Center Name	Cite Id	Reference Number	Short Description	Long Description	Frequency
Drugs	1105	21 CFR 211.22(d)	Procedures not in writing, fully followed	The responsibilities and procedures applicable to the quality control unit are not [in writing] [fully followed]. Specifically, ***	160
Drugs	3603	21 CFR 211.160(b)	Scientifically sound laboratory controls	Laboratory controls do not include the establishment of scientifically sound and appropriate [specifications] [standards] [sampling plans] [test procedures] designed to assure that [components] [drug product containers] [closures] [in-process materials] [	130
Drugs	2027	21 CFR 211.192	Investigations of discrepancies, failures	There is a failure to thoroughly review [any unexplained discrepancy] [the failure of a batch or any of its components to meet any of its specifications] whether or not the batch has been already distributed. Specifically, ***	124
Drugs	1451	21 CFR 211.113(b)	Procedures for sterile drug products	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not [established] [written] [followed]. Specifically, ***	104
Drugs	1361	21 CFR 211.100(a)	Absence of Written Procedures	There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, ***	95
Drugs	1434	21 CFR 211.42(c)(10)(iv)	Environmental Monitoring System	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, ***	83
Drugs	1883	21 CFR 211.165(a)	Testing and release for distribution	Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the [final specifications] [identity and strength of each active ingredient] prior to release. Specifically, ***	80
Drugs	3585	21 CFR 211.110(a)	Control procedures to monitor and validate performance	Control procedures are not established which [monitor the output] [validate the performance] of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically	69
Drugs	1213	21 CFR 211.67(a)	Cleaning / Sanitizing / Maintenance	Equipment and utensils are not [cleaned] [maintained] [sanitized] at appropriate intervals to prevent [malfunctions] [contamination] that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, ***	68
Drugs	1274	21 CFR 211.68(a)	Calibration/Inspection/Checking not done	Routine [calibration] [inspection] [checking] of [automatic] [mechanical] [electronic] equipment is not performed according to a written program designed to assure proper performance. Specifically, ***	64
Drugs	1914	21 CFR 211.166(a)	Lack of written stability program	There is no written testing program designed to assess the stability characteristics of drug products. Specifically, ***	63
Drugs	1435	21 CFR 211.42(c)(10)(v)	Cleaning System	Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the [room] [equipment] to produce aseptic conditions. Specifically, ***	60
Drugs	1177	21 CFR 211.63	Equipment Design, Size and Location	Equipment used in the manufacture, processing, packing or holding of drug products is not [of appropriate design] [of adequate size] [suitably located] to facilitate operations for its [intended use] [cleaning and maintenance]. Specifically, ***	56
Drugs	2009	21 CFR 211.188	Prepared for each batch, include complete information	Batch production and control records [are not prepared for each batch of drug product produced] [do not include complete information relating to the production and control of each batch]. Specifically, ***	56
Drugs	1215	21 CFR 211.67(b)	Written procedures not established/followed	Written procedures are not [established] [followed] for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically, ***	53
Drugs	1452	21 CFR 211.113(b)	Validation lacking for sterile drug products	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include [adequate] validation of the sterilization process. Specifically, ***	53
Drugs	1358	21 CFR 211.100(b)	SOPs not followed / documented	Written production and process control procedures are not [followed in the execution of production and process control functions] [documented at the time of performance]. Specifically, ***	52
Drugs	1112	21 CFR 211.25(a)	Training--operations, GMPs, written procedures	Employees are not given training in [the particular operations they perform as part of their function] [current good manufacturing practices] [written procedures required by current good manufacturing practice regulations]. Specifically, ***	50
Drugs	4402	21 CFR 211.192	Written record of investigation incomplete	Written records of investigations into [unexplained discrepancies] [the failure of a batch or any of its components to meet specifications] do not [always] include the conclusions and follow-up. Specifically, ***	47
Drugs	1809	21 CFR 211.160(a)	Following/documenting laboratory controls	Established [specifications] [standards] [sampling plans] [test procedures] [laboratory control mechanisms] are not [followed] [documented at the time of performance]. Specifically, ***	40
Drugs	2419	21 CFR 211.198(a)	Complaint Handling Procedure	Procedures describing the handling of written and oral complaints related to drug products are [not written or followed] [deficiently written or followed]. Specifically, ***	40
Drugs	2031	21 CFR 211.194(a)	Complete test data included in records	Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards. Specifically, , ***	39
Drugs	1111	21 CFR 211.25(a)	Training , Education , Experience overall	Employees engaged in the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] required to perform their assigned functions. Specifically, ***	37
Drugs	4391	21 CFR 211.180(e)(2)	Items to cover on annual reviews	Written procedures are not [established] [followed] for evaluations done at least annually and including provisions for a review of [complaints] [recalls] [returned or salvaged drug products] [investigations conducted for each drug product]. Specifically	37
Drugs	1263	21 CFR 211.68(b)	Computer control of master formula records	Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically, ***	35
Drugs	1159	21 CFR 211.28(a)	Clothing appropriate for duties performed	Clothing of personnel engaged in the [manufacturing] [processing] [packing] [holding] of drug products is not appropriate for the duties they perform. Specifically, ***	33
Drugs	1890	21 CFR 211.165(e)	Test methods	The [accuracy] [sensitivity] [specificity] [reproducibility] of test methods have not been [established] [documented]. Specifically, ***	33
Drugs	1932	21 CFR 211.167(a)	Sterility/pyrogen-free testing	Each batch of drug product purporting to be [sterile] [pyrogen-free] is not laboratory tested to determine conformance to such requirements. Specifically, ***	33
Drugs	4314	21 CFR 211.84(d)(2)	Reports of Analysis (Components)	Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without [performing at least one specific identity test on each component] [establishing the reliabilit	33
Drugs	4352	21 CFR 211.160(b)(4)	Calibration - at intervals, written program, remedial action	The calibration of [instruments] [apparatus] [gauges] [recording devices] is not done at suitable intervals [in accordance with an established written program] [with provisions for remedial action in the event accuracy and/or precision limits are not met]	30
Drugs	4576	21 CFR 211.192	No written record of investigation	Written records are not [always] made of investigations into [unexplained discrepancies] [the failure of a batch or any of its components to meet specifications]. Specifically, ***	30
Drugs	1448	21 CFR 211.111	Establishment of time limitations	Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product. Specifically, ***	27
Drugs	1810	21 CFR 211.160(a)	Lab controls established, including changes	The establishment of [specifications] [standards] [sampling plans] [test procedures] [laboratory control mechanisms] including any changes thereto, are not [drafted by the appropriate organizational unit] [reviewed and approved by the quality control unit	27
Drugs	2026	21 CFR 211.192	Quality control unit review of records	Drug product production and control records, are not [reviewed] [approved] by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Specifically, ***	27
Drugs	9001	21 CFR 211.22(a)	Lack of quality control unit	There is no quality control unit. Specifically, ***	27
Drugs	1194	21 CFR 211.42(c)	Defined areas of adequate size for operations	The [separate or defined areas][control systems] necessary to prevent contamination or mix-ups are deficient. Specifically, ***	26
Drugs	1767	21 CFR 211.137(a)	Expiration date lacking	Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use. Specifically, ***	26
Drugs	1162	21 CFR 211.28(a)	Protective Apparel Not Worn	Protective apparel is not worn as necessary to protect drug products from contamination. Specifically, ***	25
Drugs	1833	21 CFR 211.84(d)(1)	Identity Testing of Each Component	The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist. Specifically, ***	25
Drugs	3565	21 CFR 211.58	Buildings not maintained in good state of repair	Buildings used in the [manufacturing] [processing] [packing] [holding] of a drug product are not maintained in a good state of repair. Specifically, ***	25
Drugs	4303	21 CFR 211.67(b)	Written procedures fail to include	Written procedures for cleaning and maintenance fail to include [assignment of responsibility] [maintenance and cleaning schedules] [description in sufficient detail of methods, equipment and materials used] [description in sufficient detail of the method	25
Drugs	2028	21 CFR 211.192	Extent of discrepancy, failure investigations	Investigations of [an unexplained discrepancy] [a failure of a batch or any of its components to meet any of its specifications] did not extend to [other batches of the same drug product] [other drug products that may have been associated with the specif	22
Drugs	1433	21 CFR 211.42(c)(10)(iii)	Air Supply	Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. Specifically, ***	21
Drugs	1436	21 CFR 211.42(c)(10)(vi)	Equipment to control conditions	Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions. Specifically, ***	21
Drugs	1450	21 CFR 211.113(a)	Procedures for non-sterile drug products	Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not [established] [written] [followed]. Specifically, ***	21
Drugs	4342	21 CFR 211.142(b)	Storage under appropriate conditions	Drug products are not stored under appropriate conditions of [temperature] [humidity] [light] so that their identity, strength, quality, and purity are not affected. Specifically, ***	21
Drugs	1912	21 CFR 211.166(a)	Written program not followed	The written stability testing program is not followed. Specifically, ***	20
Drugs	1920	21 CFR 211.166(a)(3)	Valid stability test methods	The written stability program for drug products does not include [reliable] [meaningful] [specific] test methods. Specifically, ***	20
Drugs	3572	21 CFR 211.100(b)	Procedure Deviations Recorded and Justified	Deviations from written production and process control procedures are not [recorded] [justified]. Specifically, ***	20

