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CONSULTING MEMORANDUM – QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CHECKLIST

The following table identifies the elements FDA Investigators will assess during their QSIT inspection. Regulated medical device firms are encouraged to integrate this inspection checklist into their FDA required internal audits to prepare for the QSIT process.

Some firms may be notified in advance by FDA of their QSIT inspection and requested to provide their Quality Policy, Quality Plan, and top level procedures including Management Review of Quality System procedure, in advance.

Item	QSIT Subsystem/Assessment Detail	Assessment Comment(s)	Assessment ☑	Assessment Follow-up
	MANAGEMENT CONTROLS	**Expect the Investigator to…**		**Provide any appropriate brief comment**
1	Verify firm has established a Quality Policy	…request the Quality Policy in advance	❒ **Yes** ❒ **No**	
2	Verify firm's management reviews Quality System	…request management review procedure(s) in advance	❒ **Yes** ❒ **No**	
3	Verify firm has established a Quality Audit Procedure	…request Quality Audit procedure in advance	❒ **Yes** ❒ **No**	
4	Verify firm has established Quality System (QS) procedures	…request QS procedures (Quality Manual) in advance	❒ **Yes** ❒ **No**	
5	Verify firm's Quality Policy & its objectives are implemented	…ask employees about Quality Policy & review training records	❒ **Yes** ❒ **No**	
6	Review firm's organizational structure to verify that responsibilities & resources are in place	…ask management representative how resources are obtained & allocated	❒ **Yes** ❒ **No**	
7	Verify that the firm has established & documented a management representative	…ask management representative to identify responsibility for: • Changes to procedures, device designs, manufacturing processes • Review of Quality Audit results • Oversight & interaction with Corrective & Preventive Action activities	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
8	Review the oversight of the management representative	…ask management representative to document management reviews	❒ **Yes** ❒ **No**	
9	Verify management reviews & documents the suitability of the QS	…review documented management reviews to ensure reviews include suitability of the QS	❒ **Yes** ❒ **No**	
10	Verify management reviews & documents the effectiveness of the QS	…review documented management reviews to ensure reviews include effectiveness of the QS	❒ **Yes** ❒ **No**	
11	Verify Quality Audits are being conducted & documented Verify Quality Audits include the re-audit of any deficiencies	…review Quality Audit procedures & documents to be assessed to ensure they address all elements of the QS. Expect auditor training to be assessed & auditor to be questioned about process…how often?, when?, how long?, what documents audited?, what reports sent where?, etc.	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No,** ❒ **Yes** ❒ **No,** ❒ **Yes** ❒ **No,** ❒ **Yes** ❒ **No,** ❒ **Yes** ❒ **No**	
12	**AT QSIT CONCLUSION**: Evaluate whether management with executive responsibility has ensured that an adequate & effective Quality System is implemented	At the conclusion of the QSIT inspection, expect Investigator to provide confirmation of fully implemented QS or identify QS failures or "observations" of problems requiring correction		

Item	QSIT Subsystem/Assessment Detail	Assessment Comment(s)	Assessment ☑	Assessment Follow-up
	DESIGN CONTROLS SUBSYSTEM	**Expect the Investigator to…**		**Provide any appropriate brief comment**
1	FDA Investigator will select a single design project	…focus on any device that contains software, a new device, a recently 510(k) reviewed device, or a device with a recent change	❒ **Yes** ❒ **No**	
2	Verify the firm has established design control procedures that address: • Planning • Inputs • Outputs • Specifications • Verification • Validation • Reviews • Transfer to manufacturing • Changes	…assess the procedures to ensure they address each regulatory requirement [Investigators will understand if design control procedures are specific &/or different for individual devices or families of devices]	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
3	Review the selected project's: • Design plan & organization of design activities • Documented responsibilities • Documentation of required risk analysis • Documented interfaces between activities & individuals	…assess design plan's: • Milestones • Responsibilities • Risk analysis • Activities & individual interfaces	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
4	Review the selected project to ensure that inputs were established & maintained to ensure inputs appropriate, address the intended use, user needs, patients needs, & do not contain incomplete, ambiguous or conflicting requirements	…assess that appropriate inputs included: • Intended uses • Performance &/functionality • Individual hazards • Human factors • Standards • Elimination of incomplete, ambiguous or conflicting requirements • Changes to inputs were fully assessed, reviewed & approved	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
5	Review the selected project to ensure that outputs were established & maintained to ensure proper device functioning	…assess output documentation for • Outputs conform to inputs • Drawings • Specifications • Procedures • Labeling • Acceptance criteria	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
6	Review acceptance criteria to ensure they were established prior to the performance of verification & validation activities	…review acceptance criteria to document their creation & acceptance prior to verification or validation testing and any sampling[1]	❒ **Yes** ❒ **No**	
7	Review design verification confirms outputs meets inputs	…review verification activities & any sampling activity [see footnote 1]	❒ **Yes** ❒ **No**	
8	Review design validation data demonstrates that the approved design meets the predetermined intended uses & user needs	…document that validation was performed under actual or simulated conditions of use.	❒ **Yes** ❒ **No**	

