



## Audit Briefing

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.

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. At least three production runs or batches are selected for thorough analysis to include: (a) traceability of all components or materials used in the subject batches, (b) documentation of raw material or component, in-process, and finished goods testing for the subject product batches, (c) warehousing and distribution records as they would relate to a possible recall.
3. Responses entered on the checklist are consistent. "X" for "NO"; a checkmark for "YES"; "n/a" for not applicable to questions that do not apply. An asterisk and notebook page number are entered on the checklist to identify where relevant comments or questions are recorded in the notebook.

Below is an excerpt from a checklist that VCI uses.

<b>3.3</b>	<b>Facility Maintenance and Good Housekeeping Program</b>	
3.301	§211.56 Is this facility free from infestation by rodents, birds, insects and vermin?	
3.302	Does this facility have written procedures for the safe use of suitable, (e.g. those that are properly registered) rodenticides, insecticides, fungicides, and fumigating agents?	
3.303	Is this facility maintained in a clean and sanitary condition?	
3.304	Does this facility have written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and material?	
3.305	Does this facility have written procedures for the safe and correct use of cleaning and sanitizing agents?	
3.306	§211.58 Are all parts of the facility maintained in a good state of repair?	
3.307	§211.52 Is sewage, trash and other refuse disposed of in a safe and sanitary manner (and with sufficient frequency?)	