Drugs	4389	21 CFR 211.198(a)	Procedures to be written and followed	Procedures describing the handling of all written and oral complaints regarding a drug product are not [established] [written] [followed]. Specifically, ***	20
Drugs	1098	21 CFR 211.22(c)	Approve or reject procedures or specs	The quality control unit lacks responsibility to [approve] [reject] all procedures or specifications impacting on the [identity] [strength] [quality] [purity] of drug products. Specifically, ***	19
Drugs	1133	21 CFR 211.25(a)	GMP Training Frequency	GMP training is not conducted [on a continuing basis] [with sufficient frequency] to assure that employees remain familiar with CGMP requirements applicable to them. Specifically, ***	19
Drugs	1943	21 CFR 211.180(e)(1)	Review of representative number of batches	Written procedures are not [established] [followed] for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, ***	19
Drugs	3571	21 CFR 211.100(a)	Changes to Procedures Not Reviewed, Approved	Changes to written procedures are not [drafted, reviewed and approved by the appropriate organizational unit] [reviewed and approved by the quality control unit]. Specifically, ***	19
Drugs	3559	21 CFR 211.56(a)	Sanitation--buildings not clean, free of infestation	Buildings used in the manufacture, processing, packing or holding of drug products are not [maintained in a clean and sanitary condition] [free of infestation by rodents, birds insects, and other vermin]. Specifically, ***	18
Drugs	3632	21 CFR 211.170(b)	Annual visual exams of drug products	Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration. Specifically, ***	17
Drugs	1885	21 CFR 211.165(b)	Microbiological testing	Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing. Specifically, ***	16
Drugs	4306	21 CFR 211.80(a)	Written Procedures Not Followed	Written procedures are not followed for the [receipt] [identification] [storage] [handling] [sampling] [testing] [approval] [rejection] of [components] [drug product containers] [closures]. Specifically, ***	16
Drugs	1227	21 CFR 211.67(c)	Cleaning/maintenance records not kept	Records are not kept for the [maintenance] [cleaning] [sanitizing] [inspection] of equipment. Specifically, ***	15
Drugs	1787	21 CFR 211.80(a)	Procedures To Be in Writing	Written procedures are lacking which describe in sufficient detail the [receipt] [identification] [storage] [handling] [sampling] [testing] [approval] [rejection] of [components] [drug product containers] [closures]. Specifically, ***	15
Drugs	1891	21 CFR 211.165(f)	Failing drug products not rejected	Drug products failing to meet established [standards] [specifications] [quality control criteria] are not rejected. Specifically, ***	15
Drugs	1975	21 CFR 211.182	Written records kept in individual logs	Written records of major equipment [cleaning] [maintenance] [use] are not included in individual equipment logs. Specifically, ***	15
Drugs	4340	21 CFR 211.142	Written warehousing procedures established/followed	Procedures describing the warehousing of drug products are not [established] [followed]. Specifically, ***	15
Drugs	1801	21 CFR 211.84(a)	Components withheld from use pending release	Each lot of [components] [drug product containers] [closures] is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit. Specifically, ***	14
Drugs	3547	21 CFR 211.46(b)	Equipment for Environmental Control	Equipment for adequate control over [air pressure] [micro-organisms] [dust] [humidity] [temperature] is not provided when appropriate for the manufacture, processing, packing or holding of a drug product. Specifically, ***	14
Drugs	1033	21 CFR 211.22(a)	Authority lacking to review records, investigate errors	The quality control unit lacks authority to [review production records to assure that no errors have occurred] [fully investigate errors that have occurred]. Specifically, ***	13
Drugs	1169	21 CFR 211.42(a)	Buildings of Suitable Size, Construction, Location	Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable [size] [construction] [location] to facilitate cleaning, maintenance, and proper operations. Specifically, ***	13
Drugs	1395	21 CFR 211.103	Actual vs. theoretical yields not determined	Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of [manufacturing] [processing] [packaging] [holding] of the drug product. Specifically, ***	13
Drugs	1540	21 CFR 211.125(a)	Strict control not exercised over labeling issued	Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, ***	13
Drugs	1790	21 CFR 211.80(b)	Handling and Storage to Prevent Contamination	There was a failure to handle and store [components] [drug product containers] [closures] at all times in a manner to prevent contamination. Specifically, ***	13
Drugs	2205	21 CFR 211.186(b)(9)	Manufacturing Instructions and Specifications	The master production and control records are deficient in that they do not include complete [manufacturing] [control] [instructions] [sampling] [testing] [procedures] [specifications] [special notations] [precautions]. Specifically, ***	13
Drugs	4315	21 CFR 211.84(d)(2)	Testing Each Component for Conformity with Specs	Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality. Specifically, ***	13
Drugs	4401	21 CFR 211.186(b)(9)	Complete instructions, procedures, specifications et. al.	Master production and control records lack [complete manufacturing and control instructions] [sampling and testing procedures] [specifications] [special notations] [precautions to be followed]. Specifically, ***	13
Drugs	6730	21 CFR 314.80(b)	Failure to develop written procedures	Written procedures have not been developed for the [surveillance] [receipt] [evaluation] [reporting to FDA] of post marketing adverse drug experiences. Specifically, ***	13
Drugs	1933	21 CFR 211.167(a)	Sterility/pyrogens - test methods written, followed	Test procedures relative to appropriate laboratory testing for [sterility] [pyrogens] are not [written] [followed]. Specifically, ***	12
Drugs	1942	21 CFR 211.180(e)	Records reviewed annually	Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures. Specifically, ***	12
Drugs	2619	21 CFR 211.198(b)(2)	Complaint Investigation/Follow-Up Findings	Complaint records are deficient in that they do not include the findings of the [investigation] [follow-up]. Specifically, ***	12
Drugs	4372	21 CFR 211.188(b)(8)	Labeling control records including specimens or copies	Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced. Specifically, ***	12
Drugs	4413	21 CFR 211.194(a)(8)	Second person sign off	Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for [accuracy] [completeness] [compliance with established standards]. Specifically, ***	12
Drugs	6732	21 CFR 314.80(c)(1)(i)	Late submission of 15-day report	Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information. Specifically, ***	12
Drugs	1550	21 CFR 211.125(f)	Procedures Written and Followed	Procedures describing in sufficient detail the controls employed for the issuance of labeling are not [written] [followed]. Specifically, ***	11
Drugs	3583	21 CFR 211.110(a)	Written in-process control procedures	Written procedures are not [established] [followed] that describe the [in-process controls] [tests] [examinations] to be conducted on appropriate samples of in-process materials of each batch. Specifically, ***	11
Drugs	3602	21 CFR 211.160(a)	Deviations from laboratory control requirements	Deviations from written [specifications] [standards] [sampling plans] [test procedures] [laboratory mechanisms] are not [recorded] [justified]. Specifically, ***	11
Drugs	1174	21 CFR 211.42(b)	Product flow through building is inadequate	The flow of [components] [drug product containers] [closures] [labeling] [in-process materials] [drug products] though the building is not designed to prevent contamination. Specifically, ***	10
Drugs	1421	21 CFR 211.42(c)(10)	Aseptic Processing Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products. Specifically,***	10
Drugs	2008	21 CFR 211.186(a)	Written procedures followed	Procedures for the preparation of master production and control records are not [described in a written procedure] [followed]. Specifically, ***	10
Drugs	8907	21 CFR 314.81(b)(1)(ii)	Contamination, chemical or physical change, deterioration	An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning [bacteriological contamination] [significant chemical, physical, or other change or deterioration] in a distributed drug product. Specifically, **	10
Drugs	1049	21 CFR 211.22(a)	Approve or reject components, products	The quality control unit lacks the responsibility and authority to [approve] [reject] all [components] [drug product containers] [closures] [in process materials] [packaging material] [labeling] [drug products]. Specifically, ***	9
Drugs	1270	21 CFR 211.68(b)	input/output verification	Input to and output from [the computer] [related systems of formulas] [records or data] are not checked for accuracy. Specifically, ***	9
Drugs	1626	21 CFR 211.130	Procedures are written, and followed	Procedures designed to assure that correct [labels] [labeling] [packaging materials] are used for drug products are not [written] [followed]. Specifically, ***	9
Drugs	1728	21 CFR 211.87	Retest of approved components/containers/closures	Approved [components] [drug product containers] [closures] are not retested or reexamined as appropriate for identity, strength, quality and purity after [storage for long periods] [exposure to conditions that might have an adverse effect] with subsequen	9
Drugs	1802	21 CFR 211.84(b)	Representative Samples	Representative samples are not taken of each shipment of each lot of [components] [drug product containers] [closures] for testing or examination. Specifically, ***	9
Drugs	3570	21 CFR 211.100(a)	Approval and review of procedures	Written procedures are not [drafted, reviewed and approved by the appropriate organizational units] [reviewed and approved by the quality control unit]. Specifically, ***	9
Drugs	3613	21 CFR 211.160(b)(4)	Establishment of calibration procedures	Procedures describing the calibration of instruments, apparatus, gauges and recording devices are [not written or followed] [deficiently written or followed]. Specifically, ***	9
Drugs	3616	21 CFR 211.165(d)	Acceptance criteria for sampling & testing	Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet [each appropriate specification] [appropriate statistical quality control criteria] as a condition for thei	9
Drugs	4357	21 CFR 211.166(a)	Results not used for expiration dates, storage cond.	Results of stability testing are not used in determining [appropriate storage conditions] [expiration dates]. Specifically, ***	9
Drugs	4409	21 CFR 211.194(a)(4)	Data secured in course of each test	Laboratory records do not include a complete record of all data secured in the course of each test, including all [graphs] [charts] [spectra] from laboratory instrumentation, properly identified to show the [specific component] [drug product container] [c	9
Drugs	8911	21 CFR 314.81(b)(1)(ii)	Failure to meet specifications	An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application. Specifically, ***	9
Drugs	1261	21 CFR 211.68(a)	Written calibration / inspection records not kept	Records of the [calibration checks] [inspections] of automatic, mechanical or electronic equipment, including computers or related systems are not maintained. Specifically, ***	8
Drugs	1495	21 CFR 211.122(a)	Written procedures describing in detail	There is a lack of written procedures describing in sufficient detail the [receipt] [identification] [storage] [handling] [sampling] [examination] [testing] of labeling and packaging materials. Specifically, ***	8

