REGULATORY SPECIALISTS INC.

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

INTERNAL AUDIT CHECKLIST

Subsystem	Major Steps	Verified (Yes or No)
Management	Verify that a quality manual, management review and quality audit procedures, quality plan, and quality management system procedures and instructions have been defined and documented. (ISO 13485:2003: 4.1, 4.2)	
	Verify that a quality policy and objectives have been defined and documented and steps taken to achieve them. (ISO 13485:2003: 5.3, 5.4)	
	Verify that the product realization process incorporates risk management planning, and ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established for analyzing, evaluating and controlling risk. (ISO 13485:2003: 7.1)	
	Review the manufacturer's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), resources, competencies and training. (ISO 13485:2003: 5.1, 5.5.1, 5.5.2, 6.1, 6.2)	
	Verify that management reviews are being conducted and that they include a review of the suitability and effectiveness of the quality management system. (ISO 13485:2003: 5.6)	
	Verify that internal audits of the quality management system are being conducted and that they include verification of corrective and preventive actions.(ISO 13485:2003: 8.2.2)	
	Verify whether top management has taken the appropriate actions to ensure a suitable and effective quality management system is in place.	
Design and Development	Verify if products are by regulation subject to design and development procedures including risk management (e.g., hazard identification, risk evaluation and risk control). (ISO 13485:2003: 7.1, 7.3)	
	Review documents describing the design process and select sufficient records to cover the manufacturer's product range. Focus on individual products rather than families. Criteria for selection: • product risk • complaints or known problems • age of design (prefer most recent	

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

	Review the design plan for the selected product(s) to understand the design and development activities, including assigned responsibilities and interfaces. (ISO 13485:2003: 7.3.1)	
	For the product design record(s) selected, verify that design and development procedures have been established and applied. (ISO 13485:2003: 7.3.1)	
	Verify that design inputs were established and address customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements essential for design and development. (ISO 13485:2003: 7.2.1, 7.3.2)	
	Review medical device specifications to confirm that design and development outputs meet design input requirements. Verify that the design outputs essential for the proper functioning of the medical device have been identified. (ISO 13485:2003: 7.3.3)	
	Verify that risk management activities are defined and implemented and that risk acceptability criteria are established and met throughout the design and development process. Verify that any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices, etc). (ISO 13485:2003: 7.1, 7.3.2)	
	Verify that design validation data show that the approved design meets the requirements for the specified application or intended use(s). (ISO 13485:2003: 7.3.6)	
	Verify that clinical evaluations and/or evaluation of the medical device safety and performance were performed if required by national or regional regulations. (ISO 13485:2003: 7.3.6)	
	If the medical device includes software, verify that the software was part of the medical device's design and development validation. (ISO 13485:2003: 7.3.1, 7.3.6)	
	Verify that design changes were controlled and verified or where appropriate validated and that design changes have been addressed. (ISO 13485:2003: 7.1, 7.3.5, 7.3.7)	
	Verify that design reviews were conducted. (ISO 13485:2003: 7.3.1, 7.3.4)	

REGULATORY SPECIALISTS INC.

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

	Verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained. (ISO 13485:2003: 7.3.7)	
	Determine if the design was correctly transferred to production. ISO 13485:2003: 7.3.1)	
Product Documentation	Verify if there are documents needed by the organization to ensure planning, operation and control of its processes. (ISO 13485:2003: 4.2.1d)	
	Select Product Documentation for sufficient product(s) to cover the manufacturer's product range. (ISO 13485:2003: 7.1, 7.2, 7.3.3) Criteria for selection: • product risk • complaints or known problems • age of design (prefer most recent)	
	For the product(s) selected verify that documentation includes (if required by national or regional regulations): • evidence of conformity to requirements, including standards used • medical device description including instruction for use, materials and specification • summary of design verification and validation documents including clinical evidence • labeling • risk management documents • manufacturing information including major suppliers	
Product and Process Controls	Verify that the product realization processes are planned – including any necessary controls and controlled conditions. (ISO 13485:2003: 7.1, 7.5.1)	
	Verify that the planning of product realization is consistent with the requirements of the other processes of the quality management system. (ISO 13485:2003: 7.1)	
	Review production processes considering the following criteria. Select one or more production processes to audit. Criteria for selection: • CAPA indicators of process problems • use of production process for higher risk products • new production processes or new technologies • use of the process in manufacturing multiple products • processes not covered during previous audits	

