Audit #: _____ Auditor(s): _____ Date: _____

Subpart B		
Responsibilities of the Quality Control Unit – 21 CFR 211.22	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
A quality unit is defined – including QA and QC activities – that is independent of production.		☐ Yes ☐ No
Quality control personnel have established roles and responsibilities covering requirements defined in 21 CFR 211, and procedures have been established to carry out these responsibilities.		☐ Yes ☐ No
Quality control operations and authority have been established for manufacturing records.		☐ Yes ☐ No
Quality control operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.		☐ Yes ☐ No
Quality control has not approved and released product in any form that does not meet specifications and unless any deviations have been investigated and approved by Quality Control.		☐ Yes ☐ No
The QC Unit performs cGMP Internal Audits periodically. A documented corrective action file is maintained.		☐ Yes ☐ No
Procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (ICH Q7A).		☐ Yes ☐ No
Personnel Qualification and Responsibilities – 21 CFR 211.25 and 211.28	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Procedures have been established that define work requirements for personnel to prevent microbial		☐ Yes ☐ No

contamination from illness or hygienic practices.		
Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitation, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated.		☐ Yes ☐ No
Procedures have been established for removal of jewelry and other items and/or use of appropriate coverings.		☐ Yes ☐ No
Procedures have been established for the use of impermeable gloves, hairnets, beard covers, etc. and for restrictions of food, drinks, gum, tobacco, etc. in areas where product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources.		☐ Yes ☐ No
Appropriate change rooms are available if needed and there is adequate storage of personal effects.		☐ Yes ☐ No
Personnel must be qualified and have adequate training, experience and/or education necessary to perform job functions.		☐ Yes ☐ No
Procedures have been established to define requirements for personnel who will supervise activities.		☐ Yes ☐ No
Personnel who are designated as supervisors are qualified and have written requirements.		☐ Yes ☐ No
Procedures have been established and records are maintained documenting compliance to these procedures.		☐ Yes ☐ No
Consultants – 21 CFR 211.34	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
If consultants are used, records of their qualifications and the type of service they provide shall be maintained.		☐ Yes ☐ No