Drugs	1777	21 CFR 211.150(b)	Distribution Recall System	The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary. Specifically, ***	8
Drugs	1868	21 CFR 211.94(b)	Protection from external factors	Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product. Specifically, ***	8
Drugs	1926	21 CFR 211.166(b)	Adequate number of batches on stability	An adequate number of batches of each drug product are not tested [nor are records of such data maintained] to determine an appropriate expiration date. Specifically, ***	8
Drugs	3561	21 CFR 211.56(b)	Written sanitation procedures lacking	There is a lack of written procedures [assigning responsibility] [providing cleaning schedules] [describing in sufficient detail the methods, equipment and materials to be used] for sanitation. Specifically, ***	8
Drugs	4351	21 CFR 211.160(b)(3)	Drug products - samples representative, identified properly	Samples taken of drug products for determination of conformance to written specifications are not [representative] [properly identified]. Specifically, ***	8
Drugs	2012	21 CFR 211.188(b)	Batch production and Batch Control Record Requirements	The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in [manufacturing] [processing] [packing] [holding]. Specifically, ***	7
Drugs	2020	21 CFR 211.188(b)(8)	Labeling Control Records and Label Copies	The batch production and control records are deficient in that they do not include [complete labeling control records] [specimen] [copy] of labeling. Specifically, ***	7
Drugs	3639	21 CFR 211.204	Returned drug procedures in writing and followed	Procedures describing the [holding] [testing] [reprocessing] of returned drug products are not [in writing] [followed]. Specifically, ***	7
Drugs	4353	21 CFR 211.160(b)(4)	Instruments, apparatus, et. al. not meeting specs	The use of [instruments] [apparatus] [gauges] [recording devices] not meeting established specifications was observed. Specifically, ***	7
Drugs	4406	21 CFR 211.194(a)(2)	Suitability of testing methods verified	The suitability of all testing methods is not verified under actual conditions of use. Specifically, ***	7
Drugs	1086	21 CFR 211.22(b)	Adequate lab facilities not available	Adequate lab facilities for testing and approval or rejection of [components] [drug product containers] [closures] [packaging materials] [in-process materials] [drug products] are not available to the quality control unit. Specifically, ***	6
Drugs	1136	21 CFR 211.25(c)	Inadequate number of personnel	The number of qualified personnel is inadequate to [perform] [supervise] the [manufacture] [processing] [packing] [holding] of each drug product. Specifically, ***	6
Drugs	1844	21 CFR 211.84(d)(2)	Establish reliability of supplier's C of A	Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals. Specifically, ***	6
Drugs	1869	21 CFR 211.94(c)	Containers & Closures Clean, Sterilized, Pyrogen-free	Drug product [containers] [closures] were not [clean] [sterilized and processed to remove pyrogenic properties] to assure that they are suitable for their intended use. Specifically, ***	6
Drugs	2034	21 CFR 211.194(d)	Laboratory equipment calibration records	Laboratory records do not include complete records of the periodic calibration of laboratory [instruments] [apparatus] [gauges] [recording devices]. Specifically, ***	6
Drugs	3557	21 CFR 211.52	Washing and toilet facilities are deficient	Washing and toilet facilities lack [hot and cold water] [soap or detergent] [air driers or single-service towels] [cleanliness]. Specifically, ***	6
Drugs	3629	21 CFR 211.170(b)	Reserve samples identified, representative, stored	Reserve drug product samples are not [appropriately identified] [representative of each lot or batch of drug product] [retained and stored under conditions consistent with product labeling]. Specifically, ***	6
Drugs	4320	21 CFR 211.84(d)(6)	Microbiological Contamination Exam	Each lot of a [component] [drug product container] [closure] that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use. Specifically, ***	6
Drugs	4343	21 CFR 211.160(b)(1)	Incoming lots - conformance to written specs-	Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of [components] [drug product containers] [closures] [in-process materials] [labeling] [drug products	6
Drugs	4344	21 CFR 211.160(b)(1)	Sampling and testing procedures described	Written specifications for laboratory controls do not include a description of the [sampling] [testing] procedures used. Specifically, ***	6
Drugs	6831	21 CFR 314.80(c)(2)	Late submission of quarterly safety reports	Not all quarterly periodic adverse drug experience reports have been submitted within 30 days of the close of the quarter. Specifically, ***	6
Drugs	1134	21 CFR 211.25(b)	Supervisor Training/Education/Experience	Individuals responsible for supervising the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] to perform their assigned functions in such a manner as to assure the drug product has the safety, i	5
Drugs	1505	21 CFR 211.122(d)	Label storage access limited to authorized personnel	Access to the storage area for labels and labeling materials is not limited to authorized personnel. Specifically, ***	5
Drugs	1851	21 CFR 211.84(e)	Rejecting When Specifications Not Met	Failure to reject any lot of [components] [drug product containers] [closures] that did not meet the appropriate written specifications for identity, strength, quality, and purity. Specifically, ***	5
Drugs	1852	21 CFR 211.94(a)	Reactive/Additive/Absorptive Containers/Closures	Drug product containers or closures are [reactive] [additive] [absorptive] so as to alter the safety, identity, strength, quality, and purity of the drug beyond the official or established requirements. Specifically, ***	5
Drugs	1922	21 CFR 211.166(a)(4)	Testing in same container - closure system	The written stability program does not assure testing of the drug product in the same container-closure system as that in which the drug product is marketed. Specifically, ***	5
Drugs	2033	21 CFR 211.194(c)	Testing and standardization of standards et. al.	Laboratory records do not include complete records of any testing and standardization of laboratory [reference standards] [reagents] [standard solutions]. Specifically, ***	5
Drugs	2567	21 CFR 211.198(a)	Adverse Drug Experience	Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent [serious) [unexpected adverse drug experiences] which are required to be reported to FDA. Specifically, ***	5
Drugs	2569	21 CFR 211.198(b)	Maintenance of Complaint File	Complaint procedures are deficient in that written complaint records are not maintained in a file designated for drug product complaints. Specifically, ***	5
Drugs	2618	21 CFR 211.198(b)(1)	Complaint Record required information	Complaint records are deficient in that they do not include the known [name and strength of the drug product] [lot number] [name of complainant] [nature of complaint] [reply to complainant]. Specifically, ***	5
Drugs	3592	21 CFR 211.110(c)	In-process materials characteristics testing	In-process materials are not tested for [identity] [strength] [quality] [purity] and approved or rejected by the quality control unit [during the production process] [after storage for long periods]. Specifically, ***	5
Drugs	3614	21 CFR 211.160(b)(4)	Written calibration procedures	Written calibration procedures for instruments, apparatus, gauges, and recording devices are deficient in that they do not include specific [directions] [schedules] [limits for accuracy and precision] [provisions for remedial action if limits are not met]	5
Drugs	4302	21 CFR 211.56(b)	Written sanitation procedures not followed	Written procedures for sanitation are not followed. Specifically, ***	5
Drugs	4349	21 CFR 211.160(b)(2)	In-process samples representative, identified properly	Samples taken of in-process materials for determination of conformance to specifications are not [representative] [properly identified]. Specifically, ***	5
Drugs	4387	21 CFR 211.198(a)	Reporting of adverse drug experience to FDA	Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food	5
Drugs	4388	21 CFR 211.198(a)	Complaints reviewed by Quality Control Unit	Written procedures describing the handling of complaints do not include provisions for [review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications] [a determination as to the need	5
Drugs	4418	21 CFR 211.42(b)	Adequate space lacking to prevent mix-ups and contamination	The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between [different components] [drug product containers] [closures] [labeling] [in-process materials] [drug products] and to prevent contamination.	5
Drugs	8912	21 CFR 314.81(b)(2)	Timely submission	An annual report was not submitted [each year] [within 60 days of the anniversary date of U.S. approval of the application] to the FDA division responsible for reviewing the application. Specifically, ***	5
Drugs	17763	21 CFR 212.20(d)	Determination need for investigation	When errors occurred or a production batch failed to meet specifications, you did not [determine the need for an investigation] [conduct an investigation] [take appropriate corrective actions] when necessary. Specifically,***	5
Drugs	1163	21 CFR 211.28(b)	Habits of good sanitation & health	Production personnel were not practicing good sanitation and health habits. Specifically, ***	4
Drugs	1388	21 CFR 211.101(d)	Component addition checked by 2nd person	Each component is not added to a batch by one person and verified by a second person. Specifically, ***	4
Drugs	1411	21 CFR 211.105(b)	Distinctive ID or code not recorded in batch record	The batch records do not record the distinctive [identification number] [code] [name of equipment] to identify major equipment to show the specific equipment used in the manufacture of a batch of a drug product. Specifically, ***	4
Drugs	1449	21 CFR 211.111	Deviations of production time limits	Deviations from production time limits [are not justified] [are not documented] [compromise the quality of the drug product]. Specifically, ***	4
Drugs	1636	21 CFR 211.130(e)	Packaging line inspection before use	Inspection of the [packaging] [labeling] facilities immediately before use is not done to assure that all drug products have been removed from previous operations. Specifically, ***	4
Drugs	1724	21 CFR 211.134(b)	Representative samples after completion	Samples of representative units were not [collected] [visually examined] for correct labeling at the completion of finishing operations. Specifically, ***	4
Drugs	1774	21 CFR 211.142(a)	Quarantine - actual practice	Drug products are not quarantined before being released by the quality control unit. Specifically, ***	4
Drugs	1842	21 CFR 211.84(d)(1)	Component identity verification	Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed. Specifically,***	4
Drugs	1849	21 CFR 211.84(d)(6)	Objectionable microbiological contamination	Each lot of a [component] [drug product containers] [closures] liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use. Specifically, ***	4
Drugs	1876	21 CFR 211.180(b)	Record maintenance 1 year (except exempt OTC)	All records of [production] [control] [distribution] [components] [drug product containers] [closures] [labeling] associated with a batch of drug product are not maintained at least one (1) year after the expiration date. Specifically, ***	4
Drugs	1918	21 CFR 211.166(a)(2)	Stability sample storage conditions described	The written stability program for drug products does not describe the storage conditions for samples retained for testing. Specifically, ***	4
Drugs	1927	21 CFR 211.166(b)	Accelerated stability studies	Accelerated stability studies, combined with basic stability information, used to support tentative expiration dates are not supported with ongoing full shelf life studies. Specifically, ***	4
Drugs	1957	21 CFR 211.180(e)(2)	Review of problem drugs	The procedures for the annual quality standards record evaluation are deficient in that they do not address a review of [complaint] [recall] [returned drug product] [salvaged drug product] [investigation] records for each drug product. Specifically, ***	4

