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Audit Briefing for Medical Device Industry

A good audit starts with a good **plan**. Before starting an on-site audit VCI reviews past audits. The auditors note indications of possible problem areas and items, if any, that were identified for corrective action in a previous audit. The auditor must know the type of products produced at the facility and how it is organized by personnel and function. The scope of work by VCI includes:

- Buildings, facilities, equipment, laboratories, and processes
- Standard Operating Procedures
- Training
- Documentation
- Personnel observation

VCI uses a checklist to guide the auditor. The checklist also serves as reference to a notebook into which detailed entries are made during the audit.

Below are the instructions and an excerpt from the checklist VCI uses for audits:

1. While the checklist is to guide the auditor, is not intended to be a substitute for knowledge of the GMP regulations and general manufacturing experience.
2. Although a single question may be included about any requirement, the answer will usually be a multi-part one since the auditor should determine the audit trail for several products that may use many different components. Enter details in your notebook and cross reference your comments with the questions.
3. At least three devices should be selected for thorough analysis to include: (a) traceability of all components or materials used in the subject devices, (b) documentation of raw material or component, in-process, and finished goods testing for the subject product devices, (c) warehousing and distribution records as they would relate to a possible recall.
4. Responses entered on the checklist should be consistent. "X" is recommended for "NO"; a checkmark for "YES"; "n/a" for not applicable to questions that do not apply. An asterisk and notebook page number should be entered on the checklist to identify where relevant comments or questions are recorded in your notebook.
5. Record the comments in the addendum referencing the checklist question.
6. The references to sections in the GMP regulation are for your convenience should a question arise. In some instances, two or more sections within the GMP regulation may have bearing on a specific subject. The headings in the GMP regulation will usually offer some guidance on the areas covered in each section.
7. A general suggestion for a successful audit is to spend most of your time on major issues and a smaller portion of your time on small issues. There may be observations that you may wish to point out to supervisory personnel that deserve attention, but do not belong in an audit report because they are relatively insignificant. By the same token, *too many* small items suggests a trend of non-compliance and deserve attention as such. When citing these, be specific.
8. The documentation to be collected during the audit and to be supplied to the customer as part of the completed audit package will include:
   - 8.1. Checklists used by auditors during the audit
   - 8.2. Record of documents reviewed
   - 8.3. Hand-written or other notes made by the auditors during the audit

8.4. Record of processes, device designs and corrective action inputs audited

8.5. Copies of manufacturer's documentation collected during the audit

8.6. Observations and non-conformities identified during the audit

8.7. Names of the key staff interviewed

8.8. Record of medical devices affected by major non-conformities

8.9. Report prepared by the audit team at the end of the audit

8.10. Opening and closing meeting attendance record

8.11. Action items recommended for next audit

8.12. Advisory information for manufacturer for maintaining and improving the quality system

9. At the end of the audit critique and improve this checklist based on customer input and what you learned during the audit.

Customer's Name

Date(s) of Audit

Audit Leader Name

Instructions/questions (note any exceptions and comments in notebook).	**Yes, No, or NA**
§820.20 Management Responsibilities	
§820.20(a) Does this facility/business unit operate under a facility or corporate quality policy?	
§820.20(b)1 Does a Quality Assurance unit (functionality) have the independence and authority to manage, perform, and assess work affecting quality?	
§820.20(b)2 Does the manufacturer provide adequate resources to meet the requirements of the QSR's?	
§820.20(b)3 Has executive management documented the appointment of a member of management with authority over and responsibility for (i)establishing and maintaining QSR's and (ii)reporting on the performance of the QSR's?	
§820.20(c) Does executive management review the effectiveness of the QSR's at defined intervals and according to established procedures?	
§820.20(d) Does a quality plan exist which defines how the requirements for quality will be met?	
§820.20(e) Has the manufacturer established quality system procedures?	
§820.20(e) Has an outline of the structure of the documentation been established?	