[1] If verification or validation sampling is performed, it should be based on accepted sampling plans, see Sampling Plan Tables, last page. Expect the review of any sampling activity to be based on FDA sampling criteria.

Item	QSIT Subsystem/Assessment Detail	Assessment Comment(s)	Assessment ☑	Assessment Follow-up
	DESIGN CONTROLS SUBSYSTEM (continued)	**Expect the Investigator to…**		**Provide any appropriate brief comment**
9	Review that the completed design validation data eliminated all unresolved design issues	…carefully assess design changes or specification changes	❒ **Yes** ❒ **No**	
10	Review all device software component(s) to document software validation & change control	…concentrate on any software component & software validation & change controls activities	❒ **Yes** ❒ **No**	
11	Review design validation records to ensure that design validation was performed on initial production devices or their equivalents	…document that initial production units were used or documentation of the equivalent device(s) were used	❒ **Yes** ❒ **No**	
12	Review finished risk analysis records	…document individual hazards & trace their elimination or mitigation through appropriate records	❒ **Yes** ❒ **No**	
13	Review records to document that design changes were: • Controlled • Validated • or where appropriate, Verified	…document design change: Control Validation Verification, where appropriate	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
14	Review records to document design reviews performed at appropriate stages of design life cycle	…document that design reviews included an individual without direct responsibility for the design stage being reviewed	❒ **Yes** ❒ **No**	
15	Review documents to document that the design was correctly transferred to manufacturing specification(s)	…review the Device Master Record (DMR) and any device sampling data	❒ **Yes** ❒ **No**	
Item	**QSIT Subsystem/Assessment Detail**	**Assessment Comment(s)**	**Assessment ☑**	**Assessment Follow-up**
	CORRECTIVE & PREVENTIVE ACTIONS (CAPA)	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Review CAPA procedures to document that they comply with QS Regulations requirements	…document that CAPA procedures are established & maintained	❒ **Yes** ❒ **No**	
2	Review records to document that appropriate records of quality problems have been created & used	…review records of acceptance activities, production test failures, returned products, service records, & complaints	❒ **Yes** ❒ **No**	
3	Review records to determine if trending reveals any quality problems and that analysis of this data was used to identify corrective & preventive actions	…review procedures & records of incoming products & components, product & component testing, & any statistical process control (SPC) data	❒ **Yes** ❒ **No**	
4	Review CAPA records to document that the CAPA system is • Complete • Accurate • Timely	…assess for: • Completeness • Accuracy • Timeliness The selection will be of one or more data sources & the Investigator will use the data tables to determine the number of records to review [see Sampling Tables on last page]	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
5	Review records to document that: • Statistical techniques are implemented wherever necessary to identify recurring quality problems • Results are compared across various data sources to identify the extent of quality problems	…review any statistical techniques used, SPC, pie charts, spreadsheets & Pareto analysis for: • Recurring quality problems • Comparing results across data sources to ID the depth of quality problems [see Sampling Tables on last page]	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
6	Review investigation records of device failures to document that • Failure investigation procedures are completed to root cause • The level of investigation is proportionate with the risk of the failure • No identified non-conforming product has been released	…review: Root cause determinations Investigations are proportionate to classifications of failures Established controls to prevent distribution of non-conforming product	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	