Drugs	2007	21 CFR 211.186(a)	Signature and checking of records -- 2 persons	The master production and control records for each batch size of drug product are not [prepared, dated, and signed by one person with a full handwritten signature] [independently checked, dated, and signed by a second person]. Specifically, ***	4
Drugs	2401	21 CFR 211.194(a)(4)	Complete Test Data	Laboratory records are deficient in that they do not include a complete record of all data obtained during testing. Specifically, ***	4
Drugs	3567	21 CFR 211.84(d)(2)	Component identification test	Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis. Specifically, ***	4
Drugs	3569	21 CFR 211.89	Quarantine of Rejected Components et. al.	Rejected [components] [drug product containers] [closures] are not controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable. Specifically, ***	4
Drugs	3582	21 CFR 211.105(a)	Identification of containers, lines, equipment	All [compounding and storage containers] [processing lines] [major equipment] used during the production of a batch of drug product is not properly identified at all times to indicate [contents] [the phase of processing of the batch]. Specifically, ***	4
Drugs	3591	21 CFR 211.110(b)	In-process materials specifications	In-process specifications are not [consistent with drug product final specifications] [derived from previous acceptable process average and process variability estimates where possible] [determined by the application of suitable statistical procedures whe	4
Drugs	3630	21 CFR 211.170(b)	Drug product reserve containers	Drug product reserve samples are not stored in [the same immediate container-closure system as the marketed product] [an immediate container-closure system that has essentially the same characteristics as the marketed product]. Specifically, ***	4
Drugs	4305	21 CFR 211.68(b)	Backup data not assured as exact and complete	Backup data is not assured as [exact] [complete] [secure from alteration, erasure or loss] through keeping hard copy or alternate systems. Specifically, ***	4
Drugs	4307	21 CFR 211.80(d)	Status of Each Lot Identified	Each lot of [components] [drug product containers] [closures] was not appropriately identified as to its status in terms of being quarantined, approved or rejected. Specifically, ***	4
Drugs	4316	21 CFR 211.84(d)(3)	Testing Containers & Closures Conformity with Specs	Containers and closures are not tested for conformance with all appropriate written procedures. Specifically, ***	4
Drugs	4336	21 CFR 211.150	Written distribution procedure	Written distribution procedures are not [established] [followed]. Specifically, ***	4
Drugs	4338	21 CFR 211.150(b)	Recall facilitation	A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, has not been established. Specifically, ***	4
Drugs	4355	21 CFR 211.165(c)	Sampling and testing plans not followed	Written procedures for sampling and testing plans are not followed for each drug product. Specifically, ***	4
Drugs	4382	21 CFR 211.198(b)(2)	Written record of complaint to include findings, follow-up	Written records of investigation of a drug complaint do not include [the findings of the investigation] [the follow-up]. Specifically, ***	4
Drugs	4386	21 CFR 211.198(b)	Written complaint record to be maintained at facility	A written record of each complaint is not maintained in a file designated for drug product complaints [at the facility where the drug product was manufactured, processed or packed] [at a facility other than the facility in which the drug product was manuf	4
Drugs	4404	21 CFR 211.194(a)(1)	Sample identification and other information	Laboratory records do not include [a description of the sample received for testing] [the source or location from where the sample was obtained] [the quantity of the sample] [the lot number or other distinctive code of the sample] [the date the sample was	4
Drugs	4410	21 CFR 211.194(a)(5)	Calculations performed are in the records	Laboratory records do not include a record of all calculations performed in connection with the test. Specifically, ***	4
Drugs	4411	21 CFR 211.194(a)(6)	Test results, comparison with standards not included	Laboratory records do not include a statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the [component] [drug product container] [closure] [in-process material] [drug prod	4
Drugs	8906	21 CFR 314.81(b)(1)(i)	Mix-up	An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning an incident that caused a drug product or its labeling to be [mistaken for] [applied to] another article. Specifically, ***	4
Drugs	17749	21 CFR 212.30(a)	Prevention of contamination	Your facilities are not adequate to ensure the prevention of contamination of [equipment] [product] by [substances] [personnel] [environmental conditions] that could reasonably be expected to have an adverse effect on product quality. Specifically,***	4
Drugs	17764	21 CFR 212.20(e)	Written QA procedures established, followed	You did not [establish] [follow] written quality assurance procedures. Specifically,***	4
Drugs	1079	21 CFR 211.22(a)	Contract drug products--lack of responsibility	The quality control unit lacks responsibility for approving or rejecting drug products [manufactured] [processed] [packed] [held] under contract by another company. Specifically, ***	3
Drugs	1219	21 CFR 211.67(b)(2)	Cleaning SOPs/schedules	Procedures for the cleaning and maintenance of equipment are deficient regarding maintenance and cleaning schedules, including, where appropriate, sanitizing schedules. Specifically, ***	3
Drugs	1220	21 CFR 211.67(b)(3)	Cleaning SOPs/instructions	Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necess	3
Drugs	1371	21 CFR 211.101(a)	Batches Formulated to less than 100%	Written production and control procedures include batches formulated with the intent to provide less than 100 percent of the labeled or established amount of active ingredient. Specifically, ***	3
Drugs	1430	21 CFR 211.42(c)(10)(i)	Floors, walls, ceiling surfaces	Aseptic processing areas are deficient in that [floors] [walls] [ceilings] are not smooth and/or hard surfaces that are easily cleanable. Specifically,***	3
Drugs	1454	21 CFR 211.115(a)	Reprocessing procedures not written or followed	Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not [written] [followed]. Specifically, ***	3
Drugs	1632	21 CFR 211.130(c)	Lot or control number assigned	The drug product is not identified with a lot or control number that permits the determination of the history of the manufacture and control of the batch. Specifically, ***	3
Drugs	1798	21 CFR 211.82(b)	Quarantine Storage of Components	Incoming [components] [drug product containers] [closures] are not stored under quarantine until they have been tested or examined, as appropriate, and released. Specifically, ***	3
Drugs	1803	21 CFR 211.84(b)	Representative Samples Criteria	The [number of containers to be sampled] [amount of material taken from each container] is not based upon appropriate criteria. Specifically, ***	3
Drugs	1843	21 CFR 211.84(d)(2)	Component written specification	Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality. Specifically, ***	3
Drugs	1870	21 CFR 211.94(d)	Written Procedures to Remove Pyrogens	There are no written [standards or specifications] [methods of testing] [methods of cleaning] [methods of sterilization] [methods of processing] to remove pyrogenic properties. Specifically, ***	3
Drugs	1917	21 CFR 211.166(a)(1)	Sample size - test intervals	The written stability program for drug products does not include [sample size] [test intervals] based on statistical criteria for each attribute examined to assure valid estimates of stability. Specifically, ***	3
Drugs	1928	21 CFR 211.166(c)(1)	Homeopathic drugs, assessment of stability	There is no written assessment of stability of homeopathic drug products based at least on [testing or examination of the drug product for compatibility of the ingredients] [marketing experience with the drug product to indicate that there is no degradati	3
Drugs	1978	21 CFR 211.182	Personnel dating/signing equipment log	The persons [performing] [double-checking] the cleaning and maintenance are not [dating] [signing or initialing] the equipment cleaning and use log. Specifically, ***	3
Drugs	2019	21 CFR 211.188(b)(7)	Documentation of Actual Yield and Theoretical Yield	The batch production and control records are deficient in that they do not include a statement of the [actual yield] [percentage of theoretical yield]. Specifically, ***	3
Drugs	2032	21 CFR 211.194(b)	Test method modification records not maintained	Complete records are not maintained of any modification of an established method employed in testing. Specifically, ***	3
Drugs	2044	21 CFR 211.196	Distribution Record Requirements	Distribution records do not contain the [name and strength of the drug product] [description of dosage form] [name and address of consignee] [date and quantity shipped] [lot or control number of drug product]. Specifically, ***	3
Drugs	2203	21 CFR 211.186(b)(7)	Theoretical Yield and Percentages	The master production and control records are deficient in that they do not include a statement of theoretical yield and [minimum] [maximum] [yield percentages]. Specifically, ***	3
Drugs	2420	21 CFR 211.198(a)	Quality Control Review	Complaint procedures are deficient in that they do not include provisions that allow for the review and determination of an investigation by the quality control unit. Specifically, ***	3
Drugs	3562	21 CFR 211.56(c)	Written procedures lacking for use of pesticides etc.	Written procedures are lacking for the use of [rodenticides] [insecticides] [fungicides] [fumigating agents] [cleaning and sanitizing agents] designed to prevent the contamination of [equipment] [components] [drug product containers] [closures] [packagin	3
Drugs	4321	21 CFR 211.101(b)	Identification of new containers	For components removed from the original containers, the new container fails to be identified with [component name or item code] [receiving or control number] [weight or measure] [batch for which component was dispensed including product name, strength an	3
Drugs	4323	21 CFR 211.115(a)	Reprocessing procedures lack steps to be taken	Reprocessing procedures lack the steps to be taken to insure that reprocessed batches will conform with all established standards, specifications, and characteristics. Specifically, ***	3
Drugs	4324	21 CFR 211.110(b)	In-process materials specifications testing	Examination and testing of samples is not done to assure that in-process materials conform to specifications. Specifically, ***	3
Drugs	4350	21 CFR 211.160(b)(3)	Drug products-sampling procedures/specifications	Laboratory controls do not include a determination of conformance to [written descriptions of sampling procedures] [appropriate specifications] for drug products. Specifically, ***	3
Drugs	4364	21 CFR 211.176	Failing to test for penicillin cross-contamination	Non-penicillin drug products were not tested for the presence of penicillin, when a reasonable possibility existed that a non-penicillin drug product has been exposed to a cross-contamination with penicillin. Specifically, ***	3
Drugs	4366	21 CFR 211.188(a)	Accurate reproduction included	Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed. Specifically, ***	3
Drugs	4368	21 CFR 211.188(b)(12)	Investigations made into any unexplained discrepancy	Batch production and control records do not include the results of any investigation made into any unexplained discrepancy, whether or not the batch of drug product had already been distributed. Specifically, ***	3
Drugs	4371	21 CFR 211.188(b)(9)	Description of containers and closures	Batch production and control records do not include a description of drug product [containers] [closures] used for each batch of drug product produced. Specifically, ***	3
Drugs	4377	21 CFR 211.188(b(3)	Identification of each component or in-process material	Batch production and control records do not include the specific identification of each batch of [component] [in-process material] used for each batch of drug product produced. Specifically, ***	3