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

	Verify that the processes have been validated if the result of the process cannot be verified. Verify that the validation demonstrates the ability of the processes to achieve planned result. (ISO 13485:2003: 7.5.2)	
	Verify that the equipment used in production and process control has been adjusted, calibrated and maintained. (ISO 13485:2003: 7.5 , 7.6)	
	Verify that the processes are controlled and monitored and operating within specified limits. In addition, verify that risk control measures identified by the manufacturer in production processes are controlled, monitored and evaluated. (ISO 13485:2003: 7.1, 7.5)	
	Verify that risk control measures are applied to delivery, installation and servicing, where applicable. (ISO 13485:2003: 7.5.1.1, 7.5.1.2.2 and 7.5.1.2.3)	
	Determine the links to other processes. (ISO 13485:2003: 4.1, 4.2)	
	Verify that personnel are appropriately qualified and/or trained to implement/maintain the processes. (ISO 13485:2003: 6.2.2)	
	Verify that the infrastructure and the work environment are adequate. (ISO 13485:2003: 6.3, 6.4)	
	Verify that identification and traceability for processes and products are in place and are adequate. (ISO 13485:2003: 7.5.3)	
	If the process is software controlled, verify that the software is validated for its intended use. (ISO 13485:2003: 7.5.2.1)	
	Verify that the control of the monitoring and measuring devices is adequate. (ISO 13485:2003: 7.6)	
	Verify that the system for monitoring and measuring of products is adequate. Ensure that any identified risk control measures are implemented. (ISO 13485:2003: 7.6, 8.2.4)	
	Verify that acceptance activities assure conformance with specifications and are documented. (ISO 13485:2003: 8.2.4, 8.2.4.1, 8.2.4.2)	
	Verify that the control of nonconforming products is adequate. (ISO 13485:2003: 8.3)	
CAPA	Verify that CAPA system procedure(s) which address the requirements of the quality management system have been established. (ISO 13485:2003: 4.1, 4.2, 8.5)	

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

	Verify that accurate information is analyzed for input into the CAPA system and that corrective and preventive actions were effective. (ISO 13485:2003: 8.4, 8.5)	
	When a CAPA results in a design change, verify that the hazard(s) and any new risks are evaluated under the risk management process. (ISO 13485:2003: 7.1)	
	Determine if all appropriate sources of CAPA data have been identified and are being monitored to determine action when indicated. Confirm that data from these sources are analyzed, using valid statistical methods where appropriate, to identify existing product and quality problems that may require corrective action. (ISO 13485:2003: 8.1, 8.2.3, 8.4)	
	Determine if failure investigations are conducted to identify the causes of nonconformities, where possible. (ISO 13485:2003: 8.5.2)	
	Verify that controls are in place to prevent distribution of nonconforming products. (ISO 13485:2003: 8.3)	
	Confirm that corrective and preventive actions were implemented, effective, documented and did not adversely affect finished devices. (ISO 13485:2003: 8.2.3 8.5.2, 8.5.3)	
	Determine if relevant information regarding nonconforming product and quality problem(s) and corrective and preventive actions has been supplied to management for management review. (ISO 13485:2003: 5.6.3)	
	Verify that medical device reporting is done according to the applicable regulatory requirements. (ISO 13485:2003: 8.5.1)	
	Confirm that the manufacturer has made effective arrangements for gaining experience from the post production phase, handling complaints (see also 7.8.3), and investigating the cause of non-conformance related to advisory notices/recalls with provision for feed back into the corrective and preventive action subsystem. (ISO 13485:2003: 7.2.3, 8.2.1)	
	Confirm that the manufacturer has made effective arrangements for the issue and implementation of advisory notices/recalls. (ISO 13485:2003: 8.5.1)	
Purchasing	Verify that procedures for conducting supplier evaluations have been established. (ISO 13485:2003: 7.4.1)	

