BIOTEKNICA
ENGINEERING & REGULATORY SERVICES

QSIT Inspection Preparation Check list

QS	System Requirement	Support Items	SME
Management Controls	A Quality Policy is defined and documented	Prepare copy of quality policy	Management representative
	The Quality Policy and its objectives are implemented	Confirm postings of the quality policy Prepare to demonstrate with training records that employees are trained to the quality policy	All employees should be ready to state the policy and/or show where the policy is posted
	Procedure for management review defined and documented	Prepare copy of management review procedure	Management representative
	Procedure for quality audits are defined and documented	Prepare copy of quality audit procedure	Compliance Director (or Audit Manager)
	Procedure for quality plan is defined and documented	Prepare copy of quality plan procedure and copy of current quality plan	Management representative
	Quality system procedures are defined and documented	Prepare copy of the Quality Manual, and index of quality system procedures	Quality System Director
	The organization structure and responsibilities/authorities and necessary resources are defined and in place	Prepare copy of organization chart , prepare SME to represent	Management representative
	A management representative has been appointed	Prepare a copy of the record that demonstrates the management representative appointment is documented	Management representative
	The management representative ensures that quality system requirements are effectively established and reports on the performance of the quality system to management with executive responsibility	Prepare documents that demonstrate the management representative: • approves Changes to procedures, device designs, manufacturing processes • Reviews quality audits • Oversight and interaction with CAPA activities	Management representative

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Management Controls	Management reviews are conducted and include a review of the suitability and effectiveness of the quality system	Prepare management review schedule demonstrating frequency of reviews and procedure requirements that management reviews results are documented and records showing meetings were conducted. Note: Record should show planned agenda, attendees, and completion of meeting. *Actual information reviewed, decisions made, and specific follow-up action items should not be shared during an inspection.*	Management representative or Quality System Director
	Quality audits are conducted and documented Quality audits include the re-audit of any deficiencies	Procedure for quality audits Prepare the following records: • Internal audit schedule (highlights where re-audits are being performed) • Auditor qualifications and training • List of internal audit CAPA. Note: Internal Audit CAPA records do not need to be shared. Only Corrective and Preventive Actions taken need to be reviewed during an inspection.	Management Representative or Audit Manager / Director
	Audits are conducted by those who are not directly responsible for the matters being audited	Prepare an organization chart that illustrates independence of auditors	Management Representative or Audit Manager / Director
Design Controls	FDA investigator will typically select a single design project	Be prepared to suggest a project and/or target likely products for preparation based on: • Devices with recent changes • New device • Contains software Prepare a listing of design projects and or design changes	R&D Director and/or specific Project Manager/Director
	The design control procedures document requirements for design: planning, inputs, outputs, specifications, verification, validation, reviews, transfer, changes	Prepare design procedures	R&D Director and/or specific Project Manager/Director

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Design Controls	Design plan documentation comprehends the layout of the design and development activities, assigned responsibilities, interfaces between activities and personnel, and risk analysis	Prepare to: • Show how design plan requirements are specified in procedures • Provide design plan documents	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices representing requirements and where /how they are documented in design plans
	Design Inputs (DI) are established	Prepare to demonstrate: • Inputs are documented • Sources used to develop inputs • Relevant aspects are covered o Intended use o Performance Characteristics o Risk o Biocompatibility o Electromagnetic compatibility o Human factors o Voluntary standards o Sterility	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices walking an investigator through design input requirements and how they were established and are included in the DI documentation.
	Design Outputs (DO) that are essential for the proper functioning of the device are identified	Prepare to demonstrate: • How outputs were identified (according to procedure) • Risk analysis tools used • Outputs conform to inputs o Drawings o Specifications o Labeling o Procedures	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices showing an investigator the documented DO and how they trace and conform to the design inputs