Drugs	4380	21 CFR 211.198(b)(3)	Determination not to conduct investigation of complaint	The written record did not include the [reason an investigation was found not to be necessary] [name of the responsible person making the determination not to conduct an investigation] when an investigation into [unexplained discrepancies] [the failure of	3
Drugs	4405	21 CFR 211.194(a)(2)	Statement of methods and data	Laboratory records do not include a statement of [each method used in the testing of a sample] [the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the prod	3
Drugs	6735	21 CFR 314.80(c)(1)(ii)	Failure to investigate serious, unexpected events	Adverse drug experiences that were the subject of post marketing 15-day reports were not [promptly] investigated. Specifically, ***	3
Drugs	10021	21 CFR 314.98(a)	(Flag to indicate ANDA applicant)	(DO NOT PRINT ON FDA 483. This cite is to be used as a flag to indicate that the recipient of an FDA 483 involving ADE reporting is the applicant for one or more approved ANDAs, as opposed to approved NDAs. No specifics text is required for this cite.)	3
Drugs	17812	21 CFR 212.50	Adequate controls (general)	Your firm lacks adequate production and process controls to ensure the consistent production of a PET drug that meets the applicable standards of identity, strength, quality and purity. Specifically,***	3
Drugs	17851	21 CFR 212.60(c)	Analytical methods	Your laboratory analytical methods [are not suitable for their intended use] [are not sufficiently sensitive] [are not sufficiently specific] [are not accurate] [are not reproducible]. Specifically,***	3
Drugs	1164	21 CFR 211.28(c)	Unauthorized Personnel in Limited Access Areas	Unauthorized personnel have access to enter areas of the buildings and facilities designated as limited access areas. Specifically, ***	2
Drugs	1168	21 CFR 211.34	Consultant Records	Records are not maintained stating the consultant's [name] [address] [qualifications] [type of service provided]. Specifically, ***	2
Drugs	1218	21 CFR 211.67(b)(1)	Cleaning SOP/responsibility	Procedures for the cleaning and maintenance of equipment are deficient regarding assignment of responsibility for cleaning and maintaining equipment. Specifically, ***	2
Drugs	1224	21 CFR 211.67(b)(6)	Cleaning SOP/inspection	Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use. Specifically, ***	2
Drugs	1266	21 CFR 211.42(d)	Penicillin processing area not kept separate	The operations relating to the [manufacture] [processing] [packing] of penicillin are not performed in facilities separate from those used for other drug products for human use. Specifically, ***	2
Drugs	1396	21 CFR 211.42(c)(2)	Rejected Material Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected [components] [drug product containers] [closures] [labeling] before disposition. Specifically,***	2
Drugs	1409	21 CFR 211.42(c)(4)	In-Process Material Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the storage of in-process materials. Specifically, ***	2
Drugs	1413	21 CFR 211.42(c)(5)	Mfg / Processing Operations Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations. Specifically, ***	2
Drugs	1431	21 CFR 211.42(c)(10)(ii)	Temperature / Humidity Controls	Aseptic processing areas are deficient regarding [temperature] [humidity] controls. Specifically, ***	2
Drugs	1496	21 CFR 211.122(a)	Sampling/testing of labeling/packaging materials	Labeling and packaging materials are not [representatively sampled] [examined] [tested] upon receipt and before use in packaging and labeling of a drug product. Specifically, ***	2
Drugs	1545	21 CFR 211.125(c)	Label reconciliation discrepancies evaluation/investigation	Discrepancies found outside preset limits when reconciling the quantities of labeling issued, used and returned, were not [evaluated] [investigated]. Specifically, ***	2
Drugs	1629	21 CFR 211.130(a)	Prevention of cross contamination, mix-ups	There is insufficient physical or spatial separation from operations and other drug products to prevent mix-ups and cross-contamination. Specifically, ***	2
Drugs	1630	21 CFR 211.130(b)	Unlabeled filled containers controls	Filled drug product containers which are set aside and held in an unlabeled condition are not [identified] [handled] to preclude mislabeling of individual containers, lots or portions of lots. Specifically, ***	2
Drugs	1722	21 CFR 211.134(a)	Correct labels during finishing operations	Packaged and labeled products are not examined during finishing operations to provide assurance that containers and packages in the lot have the correct label. Specifically, ***	2
Drugs	1776	21 CFR 211.150(a)	Distribution of oldest approved drugs	The oldest approved stock of drug products are not distributed first and there is no justification for this practice. Specifically, ***	2
Drugs	1796	21 CFR 211.80(d)	Identification of Each Lot in Each Shipment	Each lot in each shipment received was not identified with a distinctive code for each container or grouping of containers for [components] [drug product containers] [closures]. Specifically, ***	2
Drugs	1879	21 CFR 211.180(c)	Records not made readily available to FDA	Records associated with drug product [components] [containers] [closures] [labeling] [production] [control] [distribution] and within the retention period for such records, were not made readily available for authorized inspection. Specifically, ***	2
Drugs	1886	21 CFR 211.165(c)	Sampling and testing plans not described	Sampling and testing plans for drug products are not described in written procedures which include the [method of sampling] [number of units per batch to be tested]. Specifically, ***	2
Drugs	1924	21 CFR 211.166(a)(5)	Testing of reconstituted drugs	The written stability program does not include testing of drug products for reconstitution [at time of dispensing - as directed in the labeling] [after they are reconstituted]. Specifically, ***	2
Drugs	1976	21 CFR 211.182	Specific information required in individual logs	Individual equipment logs do not show [time] [date] [product] [lot number of each batch processed]. Specifically, ***	2
Drugs	2001	21 CFR 211.184(b)	Component Test Records	The [component] [drug product container] [closure] [labeling] records do not include the [results of tests or examinations performed] [the conclusions derived from tests or examinations performed]. Specifically, ***	2
Drugs	2004	21 CFR 211.184(d)	Labeling: documentation of exam and review	There is no documentation of the examination and review of labels and labeling for conformity with [established specifications] [the assigning of a lot or control number]. Specifically, ***	2
Drugs	2023	21 CFR 211.188(b)(11)	Identification of Persons Performing Significant Steps	The batch production and control records are deficient in that they do not include identification of persons [performing] [supervising] [checking] each significant step in the operation. Specifically, ***	2
Drugs	3550	21 CFR 211.46(c)	Exhaust systems inadequate to control air contamination	Adequate exhaust systems or other systems to control contaminants are lacking in areas where air contamination occurs during production. Specifically, ***	2
Drugs	3590	21 CFR 211.110(a)(5)	Solution clarity, completeness, pH	The in-process control procedures were deficient in that they did not include an examination of the [clarity] [completeness] [pH] of solutions. Specifically, ***	2
Drugs	3611	21 CFR 211.160(b)(3)	Acceptance of drug products	Determinations of conformance to appropriate written specifications for acceptance are [not made] [deficient] for drug products. Specifically, ***	2
Drugs	3623	21 CFR 211.170(a)	Active ingredient retained sample kept	A sample which is representative of each lot in each shipment of each active ingredient is not [appropriately identified] [retained]. Specifically, ***	2
Drugs	3640	21 CFR 211.204	Returned drug products identified and held	Returned drug products are not [identified as such] [held]. Specifically, ***	2
Drugs	4322	21 CFR 211.101(d)	Component release checked by 2nd person	Each container of component dispensed to manufacturing is not examined by a second person to assure that [the component was released by the quality control unit] [the weight or measure is correct as stated in the batch records] [the containers are properl	2
Drugs	4325	21 CFR 211.110(a)	Control procedures fail to include the following	Control procedures fail to include [tablet or capsule weight variation] [disintegration time] [adequacy of mixing to assure uniformity and homogeneity] [dissolution time and rate] [clarity, completeness or pH of solutions]. Specifically,***	2
Drugs	4328	21 CFR 211.122(a)	Written procedures not followed	Written procedures for the [receipt] [identification] [storage] [handling] [sampling] [examination] [testing] of packaging and labeling materials are not followed. Specifically, ***	2
Drugs	4330	21 CFR 211.130(e)	Packaging line inspection documentation	Results of inspection of packaging and labeling facilities are not documented in the batch production records. Specifically, ***	2
Drugs	4345	21 CFR 211.160(b)(1)	Samples (various types) representative, identified properly	Samples taken to determine conformance to appropriate written specifications for the acceptance of each lot within each shipment of [components] [drug product containers] [closures] [labeling] are not [representative] [adequately identified]. Specificall	2
Drugs	4369	21 CFR 211.188(b)(11)	Identification of persons involved, each significant step	Batch production and control records do not include the identification of the persons [performing] [directly supervising] [checking] each significant step in the operation, for each batch of drug product produced. Specifically, ***	2
Drugs	4375	21 CFR 211.188(b)(5)	In-process and laboratory control results	Batch production and control records do not include [in-process] [laboratory control] results for each batch of drug product produced. Specifically, ***	2
Drugs	4376	21 CFR 211.188(b)(4)	Weights and measures of components used	Batch production and control records do not include the weights and measures of components used in the course of processing each batch of drug product produced. Specifically, ***	2
Drugs	4383	21 CFR 211.198(b)(1)	Written complaint record must include	Written complaint records do not include, where known, [the name and strength of the drug product] [lot number] [name of complainant] [nature of complaint] [reply to complainant]. Specifically, ***	2
Drugs	4399	21 CFR 211.186(b)(7)	Theoretical yield statement including percentages	Master production and control records lack a statement of theoretical yield [including the maximum and minimum percentages of theoretical yield beyond which investigation is required]. Specifically, ***	2
Drugs	4403	21 CFR 211.194(b)	Test method modification records do not include	Records maintained of any modification of an established method employed in testing do not include [the reason for the modification] [the data to verify that the modification produced results that are at least as accurate and reliable for the material bei	2
Drugs	4412	21 CFR 211.194(a)(7)	Signatures and dates--person who performs test	Laboratory records do not include [the initials or signature of the person who performs each test] [the date(s) the tests were performed]. Specifically, ***	2
Drugs	6829	21 CFR 314.80(c)(2)	Failure to report non-alert ADEs	Individual ADEs which were not reported to FDA in a post marketing 15-day alert have not been included in a periodic safety report. Specifically, ***	2
Drugs	6830	21 CFR 314.80(c)(2)	Interval	Periodic reports of non-alert adverse drug experiences have not been submitted [quarterly for an application which was approved less than three years ago] [yearly for an application which was approved three or more years ago]. Specifically, ***	2
Drugs	6832	21 CFR 314.80(c)(2)	Late submission of annual safety reports	Not all annual periodic adverse drug experience reports have been submitted within 60 days of the anniversary date of the approval of the application. Specifically, ***	2
Drugs	8914	21 CFR 314.81(b)(2)(iv)(b)	Mfg and control changes not requiring a supplemental app.	An annual report did not include a full description of the manufacturing and control changes not requiring a supplemental application, listed by date in the order in which they were implemented. Specifically, ***	2
Drugs	8935	FDCA 760(b)(1)	Failure of responsible person to report AE (non-RX Drug)	Serious adverse event(s) for a non-prescription drug used in the United States has not been reported to the Secretary. Specifically, ***	2
Drugs	18008	FDCA 503B(a)(10)	Drug product label, outsourcer facility	The labels of your outsourcing facility?s drug products are deficient. Specifically,***	2
Drugs	1165	21 CFR 211.28(d)	Excluding Employees with Illness, Lesions	Employees with [apparent illness] [open lesions] are not excluded from direct contact with [components] [drug product containers] [closures] [in-process materials] [drug products] until the condition is [corrected] [determined by competent medical personn	1