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

	Verify that the manufacturer evaluates and maintains effective controls over suppliers, so that specified requirements are met. (ISO 13485:2003: 7.4.1)	
	Verify that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide, and defines risk management responsibilities and any necessary risk control measures. (ISO 13485:2003: 7.4.2)	
	Verify that records of supplier evaluations are maintained. (ISO 13485:2003: 7.4.1)	
	Determine that the verification of purchased products and services is adequate. (ISO 13485:2003: 7.4.3)	
Documentation	Verify that procedures have been established for the identification, storage, protection, retrieval, retention time and disposition of documents and records. (Including change control). (ISO 13485:2003: 4.2.3, 4.2.4)	
	Confirm that documents and changes are approved prior to use. (ISO 13485:2003: 4.2.3)	
	Confirm that current documents are available where they are used and that obsolete documents are no longer in use. (ISO 13485:2003: 4.2.3)	
	Verify that required documents and records are being retained for the required length of time. (ISO 13485:2003: 4.2.1, 4.2.4)	
Customer Related Process	Review product requirements to verify that they address the intended use as well as customer and regulatory requirements. (ISO 13485:2003: 7.2.1, 7.2.2)	
	Confirm that incoming orders and related information are reviewed to assure that any conflicting information is resolved and the manufacturer can fulfill the customer's requirements. (ISO 13485:2003: 7.2.2)	
	Confirm that the manufacturer has made effective arrangements for handling communications with customers including documenting customer feedback to identify quality problems and provide input into the corrective and preventive action subsystem. (ISO 13485:2003: 7.2.3, 8.2.1)	
	Confirm that customer feedback is analyzed in the product realization process and used to re-evaluate the risk assessment and, where necessary, adjust the risk management activities. (ISO 13485:2003: 7.1, 7.2.3)	

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

Sterilization	Determine that the sterilization processes are planned – including the controlled conditions. ISO 13485:2003: 7.1, 7.5.1.3	
	Determine that the planning of product sterilization is consistent with the requirements of the other processes of the quality management system. ISO 13485:2003: 7.1. 7.5.1.3	
	Determine that records of process parameters for the sterilization process for each sterilization batch are maintained and are traceable to each production batch. ISO 13485:2003: 7.5.1.3	
	Select a sterilization process (es) for review. If there is more than one sterilization process use the following criteria: • degree of difficulty to sterilize a medical device • process used for the largest number of medical devices • process that is most difficult to control	
	Determine that the sterilization process has been validated and review the validation for adequacy. Validation includes qualification of the sterilizer. Check that validation is up-to-date. ISO 13485:2003: 7.5.2.1	
	Determine that biological indicators are handled appropriately and validated. ISO 13485:2003: 8.2.3	
	Determine that the process is controlled and monitored including product bio burden. Verify that configuration of loads comply with validated configurations. ISO 13485:2003: 7.5.1.3	
	Determine that the process is operating within specified limits. ISO 13485:2003: 7.5.1.3	
	If data indicates that the process does not always meet process parameters, determine that non-conformances are handled appropriately and investigated and appropriate corrections and corrective actions are taken to address non-conformances. ISO 13485:2003: 8.1, 8.2.3, 8.3, 8.4, 8.5.2	
	If the sterilization process is software controlled, determine that the software is validated. ISO 13485:2003: 7.5.2.1	
	Determine that the equipment used has been adjusted, calibrated and maintained. ISO 13485:2003: 7.5, 7.6	
	Determine that personnel are appropriately qualified and trained to validate, implement and maintain the process. ISO 13485:2003: 6.2	

REGULATORY SPECIALISTS INC.

1801 Edgecliff Drive
Fullerton, CA 92831
949-262-0411
Fax 949-552-2821
regulatoryspecialists.com

Software	Determine that the software processes are planned. ISO 13485:2003: 7.3.1, 7.5.1.1. See also IEC 62304:2006: 5.1, 6.1.	
	Determine that software that could contribute to a hazardous situation has been included in the risk analysis. See also IEC 62304:2006: 7.1.	
	Determine that the planned software processes are appropriate to address safety issues identified by risk management activities. ISO 13485:2003: 7.1 See also IEC 62304:2006: 4.3.	
	Determine that the established software requirements include content appropriate for the software purpose, and include risk control measures implemented in the software. See also IEC 62304:2006: 5.2.	
	Determine that each general purpose software component that is being used has specified functional and performance requirements that are necessary for its intended use, including specification of the hardware and software necessary to support its proper operation. See also IEC 62304:2006: 5.3.3, 5.3.4.	
	Determine that changes to software have been analyzed for whether they might introduce additional potential causes of a hazardous situation, or interfere with existing risk control measures implemented in software. See also IEC 62304:2006: 7.4.	
	Determine that problems in software have utilized an established software problem resolution process that includes identifying the cause and evaluating the problem's relevance to safety. See also IEC 62304:2006:9.	