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Design Controls	Acceptance criteria are established prior to the performance of verification and validation activities	Prepare to provide verification documentation that demonstrates acceptance criteria were established prior to the verification or validation activity.	R&D Director and/or specific Project Manager/Director
	Design verification confirmed that design outputs met the design input requirements	Prepare to provide verification documentation that demonstrates design outputs met design input requirements	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices discussing any discrepancies or anomalies.
	Design validation data demonstrate that the approved design met the predetermined user needs and intended uses	Prepare to provide documentation of design validation testing that demonstrates it was performed under actual or simulated use conditions	R&D Director and/or specific Project Manager/Director
	The completed design validation does not leave unresolved discrepancies	Prepare to demonstrate how any discrepancies between the device specifications and the needs of the user or intended use of the device were addressed.	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices discussing any discrepancies or anomalies.
	Software components are validated	Prepare software validation documentation	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices discussing any discrepancies or anomalies.
	Risk analysis is performed	Prepare risk analysis records that demonstrate individual hazards are eliminated or mitigated	R&D Director and/or specific Project Manager/Director

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Design Controls	Initial production devices or their equivalents are to be used in Design validation	Prepare records that demonstrate initial production units, lots, or batches were used in design validation. If equivalency was used, provide documentation that justifies equivalency.	R&D Director and/or specific Project Manager/Director
	Design changes are controlled and validated/ verified	Prepare to provide a list of changes and associated change records that demonstrate validation and/or verification are performed as required	R&D Director and/or specific Project Manager/Director Conduct simulated inspection where SME practices discussing any significant changes
	Design reviews are performed	Prepare to provide: • Procedure requirements for when design reviews are completed at appropriate stages of design life cycle • Documented design reviews • Documented evidence that reviews include an individual without direct responsibility for the design stage being reviewed	R&D Director and/or specific Project Manager/Director
	The Design is correctly transferred	Prepare to provide: • Device Master Record (DMR) • Procedure requirements and process for how the design was transferred to production	R&D Director and/or specific Project Manager/Director
CAPA	CAPA system procedures define and document the requirements of the Quality System	Prepare CAPA procedures for review	Management Representative and/or Quality Director (or CAPA Manager)

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CAPA	Sources of product and quality problems are identified and data from these sources are analyzed to identify existing product and quality problems that may require corrective action	Prepare to provide: • Procedure requirements for input of product or quality problems in the CAPA subsystem • Raw data associated with acceptance activities, complaints, service, returned products, and production test failures	Management Representative and/or Quality Director (or CAPA Manager) Conduct simulated inspection where SME practices reviewing how sources of data are reviewed and analyzed.
	Sources of product and quality information that may show unfavorable trends are identified and data from these sources are analyzed to identify potential product and quality problems that may require preventive action	Prepare to provide: • Trending data • Listing of CAPAs, complaints, nonconformances • Monitoring and statistical process control data	Management Representative and/or Quality Director (or CAPA Manager)
	Data received by the CAPA system are complete, accurate, and timely	Prepare to provide a listing of CAPAs and associated CAPA records that demonstrate they are complete, accurate, and timely	Management Representative and/or Quality Director (or CAPA Manager)
	Appropriate statistical methods are employed where necessary to identify recurring quality problems and results of analysis are compared across data sources to identify the extent of quality problems	Prepare to provide: • Statistical techniques that are used (spreadsheets, pareto analysis, trending data, pie charts) • Comparison of results across data sources •	Management Representative and/or Quality Director (or CAPA Manager)
	Failure investigation procedures are followed and are conducted to determine root cause. Quality and nonconforming product are investigated commensurate with risk. Controls are in place to prevent distribution of nonconforming product	Prepare to provide a listing of CAPAs and CAPA records sampled by the investigator and provide: • Root cause investigations • Demonstrate how risk is applied to investigations • Procedure requirements and documentation for control of nonconforming product	Management Representative and/or Quality Director (or CAPA Manager) For key CAPA records, conduct simulated inspection where SME practices discussing how root cause was determined.