Item	QSIT Subsystem/Assessment Detail	Assessment Comment(s)	Assessment ☑	Assessment Follow-up
	CORRECTIVE & PREVENTIVE ACTIONS (CAPA) (continued)	Expect the Investigator to…		**Provide any appropriate brief comment**
7	Review quality problem records & documents to confirm that appropriate actions are taken	…review major corrective action activities to determine if implemented corrections were adequate or additional actions should have been implemented	❒ **Yes** ❒ **No**	
8	Review CAPA records to document that CAPA actions taken were: • Effective • Verified, or validated	…review quality records & statistical records, facilities, equipment & processes to assess: • Effectiveness • Verification or Validation	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
9	Review CAPA records of: • Implementation • Documentation	…review records of recent corrective action records, facilities, equipment & processes to assess: Implementation Documentation	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
10	Review CAPA records to document that documented CAPA's were appropriately disseminated for: • Management review • Individuals responsible for product quality & prevention of quality problems	…review CAPA documents provided to: • Management for review • All individuals responsible for product quality & quality problem prevention	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
Item	**QSIT Subsystem/Assessment Detail**	**Assessment Comment(s)**	**Assessment ☑**	**Assessment Follow-up**
	CAPA Subsystem: Reports of Corrections & Removals (C&R)	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Determine if firm has C&R procedure(s)	…review the firm's C&R procedure(s)	❒ **Yes** ❒ **No**	
2	Review documents & records to demonstrate that the firm has implemented procedure(s) to ensure reporting requirements of 21 CFR 806	…review C&R procedure(s) to ensure that C&R regulation requirements are implemented	❒ **Yes** ❒ **No**	
3	Identify any C&R actions initiated by the firm	…request these files documenting any C&R reports	❒ **Yes** ❒ **No**	
4	Identify any appropriate C&R actions not identified or initiated by the firm	…identify any Correction or Removal events not identified or initiated by the firm	❒ **Yes** ❒ **No**	
5	Identify from documents that the firm maintains a file for all non-reportable C&Rs	…review the required file of all non-reportable C&Rs	❒ **Yes** ❒ **No**	
	CAPA Subsystem: Medical Device Reporting	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Determine if firm has MDR procedure(s)	…review the firm's MDR procedure(s)	❒ **Yes** ❒ **No**	
2	Identify & review firm's MDR event files	…review the firm's labeled MDR event file(s)	❒ **Yes** ❒ **No**	
3	Review MDR documents to verify firm has appropriately complied with regulations requiring MDR actions to • Identify • Review • Report • Document • File MDR actions	…review MDR records to verify that the firm has complied with MDR regulations & implemented actions to • Identify • Review • Report • Document • File potential MDR events	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
4	Review MDR documents to verify firm follows procedure(s) & regulations	…review records to verify procedure & regulation compliance	❒ **Yes** ❒ **No**	

Item	QSIT Subsystem/Assessment Detail	Assessment Comment(s)	Assessment ☑	Assessment Follow-up
	CAPA Subsystem: Medical Device Reporting (continued)	Expect the Investigator to…		**Provide any appropriate brief comment**
5	Review MDR documents to verify firm's MDR procedures are effective in identifying MDR events	…review quality problem records, complaints, & returned products to assess MDR effectiveness	❒ **Yes** ❒ **No**	
Item	**QSIT Subsystem/Assessment Detail**	**Assessment Comment(s)**	**Assessment ☑**	**Assessment Follow-up**
	CAPA Subsystem: Medical Device Tracking	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Identify all manufactured or imported devices requiring tracking	…review product listings to identify any products requiring device tracking	❒ **Yes** ❒ **No**	
2	Identify firm has a medical device tracking procedure	…when required, review a required device tracking procedure	❒ **Yes** ❒ **No**	
3	Verify firm's procedure complies with 21 CFR 821.25(c) requirements	…when required, review records to assure firm complies with 21 CFR 821.25(c)	❒ **Yes** ❒ **No**	
4	Verify firm's Quality Audits include oversight of firm's tracking activities	…when required, review Quality Audit procedure to ensure it requires audit of firm's device tracking activities	❒ **Yes** ❒ **No**	
Item	**QSIT Subsystem/Assessment Detail**	**Assessment Comment(s)**	**Assessment ☑**	**Assessment Follow-up**
	PRODUCTION & PROCESS CONTROLS	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Select a process for review based on: • CAPA assessment • Device's risk • New processes • Multiple devices • Robust technology • Not previously addressed	…select a production process with potential deviations based on: • Earlier CAPA assessment activities • Finished device's risk • A recently implemented process • A process that involves multiple finished devices • A process that is sophisticated or complex • A process that has not been previously reviewed	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
2	Review procedures implemented for control & oversight of the selected process	…review firm's procedure(s) that control & monitor the selected process	❒ **Yes** ❒ **No**	
3	Identify control & oversight activities including: • In-process acceptance • Finished device acceptance • Environmental control • Contamination control	…review production, equipment, maintenance & calibration records related to: • In-process acceptance criteria & acceptance • Finished device acceptance criteria & acceptance • Environmental control systems • Contamination control systems	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
4	From the Device History File (DHF) identify non-conformances	…review the DHF & identify con-conformances	❒ **Yes** ❒ **No**	
5	Review the identified DHF non-conformances & assess if: • Handled properly • Any equipment calibration failures • Any equipment maintenance failures • Any validation failures	…review the DHF calibration & maintenance non-conformances & if they were: • Properly handled • The result of equipment calibration failures • The result of equipment maintenance failures • The result of validation failures	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
6	Identify any processes that cannot be fully verified are validated through review of validation study	…review process validation procedure(s) & records to identify any processes that cannot be verified & document they were validated against predetermined specifications, review should include:	❒ **Yes** ❒ **No**	