Drugs	1207	21 CFR 211.65(b)	Substances That Come in Contact	Substances required for equipment operations such as lubricants and coolants come in contact with [components] [drug product containers] [closures] [in-process materials] [drug product] so as to alter the safety, identity, strength, quality or purity of t	1
Drugs	1222	21 CFR 211.67(b)(4)	Cleaning SOPs/equipment identification	Procedures for the cleaning and maintenance of equipment are deficient regarding the removal or obliteration of the previous batch identification. Specifically, ***	1
Drugs	1251	21 CFR 211.42(c)(1)	Incoming material area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the receipt, identification, storage, and withholding from use of [components] [drug product containers] [closures] [labeling] pending sampling, te	1
Drugs	1384	21 CFR 211.101(c)	Weighing/measuring/subdividing supervision	Component [weighing] [measuring] [subdividing] operations are not adequately supervised. Specifically, ***	1
Drugs	1393	21 CFR 211.103	Yield calculations not verified by 2nd person	Yield calculations are not performed by one person and independently verified by a second person. Specifically, ***	1
Drugs	1416	21 CFR 211.42(c)(6)	Pkg / Labeling Operations Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding the packaging and labeling operations. Specifically, ***	1
Drugs	1418	21 CFR 211.42(c)(7)	Quarantined Drug Products Area	Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the quarantine storage of drug products prior to release. Specifically, ***	1
Drugs	1456	21 CFR 211.115(b)	Reprocessing/quality control unit	Reprocessing was performed without the [review] [approval] of the quality control unit. Specifically, ***	1
Drugs	1498	21 CFR 211.122(b)	Labeling and packaging improperly approved/released	Labeling and packaging materials not meeting the appropriate written specifications were [approved] [released for use]. Specifically, ***	1
Drugs	1549	21 CFR 211.125(e)	Return of labeling	Returned labeling is not maintained and stored in a manner to [prevent mix-ups] [provide proper identification]. Specifically, ***	1
Drugs	1633	21 CFR 211.130(d)	Examination of packaging and labeling	Examination of packaging and labeling materials for suitability and correctness before packaging operations is [not performed] [not documented in the batch production records]. Specifically, ***	1
Drugs	1646	21 CFR 211.132(b)(2)	Gelatin capsules requiring tamper-evident technology	Two-piece, hard gelatin capsules (OTC) are not sealed using an acceptable tamper-evident technology. Specifically, ***	1
Drugs	1650	21 CFR 211.132(b)	Tamper-evident feature to remain intact	The tamper-evident feature [is not designed to] [does not] remain intact when handled in a reasonable manner during [manufacture] [distribution] [retail display]. Specifically, ***	1
Drugs	1725	21 CFR 211.134(c)	Examinations documented	The results of the examination of the packaged and labeled products were not documented in the batch production or control records. Specifically, ***	1
Drugs	1791	21 CFR 211.80(c)	Storage off Floor, Spaced Suitably	Bagged or boxed components of drug product [containers] [closures] are not [stored off the floor] [suitably spaced to allow cleaning and inspection]. Specifically, ***	1
Drugs	1935	21 CFR 211.167(b)	Ophthalmic ointments - testing for foreign particles	Each batch of ophthalmic ointment is not appropriately tested to determine conformance to specifications regarding the presence of [foreign particles] [harsh or abrasive substances]. Specifically, ***	1
Drugs	1936	21 CFR 211.167(b)	Ophthalmic ointments -test methods written, followed	Test procedures for ophthalmic ointments are not [written] [followed]. Specifically, ***	1
Drugs	1938	21 CFR 211.167(c)	Controlled release dosage form testing	Each batch of controlled-release dosage form drug product is not laboratory tested to determine conformance to the specifications for the rate of release for each active ingredient. Specifically, ***	1
Drugs	1939	21 CFR 211.167(c)	Controlled release test methods written, followed	Test procedures describing the testing of controlled release dosage form drug product are not [written] [followed]. Specifically, ***	1
Drugs	1956	21 CFR 211.180(e)(1)	Representative Number of Batches for Annual Review	The procedures for the annual quality standards record evaluation are deficient in that they do not address a review of a representative number of [approved] [rejected] batches. Specifically, ***	1
Drugs	1977	21 CFR 211.182	Dedicated equipment: records part of batch record	The records of [cleaning] [maintenance] [use] for dedicated equipment are not part of the batch record. Specifically, ***	1
Drugs	1979	21 CFR 211.182	Chronological Order of Equipment Log Entries	The entries in the equipment cleaning and use logs are not in chronological order. Specifically, ***	1
Drugs	1999	21 CFR 211.184(a)	Record information required	The records for [components] [drug product containers or closures] [labeling] do not include the [identity and quantity of each shipment of each lot] [name of the supplier] [supplier's lot number] [receiving code] [date of receipt] [name of the prime ma	1
Drugs	2003	21 CFR 211.184(c)	Individual inventory record	Records fail to include an individual inventory record of each [component] [reconciliation of the use of each component] [drug product container] [drug product closure] with sufficient information to allow determination of any associated batch or lot of	1
Drugs	2005	21 CFR 211.184(e)	Records of disposition of rejected material	Records do not include the disposition of rejected [components] [drug product containers] [closures] [labeling]. Specifically, ***	1
Drugs	2011	21 CFR 211.188(a)	Accurate reproduction	The batch production and control records are deficient in that they are not [an accurate reproduction of the appropriate master production or control record] [checked for accuracy, dated, and signed]. Specifically, ***	1
Drugs	2015	21 CFR 211.188(b)(3)	Identification of Components and In-Process Materials	The batch production and control records are deficient in that they do not include specific identification of each [batch of component] [in-process material] used. Specifically, ***	1
Drugs	2018	21 CFR 211.188(b)(6)	Documentation of Packaging and Labeling Area Inspections	The batch production and control records are deficient in that they do not include documentation of the inspection of the [packaging] [labeling] area before and after use. Specifically, ***	1
Drugs	2025	21 CFR 211.188(b)(13)	Results of drug product inspections and examinations	The batch production and control records are deficient in that they do not include results of drug product [examinations] [inspections]. Specifically, ***	1
Drugs	2087	21 CFR 211.208	Salvaging performed without evidence	Salvaging operations on drug products which may have been subjected to improper storage conditions proceeded in the absence of evidence from [laboratory tests and assays to establish that the drug products meet all applicable standards of identity, stre	1
Drugs	2200	21 CFR 211.186(b)(4)	Variation in the Amount of Components Used	The master production and control records are deficient in that they lack a justification for the variation in the amount of components used in the preparation of a dosage form. Specifically, ***	1
Drugs	2398	21 CFR 211.194(a)(2)	Test methods ID and data location	Laboratory records are deficient in that they do not include [a statement of the method used in testing the sample] [the location of the data that assures the accuracy and reliability of the test method]. Specifically, ***	1
Drugs	2399	21 CFR 211.194(a)(2)	Laboratory Test Method Verification	Verification of the suitability of the testing methods is deficient in that they are not [performed under actual conditions of use] [documented on the laboratory records]. Specifically, ***	1
Drugs	2405	21 CFR 211.194(a)(7)	Identification of Person Performing the Testing	Laboratory records are deficient in that they do not include the [initials] [signature] of the person performing the tests and the dates the tests were performed. Specifically, ***	1
Drugs	2406	21 CFR 211.194(a)(8)	Identification of Person Performing Review of Lab Records	Laboratory records are deficient in that they do not include the [initials] [signature] of the second person reviewing the record for accuracy. Specifically, ***	1
Drugs	2572	21 CFR 211.198(b)	Complaint File Location	Complaint procedures are deficient in that written complaint files are not maintained at the manufacturing site nor were they readily available from their off-site location. Specifically, ***	1
Drugs	2587	21 CFR 211.198(b)	Retention time of complaints	Complaint procedures are deficient in that written complaint records are not maintained for [at least one (1) year after the expiration date of the drug product] [at least one (1) year after the date that the complaint was received]. Specifically, ***	1
Drugs	2606	21 CFR 211.198(b)	Retention time of OTC drug complaints	Complaint procedures are deficient in that complaint records are not maintained for OTC drugs, without an expiration date, for at least three (3) years after distribution of the drug product. Specifically, ***	1
Drugs	2620	21 CFR 211.198(b)(2)	Complaint Record at Location of Investigation	Complaint records are deficient in that they are not maintained at the establishment where the investigation occurred. Specifically, ***	1
Drugs	2621	21 CFR 211.198(b)(3)	Reason for Not Conducting Complaint Investigation	Complaint records are deficient in that they do not document the reason and the individual making the decision not to conduct a complaint investigation. Specifically, ***	1
Drugs	3445	21 CFR 211.65(a)	Equipment construction - reactive surfaces	Equipment surfaces that contact [components] [in-process materials] [drug products] are reactive, additive or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established require	1
Drugs	3548	21 CFR 211.46(c)	Air filtration system lacking in production area	The production area air supply lacks an appropriate air filtration system. Specifically, ***	1
Drugs	3551	21 CFR 211.46(d)	Penicillin air handling systems not kept separate	Air-handling systems for the [manufacture] [processing] [packing] of penicillin are not completely separate from those for other drug products for human use. Specifically, ***	1
Drugs	3553	21 CFR 211.48(a)	Plumbing System Defects	The plumbing system contains defects that could contribute to the contamination of drug products. Specifically, ***	1
Drugs	3555	21 CFR 211.48(b)	Drains--Size, Back-siphonage Prevention	Drains are not [of adequate size] [provided with an air break or other mechanical device to prevent back-siphonage where connected directly with a sewer]. Specifically, ***	1
Drugs	3573	21 CFR 211.101(b)	Measured components for manufacturing	Components for drug product manufacturing are not [weighed] [measured] [subdivided as appropriate]. Specifically, ***	1
Drugs	3581	21 CFR 211.101(d)	Verification of component addition	Each component is not added to the batch by one person and verified by a second person.. Specifically, ***	1
Drugs	3588	21 CFR 211.110(a)(3)	Mixing adequacy	The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity. Specifically, ***	1
Drugs	3594	21 CFR 211.110(d)	Rejected in-process materials not quarantined	Rejected in-process materials are not [identified] [controlled under a quarantine system] to prevent their use in manufacturing or processing operations for which they are unsuitable. Specifically, ***	1
Drugs	3596	21 CFR 211.122(g)	Failure to include one of special control procedures	Packaging and labeling operations involving the use of cut labels fail to include one of the three special control procedures provided for in the regulations (e.g., dedicated lines, automated equipment for 100% exam, visual inspection for 100% exam). Sp	1
Drugs	3597	21 CFR 211.122(g)(3)	Visual inspection	The packaging and labeling operation involving cut labels and relying on visual inspection does not provide for [100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling] [examination to be	1
Drugs	3598	21 CFR 211.132(b)(1)	OTC products requiring tamper-evident packaging	OTC products packaged for retail sale which are not specifically excluded from the requirement for tamper-evident packaging are not sold in tamper-evident packages. Specifically, ***	1
Drugs	3599	21 CFR 211.132(b)(1)	Hard gelatin capsules	The packaging of hard gelatin capsules which are not sealed by tamper resistant technology does not include two tamper resistant packaging features. Specifically, ***	1