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CAPA	Appropriate actions are taken for significant product and quality problems	Prepare to provide examples of significant corrections (ex. containment), corrective and preventive actions	Management Representative and/or Quality Director (or CAPA Manager) For key CAPA records, conduct simulated inspection where SME practices discussing how actions were determined. Be prepared to discuss how bracketing and containment were determined including field action decisions (ties to Corrections and Removals).
	Corrective and preventive actions are effective and verified or validated prior to implementation, and do not adversely affect the finished device	Prepare to provide CAPA records	Management Representative and/or Quality Director (or CAPA Manager)
	Corrective and preventive actions for product and quality problems are implemented and documented	Prepare to provide CAPA records	Management Representative and/or Quality Director (or CAPA Manager)
	Information regarding nonconforming product, quality problems, and corrective and preventive actions is properly disseminated including management review	Prepare to provide: • Documentation demonstrating CAPAs are reported on in management review • The methods used to disseminate relative CAPA information to those individuals directly responsible for assuring product quality	Management Representative and/or Quality Director (or CAPA Manager)

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Medical Device Reporting	Medical Device Reporting (MDR) procedures are defined that meet the requirements of 21 CFR Part 803.17	Prepare procedures that demonstrate requirements are defined and documented.	Management Representative and/or Quality Director
	MDR event files are established and maintained that comply with 21 CFR Part 803.18	Prepare to provide a listing of MDRs and sampled event files	Management Representative and/or Quality Director
	Investigator will confirm that the appropriate MDR information is being identified, reviewed reported, documented and filed	Prepare to provide MDR records and demonstrate that you identify, review, report, document, and file potential MDR events	Management Representative and/or Quality Director
	The company follows their procedures and are effectively identifying MDR reportable deaths, serious injuries, and malfunctions	Prepare to provide MDR records, and records documenting rationales when MDRs are not reported.	Management Representative and/or Quality Director For key complaint records and/or trends, conduct simulated inspection where SME practices discussing any anomalies on late MDR reporting or reasons for inconsistent reporting
Corrections and Removals	Procedures are defined for corrections and removals	Provide procedure demonstrating requirements are defined and documented	Management Representative and/or Quality Director
	The company's management has implemented the reporting requirements of 21 CFR Part 806	Provide a listing of corrections and removals and sampled records of	Management Representative and/or Quality Director
	The company maintains a file for all non-reportable corrections and removals per 21 CFR Part 806	Provide a listing of non-reportable correction and removals and files / records associated with non-reportable corrections	Management Representative and/or Quality Director For key nonconformance events and/or trends, conduct simulated inspection where SME practices discussing any anomalies or reasons for inconsistent correction and removal decisions or reporting

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Medical Device Tracking	Investigator will determine whether or not a company manufactures or imports a tracked device	Provide a product listing that indicates those that require device tracking	Management Representative and/or Quality Director
	The company has procedures for tracking that complies with the requirements of 21 CFR Part 821.25(c)	Prepare to provide procedure that defines and documents the requirements for device tracking	Management Representative and/or Quality Director
	The company performs audits of its tracking system within the appropriate time-frames	Prepare to show audit procedures and schedule that demonstrate inclusion of audits for the tracking system	Management Representative and/or Quality Director
Production and Process Controls	FDA investigator will select a process for review based on: CAPA indicators, device risk, processes that are new, use of process in multiple devices; variety in technology; not previously covered	Review your CAPA and process monitoring data to understand possible production processes that may be targeted during inspection.	Director of Operations
	There are procedures in place for manufacturing processes	Prepare to: • provide manufacturing procedures associated with the selected process • Monitoring and controls • In-process acceptance criteria • Environmental control • Contamination control	Director of Operations
	FDA investigator will review sampling of DHR	Prepare to: • Provide the DHR • Demonstrate that nonconformances are recognized and addressed	Director of Operations
	Processes that cannot be fully verified are validated	Prepare to provide Master Validation Plans, inventory, and status. Prepare to provide validation studies of critical processes (if not fully verified), Test Methods, and Facilities/Utilities.	Director of Operations For critical processes and test method validations SME practices discussing approach, statistical rationale and acceptance criteria, and any anomalies or discrepancies encountered.

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Production and Process Controls	Software controlled processes are validated	Prepare to provide validation documentation for software controlled processes. Be prepared to provide non-Product Software Master Validation Plans, inventory, and status.	Director of Operations
	Personnel are appropriately qualified to implement manufacturing processes	Prepare to provide training and qualifications for operations employees. Prepare to demonstrate that employees are trained to recognize defects that may occur from failure to follow procedures or during the operation	Director of Operations