		• Documented qualification of all process operators • Full change control of all processes • Calibration & maintenance of all instruments • All equipment is properly installed, adjusted & maintained • Establishment of predetermined product specifications • All test sampling plans and sampling is performed according to statistically valid rationale • All process tolerance limits are challenged	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
Item	**QSIT Subsystem/Assessment Detail**	**Assessment Comment(s)**	**Assessment** ☑	**Assessment Follow-up**
	PRODUCTION & PROCESS CONTROLS	Expect the Investigator to…		**Provide any appropriate brief comment**
7	Review all automated or software driven processes to document processes are validated for their intended use	…review these processes to ensure they were fully validated for their intended purpose against a validation protocol	❒ **Yes** ❒ **No**	
8	Review personnel records to document that personnel are trained in their manufacturing process(es) & aware of potential defects	…review personnel records across several shifts & confirm employees are aware of defects that may occur from failures to follow procedures & maintain & calibrate equipment	❒ **Yes** ❒ **No**	
	P&PC Subsystem: Sterilization Process Control	Expect the Investigator to…		**Provide any appropriate brief comment**
1	Review sterilization process procedure(s)	…review the sterilization process procedure(s)	❒ **Yes** ❒ **No**	
2	Review sterilization control & monitoring activities	…review sterilization records to document that the: • Processes • Equipment • Calibration are current and maintained	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
3	Review sterilization process validation	…review the sterilization process validation procedure …review sterilization validation records to document that the processes are consistently effective in: • Obtaining the SAL • Do not adversely affect the product(s) performance • Do not adversely affect the packaging	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
4	Review DHF for sterilization failures & assess to determine if • Handled appropriately • Required review of equipment adjustment, calibration & maintenance	…review sterilization failures & verify that they are • Integrated into CAPA activities • Provide feed-back for appropriate CAPA changes in equipment adjustment, calibration & maintenance	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
5	Review personnel training records to document that personnel are: • Qualified to implement sterilization activities • Trained in implemented sterilization activities	…review personnel & training records from several shifts to confirm personnel are: • Qualified to implement sterilization activities • Trained to implement sterilization activities	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	
6	Review all automated or software driven sterilization processes to document sterilization processes are: • Controlled • Validated	…review automated/software driven sterilization equipment's intended use and verify: • Use conforms to requirements & is under change control • Validation protocol, change control & results	❒ **Yes** ❒ **No** ❒ **Yes** ❒ **No**	

Binomial Sampling may be used when trying to make a decision about an endpoint that only has two potential outcomes, e.g., the device history record (DHR) is compliant or non-compliant. Expect FDA Investigators to use the following tables in sampling random records of raw materials, in-process products, components, finished devices, & verification and validation data. If the Investigator finds problems and reports "objectionable conditions," expect the Investigator to state in the Establishment Inspection Report (EIR) the total number of records included in the population from which the sample was taken, the table used (below), the row used (below), and the sample size selected

Table 1

Binomial Staged Sampling Plans
Binomial Confidence Levels

	Confidence Limit 0.95%≤	0 out of:	1 out of:	2 out of:
A	.30 uci	11	17	22
B	.25 uci	13	20	27
C	.20 uci	17	26	34
D	.15 uci	23	35	46
E	.10 uci	36	52	72
F	.05 uci	72	115	157

Table 2

Binomial Staged Sampling Plans
Binomial Confidence Level

	Confidence Limit 0.99%≤	0 out of:	1 out of:	2 out of:
A	.30 uci	15	22	27
B	.25 uci	19	27	34
C	.20 uci	24	34	43
D	.15 uci	35	47	59
E	.10 uci	51	73	90
F	.05 uci	107	161	190

uci = Upper Confidence Level

Reference: CRC Handbook of Probability and Statistics, Second Edition