Drugs	3600	21 CFR 211.132(c)	Tamper evident-labeling requirement	OTC products packaged for retail sale which are not specifically excluded from the requirement for tamper-evident packaging do not bear a prominently-placed statement on the package which [identifies all tamper-evident features] [identifies capsule sealin	1
Drugs	3607	21 CFR 211.160(b)(2)	Acceptance of in-process materials	Determinations of conformance to appropriate written specifications for acceptance are [not made] [deficient] for in-process materials. Specifically, ***	1
Drugs	3610	21 CFR 211.160(b)(3)	Drug product sample	Drug product samples are not [representative of the entire batch] [properly identified]. Specifically, ***	1
Drugs	3615	21 CFR 211.160(b)(4)	Test devices not meeting specifications	Test devices are deficient in that [instruments] [apparatus] [gauges] [recording devices] not meeting established specifications are used. Specifically, ***	1
Drugs	3633	21 CFR 211.170(b)(1)	Reserve sample retention time	The retention period for drug product reserve samples (except those described in 211.170(b)(2) and (3)) is deficient in that they are not retained for one year after the expiration date of the drug product. Specifically, ***	1
Drugs	3641	21 CFR 211.204	Record information inclusions	Records of returned drug products do not include the [name] [labeled potency] [lot, control or batch number] [reason for return] [quantity] [date of disposition] [ultimate disposition]. Specifically, ***	1
Drugs	4304	21 CFR 211.68(b)	Written record not kept of program and validation data	A written record of the program along with appropriate validation data has not been maintained in situations where backup data is eliminated by computerization or other automated processes. Specifically, ***	1
Drugs	4309	21 CFR 211.84(c)(2)	Containers sampled so as to prevent contamination	Containers are not [opened] [sampled] [resealed] in a manner designed to prevent contamination of [their contents] [other components] [other drug product containers or closures]. Specifically, ***	1
Drugs	4311	21 CFR 211.84(c)(4)	Compositing of Sub Samples	Components which must be sampled from top, middle and bottom of the container are not kept separate, but instead are composited for testing. Specifically, ***	1
Drugs	4326	21 CFR 211.122(g)(2)	Electronic or electromechanical equipment	The packaging and labeling operation for cut labels which relies on the use of electronic or electromechanical equipment does not provide for 100-percent examination for correct labeling [during] [after completion of] finishing operations. Specifically,	1
Drugs	4337	21 CFR 211.150(a)	Distribution of oldest stock first	Distribution procedures do not include a procedure whereby the oldest approved stock of a drug product is distributed first. Specifically, ***	1
Drugs	4341	21 CFR 211.142(a)	Quarantine - written procedures	Written procedures for the warehousing of drug products do not include quarantine of drug products before release by the quality control unit. Specifically, ***	1
Drugs	4354	21 CFR 211.165(d)	Acceptance/Rejection Levels	The statistical quality control criteria fail to include appropriate [acceptance levels] [rejection levels]. Specifically, ***	1
Drugs	4356	21 CFR 211.166(b)	Tentative expiration date	Where data from accelerated studies was used to project a tentative expiration date beyond a date supported by actual shelf life studies, there were no [stability studies] [drug product testing at appropriate intervals] conducted until the tentative expir	1
Drugs	4359	21 CFR 211.170(b)(1)	Retention time of reserve samples, in general	Reserve samples for drug products are not retained for one year after the expiration date of the drug product. Specifically, ***	1
Drugs	4360	21 CFR 211.170(b)	Reserve drug product sample quantity - all tests	The reserve sample of drug product does not consist of at least twice the quantity necessary to perform all the required tests of drug product. Specifically, ***	1
Drugs	4365	21 CFR 211.176	Marketing of drug products with penicillin levels	Marketing of drug products which contain detectable levels of penicillin occurred, when tested according to FDA-approved procedures for detecting and measuring penicillin contamination in drugs. Specifically, ***	1
Drugs	4370	21 CFR 211.188(b)(10)	Records of any sampling performed	Batch production and control records do not include a record of any sampling performed, for each batch of drug product produced. Specifically, ***	1
Drugs	4373	21 CFR 211.188(b)(7)	Actual yield, % of theoretical yield	The batch production and control records do not include a statement of the [actual yield] [percentage of theoretical yield] at appropriate stages of processing for each batch of drug product produced. Specifically, ***	1
Drugs	4378	21 CFR 211.188(b)(2)	Identity of major equipment and lines used	Batch production and control records do not include the identity of individual major [equipment] [lines] used for each batch of drug product produced. Specifically, ***	1
Drugs	4381	21 CFR 211.198(b)(2)	Written investigation record or copy kept at establishment	The written record or copy of the record of an investigation of a complaint conducted in relation to [any unexplained discrepancy] [the failure of a batch or any of its components to meet any of its specifications] is not maintained at the establishment	1
Drugs	4384	21 CFR 211.198(b)	Records maintained for 3 years (exempt OTC drugs)	Written complaint file records for OTC drugs lacking expiration dating because they meet the criteria for exemption, are not maintained for 3 years after distribution of the drug product. Specifically, ***	1
Drugs	4385	21 CFR 211.198(b)	Records maintained for 1 year (except certain OTC drugs)	Written complaint file records involving a drug product are not maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date the complaint was received, whichever is longer. Specifically, ***	1
Drugs	4400	21 CFR 211.186(b)(8)	Description of containers, labels, et. al.	Master production and control records lack [a description of the drug product containers, closures and packaging materials] [a specimen or copy of each label and all other labeling] [the signatures and dates entered by the person or persons responsible fo	1
Drugs	4407	21 CFR 211.194(a)(2)	Reference and method not stated	Laboratory records of methods of testing used do not [indicate the method] [provide the reference] when employing methods in [recognized standard references] [an approved new drug application and the referenced method is not modified]. Specifically, ***	1
Drugs	4408	21 CFR 211.194(a)(3)	Weight or measure of sample	Laboratory records do not include a statement of the weight or measure of sample used for each test, where appropriate. Specifically, ***	1
Drugs	4415	21 CFR 211.204	Returned drug products with doubt cast as to safety et. al.	Returned drug products held, stored or shipped before or during their return under conditions which cast doubt on their safety, identity, strength, quality or purity are not [destroyed] [subjected to examination, testing or other investigation to prove th	1
Drugs	4416	21 CFR 211.204	Reprocessed returned drug products	Returned drug products were reprocessed without assuring that the subsequent drug product met the appropriate standards of safety, identity, strength, quality and purity. Specifically, ***	1
Drugs	6705	21 CFR 310.305(c)	Failure to report	Adverse drug experience information has not been reported to FDA. Specifically, ***	1
Drugs	6736	21 CFR 314.80(c)(1)(ii)	Submission of report follow-up	Follow-up reports were not submitted [within 15 calendar days of receipt of new information] [as requested by FDA] concerning post marketing 15-day reports. Specifically, ***	1
Drugs	6833	21 CFR 314.80(c)(2)(ii)	Incomplete periodic safety report	Not all periodic reports contained [a narrative summary and analysis of the information in the report] [an analysis of the post marketing 15-day Alert reports submitted during the reporting interval] [an FDA Form 3500A for each adverse drug experience not	1
Drugs	8938	FDCA 760(c)(1)	Timing of AE report submission (non-RX drugs)	An adverse event report for a nonprescription drug was not submitted to the Secretary of HHS within 15 business days of receipt of the report.	1
Drugs	10022	21 CFR 310.305(a)	Failure to develop written procedures	Written procedures have not been developed for the [surveillance] [receipt] [evaluation] [reporting to FDA] of postmarketing adverse drug experiences. Specifically, ***	1
Drugs	17723	21 CFR 212.10	Personnel not qualified	Your personnel lack the [necessary education] [background] [training] [experience] to perform their assigned functions. Specifically,***	1
Drugs	17741	21 CFR 212.30(b)	Equipment not clean	You did not implement procedures to ensure that all your equipment is clean. Specifically, ***	1
Drugs	17742	21 CFR 212.30(b)	Equipment not suitable	You did not implement procedures to ensure that all your equipment is suitable for its intended purposes. Specifically,***	1
Drugs	17744	21 CFR 212.30(b)	Equipment not properly installed	You did not document your activities in accordance with your procedures for cleaning all of your equipment. Specifically,***	1
Drugs	17755	21 CFR 212.20(a)	Oversight of production operations	You did not oversee production operations in a manner to ensure that each PET drug [meets the requirements of the FD&C Act as to safety] [has the identity and strength that it is supposed to have] [meets the quality and purity characteristics that it is s	1
Drugs	17787	21 CFR 212.40(d)	Contamination, mix-ups and deterioration	You did not handle and store [components] [containers] [closures] in a manner that prevents [contamination] [mix-ups] [deterioration] and ensures that they are and remain suitable for their intended use. Specifically,***	1
Drugs	17822	21 CFR 212.50(b)(7)	Complete instructions, procedures, specs	Your master production and control records did not contain [complete production and control instructions] [complete sampling and testing procedures] [complete specifications] [special notations] [precautions to be followed]. Specifically,***	1
Drugs	17859	21 CFR 212.60(g)	Test records complete (general)	Each laboratory used to perform tests related to the production of a PET drug did not keep complete records of all tests performed to ensure compliance with established specifications and standards, including examinations and assays. Specifically,***	1
Drugs	17863	21 CFR 212.60(g)(3)	Record of all test data	Laboratory records did not contain a complete record of all data obtained in the course of each test. Specifically,***	1
Drugs	17881	21 CFR 212.70(d)(1)	Laboratory determination completed	You did not [establish] [follow] procedures to ensure that each batch of a PET drug product was given final release before an appropriate laboratory determination was completed. Specifically,***	1
Drugs	17882	21 CFR 212.70(d)(2)	Data and documentation review	You did not [establish] [follow] procedures to ensure that each batch of a PET drug product was given final release before associated laboratory data and documentation were reviewed and they demonstrate that the PET drug product met specifications. Speci	1
Drugs	17898	21 CFR 212.71(c)	Correction of problems	You did not take [appropriate] action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem. Specifically,***	1
Drugs	17939	21 CFR 212.71(a)	Procedures to Investigate Cause of Non-Conforming Product	You did not [establish] [follow] procedures to investigate the cause(s) of the nonconforming batch(s) of a PET drug product. Specifically, ***	1
Drugs	17962	21 CFR 361.1(c)(2)	Numerical votes not in the minutes of any RDRC meetings	The minutes of an RDRC meeting did not include the numerical results of votes on protocols involving use in human subjects. Specifically, ***	1
Drugs	17968	21 CFR 361.1(c)(3)	FDA research proposals not reported +30 subjects	The RDRC did not [immediately] report to FDA a research proposal that involves exposure of more than thirty (30) subjects. Specifically, ***	1
Drugs	17983	21 CFR 361.1(d)(6)	Radioactive drug - chemical standard	The RDRC did not [consider][assure] that the radioactive drug used in a research study met the appropriate chemical standard of [identity][strength][quality][purity] as needed for safety and to be of such uniform and reproducible quality as to give signif	1
Drugs	17984	21 CFR 361.1(d)(6)	Radioactive materials for parenteral use - preparation	The RDRC did not determine that radioactive materials for parenteral use were prepared in [sterile][pyrogen-free] form. Specifically, ***	1
Drugs	17993	21 CFR 361.1(f)(1)	Packaging, labeling - Rx only	The label of a radioactive drug prepared, packaged, distributed, and primarily intended for use in the RDRC research project did not bear the statement "Rx only". Specifically, ***	1
Drugs	18009	FDCA 503B(a)(10)	Container label, outsourcer facility	The container labels of your outsourcing facility?s drug products are deficient. Specifically,***	1

According to **Data Integrity and Compliance with CGMP Guidance for Industry**, for the purposes of this guidance, ***data integrity*** **refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).**

For attributable, see §§ 211.101(d), 211.122, 211.186, 211.188(b)(11), and 212.50(c)(10);

211.101 Charge-in of components.

Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess:

(d) Each component shall either be added to the batch by one person and verified by a second person or, if the components are added by automated equipment under 211.68, only verified by one person.

211.122 Materials examination and usage criteria.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product.

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected.

(d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.

(e) Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed.

(f) Use of gang-printed labeling for different drug products, or different strengths or net contents of the same drug product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

(g) If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons, packaging and labeling operations shall include one of the following special control procedures:

(1) Dedication of labeling and packaging lines to each different strength of each different drug product;

(2) Use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations; or

(3) Use of visual inspection to conduct a 100-percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.

(4) Use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

(h) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

211.186 Master production and control records.

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

(1) The name and strength of the product and a description of the dosage form;

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit;

(3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;

(4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records;
(5) A statement concerning any calculated excess of component;
(6) A statement of theoretical weight or measure at appropriate phases of processing;
(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to 211.192 is required;
(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;
(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

211.188 Batch production and control records.

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under 211.68, the identification of the person checking the significant step performed by the automated equipment.

212.50 What production and process controls must I have?

(c) Batch production and control records. Each time a batch of a PET drug is produced, a unique batch production and control record must be created. The batch production record must include the following information:

(10) Initials or signatures of persons performing or checking each significant step in the operation;

For legible see §§ 211.180(e) and 212.110(b);

211.180 General requirements.

(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.
(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under 211.192 for each drug product.

211.110 Sampling and testing of in-process materials and drug products.

(b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.

For contemporaneously recorded (at the time of performance) see §§ 211.100(b) and 211.160(a);

211.100 Written procedures; deviations.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

211.160 General requirements.

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

For original or a true copy see §§ 211.180 and 211.194(a);

211.180 General requirements.

a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under 211.137, 3 years after distribution of the batch.

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

(c) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.

(d) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under 211.192 for each drug product.

(f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under 211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration.

211.194 Laboratory records.

(a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

(1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.

(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, AOAC INTERNATIONAL, Book of Methods, 1 or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use.

(3) A statement of the weight or measure of sample used for each test, where appropriate.

(4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested.
(5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.
(6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.
(7) The initials or signature of the person who performs each test and the date(s) the tests were performed.
(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

For accurate see §§ 211.22(a), 211.68, 211.188, and 212.60(g).

211.22 Responsibilities of quality control unit.

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

211.68 Automatic, mechanical, and electronic equipment.

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.
(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.
(c) Such automated equipment used for performance of operations addressed by 211.101(c) or (d), 211.103, 211.182, or 211.188(b)(11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation.

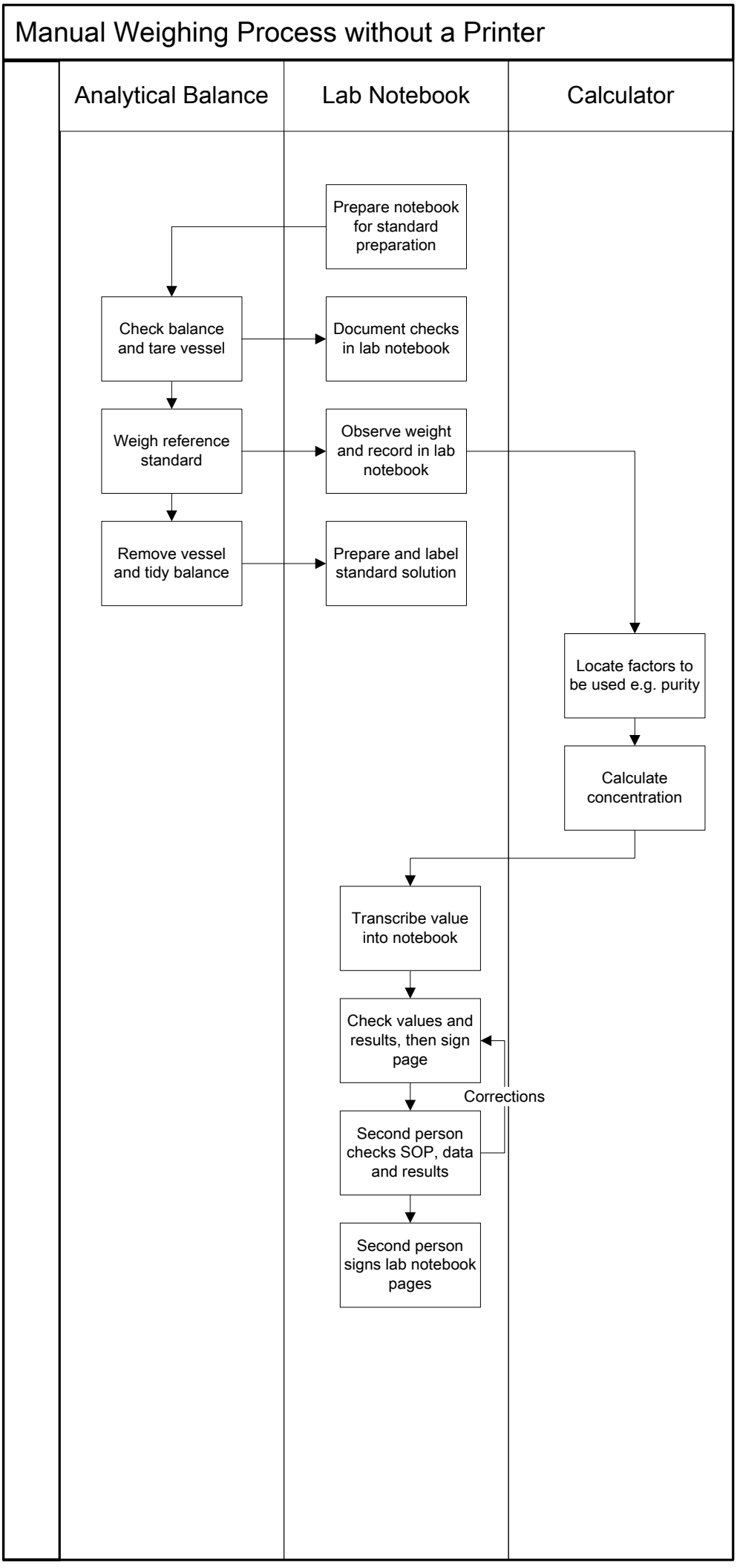
211.188 Batch production and control records.

