of benefit-risk analysis?	☐
7.5	**Risks arising from risk control measures**	
	When implementing new risk control measures, alone or in combination, is it actively considered whether or not they are introducing a new or a different hazard themselves?	☐
	Are steps taken to ensure any risk control measure introduced to reduce one risk is not increasing another risk?	☐
	Has the impact of risk control measures been evaluated?	☐
7.6	**Completeness of risk control**	
	Are all identified hazards and their consequences dealt with?	☐
	Are steps taken to ensure that no hazardous situations are left out of risk analysis activities?	☐

8. Evaluation of overall risk

Item number	Requirement	Complete?
	Has the combined impact of all individual residual risks been considered?	☐
	Has the overall residual risk as defined in the risk management plan been evaluated by balancing the overall residual risk against the benefits of the medical device?	☐
	Is all relevant information made available to users about significant residual risks to facilitate the making of informed decisions on their use of the medical device?	☐
	Is all pertinent information on residual risks included in the accompanying documentation, such as IFU/eIFU, product label, user manual, guide?	☐
	Are records of risk evaluation properly kept and maintained, including meeting records and analysis output documents?	☐
	Are senior management involved in consistent risk evaluation and re-evaluation activity?	☐

9. Risk management review

Item number	Requirement	Complete?
	Are the final results of the risk management process reviewed after executing the risk management plan?	☐
	Are the results of the risk management review recorded into a risk management report?	☐
	Is the execution of the risk management plan continually reviewed at planned intervals to confirm if the required objective has been achieved?	☐
	Is the risk management report updated as required during the lifecycle of the medical device according to production and post-production activities?	☐

	Does the risk management report summarize all risk management activities?	☐
	Does the risk management report include traceability of hazards to residual risks? Is this traceability matrix complete and maintained?	☐
	Does the traceability matrix receive review and sign-off by senior management?	☐
	Does the organization determine when subsequent reviews of the execution of the risk management plan need to be performed and when the risk management report needs to be updated?	☐

10. Production & post-production activities

Item number	Requirement	Complete?
10.1	**Information collection**	
	Is production and post-production information continually collected and reviewed to evaluate its relevance to safety?	☐
	Are procedures in place for linking information into the risk management review for:	
	Manufacturing?	☐
	CAPA?	☐
	Servicing	☐
	Purchasing?	☐
	Any other pertinent operational areas which demand risk management review?	☐
	Is best industry practice – 'state of the art' – considered, including new or revised standards for the collection and review of this information?	☐
10.2	**Information review**	
	Is production and post-production information related to new hazards or hazardous situations, possible relevance to safety, or the effect on risk estimates and/or the balance between benefit and overall residual risk, continually reviewed?	☐

10.3	**Actions**	
	Is relevant safety information considered and applied as an input for a) continual improvement and modification of the medical device and b) to improve adjoining risk management processes?	☐
	Are the outputs of prior risk management review activity translated into corrective and preventive action?	☐
	What criteria are used to determine if and when risk analysis activity should be revisited?	☐
	Does this activity encompass devices already on the market, as well as those pre-market?	☐