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**
Is the quality unit defined – including QA and QC activities – that is independent of production?		☐ Yes ☐ No
Do Quality personnel have established roles and responsibilities covering requirements defined in 21 CFR 211, and have procedures been established to carry out these responsibilities?		☐ Yes ☐ No
Has the Quality Unit operations and authority been established for manufacturing records?		☐ Yes ☐ No
Does the Quality Unit 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 unless a deviation has been investigated and approved by the Quality Unit.		☐ Yes ☐ No
Does the Quality Unit perform cGMP Internal Audits periodically? Is a documented corrective action file is maintained?		☐ Yes ☐ No
Do 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**
Have procedures been established that define work requirements for personnel to prevent microbial contamination from illness or hygienic practices?		☐ Yes ☐ No

Have 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
Have procedures been established for removal of jewelry and other items and/or use of appropriate coverings?		☐ Yes ☐ No
Have procedures 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? Have procedures been established to prevent contamination from all extraneous sources?		☐ Yes ☐ No
Are there appropriate change rooms available, if needed, and is there adequate storage of personal effects?		☐ Yes ☐ No
Are personnel qualified and have adequate training, experience and/or education necessary to perform job functions?		☐ Yes ☐ No
Have procedures been established to define requirements for personnel who will supervise activities?		☐ Yes ☐ No
Are personnel who are designated as supervisors qualified and have written requirements?		☐ Yes ☐ No
Have procedures been established and records 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**
Are records of consultants' qualifications and the type of service they provide maintained?		☐ Yes ☐ No