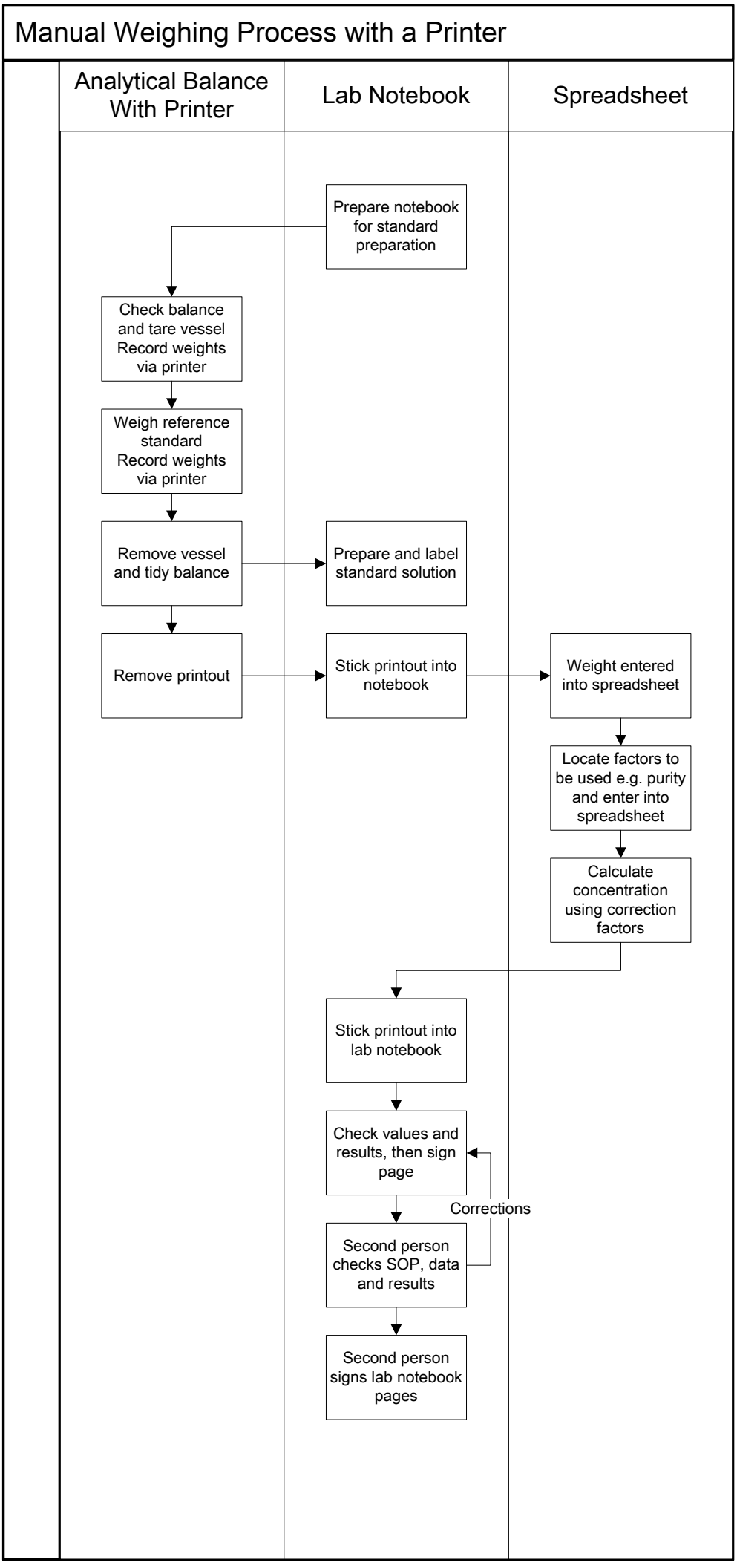
Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:
(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;
(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:
(1) Dates;
(2) Identity of individual major equipment and lines used;
(3) Specific identification of each batch of component or in-process material used;
(4) Weights and measures of components used in the course of processing;
(5) In-process and laboratory control results;
(6) Inspection of the packaging and labeling area before and after use;
(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;
(8) Complete labeling control records, including specimens or copies of all labeling used;

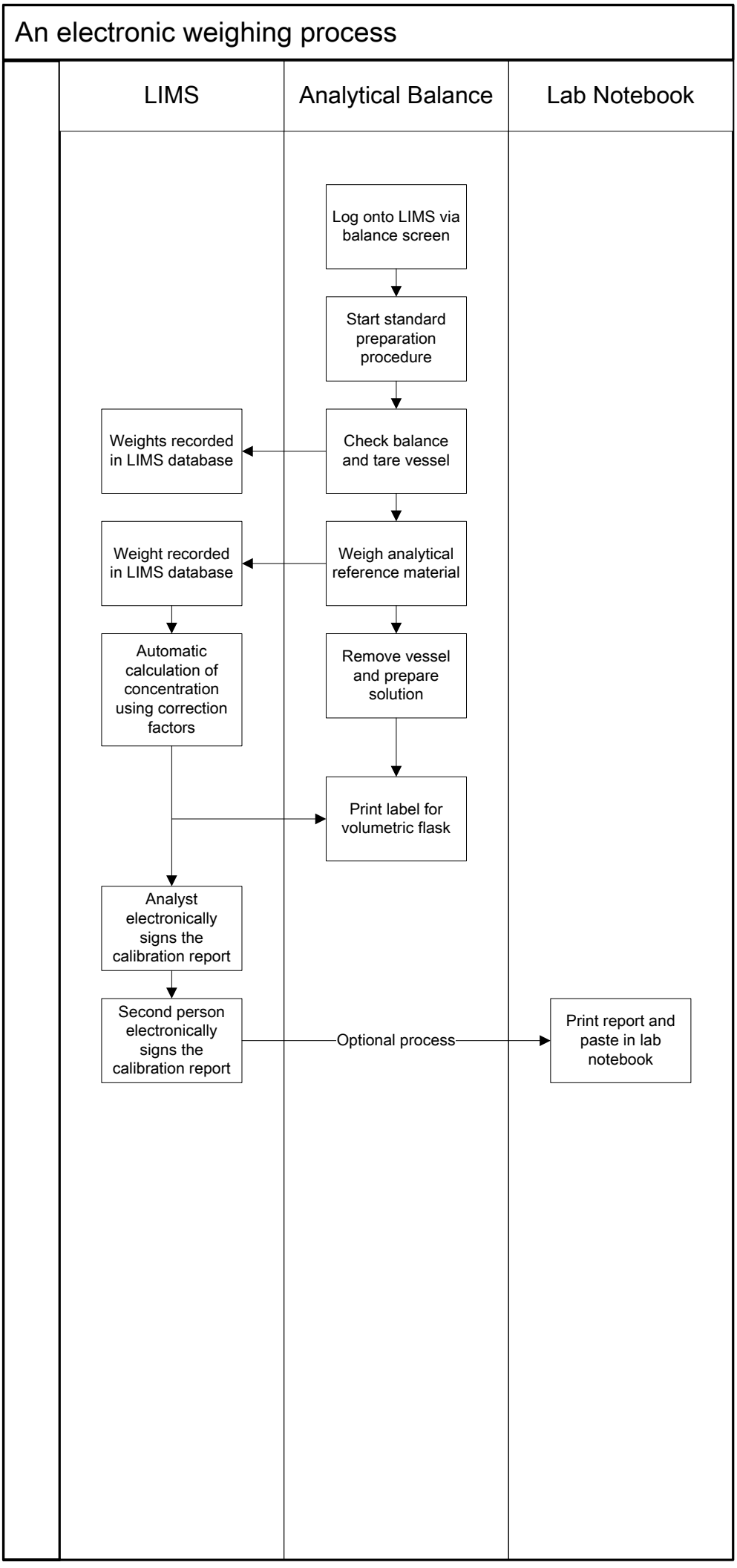
(9) Description of drug product containers and closures;
(10) Any sampling performed;
(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under 211.68, the identification of the person checking the significant step performed by the automated equipment.
(12) Any investigation made according to 211.192.
(13) Results of examinations made in accordance with 211.134.

212.60 What requirements apply to the laboratories where I test components, in-process materials, and finished PET drug products?

(g) Test records. Each laboratory performing tests related to the production of a PET drug must keep complete records of all tests performed to ensure compliance with established specifications and standards, including examinations and assays, as follows:
(1) A suitable identification of the sample received for testing.
(2) A description of each method used in the testing of the sample, a record of all calculations performed in connection with each test, and a statement of the weight or measurement of the sample used for each test.
(3) A complete record of all data obtained in the course of each test, including the date and time the test was conducted, and all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or drug product for each lot tested.
(4) A statement of the results of tests and how the results compare with established acceptance criteria.
(5) The initials or signature of the person performing the test and the date on which the test was performed.


Manual Weighing Process without a Printer
Analytical Balance
Lab Notebook
Calculator
Prepare notebook for standard preparation
Check balance and tare vessel
Document checks in lab notebook
Weigh reference standard
Observe weight and record in lab notebook
Remove vessel and tidy balance
Prepare and label standard solution
Locate factors to be used e.g. purity
Calculate concentration
Transcribe value into notebook
Check values and results, then sign page
Corrections
Second person checks SOP, data and results
Second person signs lab notebook pages


Manual Weighing Process with a Printer
Analytical Balance With Printer
Lab Notebook
Spreadsheet
Prepare notebook for standard preparation
Check balance and tare vessel Record weights via printer
Weigh reference standard Record weights via printer
Remove vessel and tidy balance
Prepare and label standard solution
Remove printout
Stick printout into notebook
Weight entered into spreadsheet
Locate factors to be used e.g. purity and enter into spreadsheet
Calculate concentration using correction factors
Stick printout into lab notebook
Check values and results, then sign page
Corrections
Second person checks SOP, data and results
Second person signs lab notebook pages


An electronic weighing process
LIMS
Analytical Balance
Lab Notebook
Log onto LIMS via balance screen
Start standard preparation procedure
Check balance and tare vessel
Weights recorded in LIMS database
Weigh analytical reference material
Weight recorded in LIMS database
Remove vessel and prepare solution
Automatic calculation of concentration using correction factors
Print label for volumetric flask
Analyst electronically signs the calibration report
Second person electronically signs the calibration report
Optional process
Print report and paste in lab notebook