

COMBINED GMP AUDIT CHECKLIST

21 CFR Part 820 (QMSR) | 21 CFR Parts 210 & 211

Medical Devices | Pharmaceutical Drug Products | Combination Products

Facility / Site Name:		Audit Date:	
Lead Auditor:		Audit Type:	Internal / External / Supplier
Auditee / Host Contact:		Product Type:	Drug / Device / Combination
Applicable Regulations:	820 / 210-211 / Both	Audit Scope:	

DISCLAIMER

This GMP Audit Checklist is intended **solely as a reference tool** to assist auditors in conducting compliance audits under 21 CFR Part 820 (Quality Management System Regulation / QMSR), 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs – General), and 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals). It does not constitute legal advice, regulatory guidance, or a comprehensive audit methodology, and should not be construed as such.

Use of this checklist does not guarantee regulatory compliance, nor does it substitute for proper audit planning, professional judgment, or auditor training. Completion of this checklist in full does not imply that all applicable cGMP or QMS requirements have been assessed, identified, or satisfied.

This tool is not a substitute for knowledge of current FDA regulations, guidance documents, or applicable industry standards. Questions and criteria contained herein may not reflect the most recent regulatory updates — including the FDA's transition to the Quality Management System Regulation (QMSR) effective February 2, 2026 — and should be verified against current requirements prior to use.

A satisfactory score or completed checklist should not be interpreted as confirmation of compliance. Serious deficiencies may exist outside the scope of this document. All findings, observations, and conclusions remain the professional responsibility of the auditor and the organization conducting the audit.

This checklist is provided as-is, without warranty of any kind, express or implied. The organization providing this tool assumes no liability for audit outcomes, regulatory findings, or enforcement actions arising from its use or misuse.

NOTE: Effective February 2, 2026, FDA replaced the Quality System Inspection Technique (QSIT) for device inspections with the updated Inspection of Medical Device Manufacturers Compliance Program (CP 7382.850), aligned with the QMSR. Auditors should reference the current CP Manual for device inspection guidance.

INSTRUCTIONS FOR USE

- Before beginning the on-site audit, plan the audit by reviewing previous audit findings, known problem areas, and applicable regulatory requirements for the product type being audited.
- This checklist covers requirements applicable to drug products (21 CFR Parts 210 and 211), medical devices (21 CFR Part 820 / QMSR), and combination products. Mark sections N/A where a regulation does not apply to the facility or product.
- Use the Yes / No / NA / Obs. column to record findings. Recommended codes: ✓ = Yes (conforming), X = No (nonconforming), N/A = Not Applicable, O = Observation requiring follow-up.
- Record all significant observations, evidence reviewed, and supporting details in an audit notebook. Cross-reference notebook entries with item numbers on this checklist.
- Ask open-ended questions (e.g., 'Show me how this procedure works') rather than simple yes/no questions. Walk through procedures step by step to confirm they are current, adequate, and followed.
- Ask the auditee: 'Are there any areas of concern you would like me to examine?' This often surfaces issues not covered by the checklist.

7. Do not rely on this checklist as the sole basis for the audit. It is a guide, not a substitute for auditor expertise, judgment, and knowledge of current regulations.
8. At least three production batches should be selected for traceability analysis covering: (a) all components and materials, (b) in-process and finished product testing, and (c) warehousing and distribution records.
9. A completed checklist does not confirm compliance. Deficiencies may exist outside the scope of this document. All findings remain the professional responsibility of the auditor.

OBSERVATION CODES

Code	Meaning
✓	Yes / Conforming — Requirement is met with adequate evidence observed.
X	No / Nonconforming — Requirement is not met. Document details in notebook and initiate CAPA.
N/A	Not Applicable — Requirement does not apply to this facility, product, or process.
O	Observation — Potential concern noted; does not currently constitute a nonconformance but warrants monitoring or follow-up.

FOR REFERENCE ONLY

SECTION 1 – Quality Management System & Organizational Controls			
Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
1.1 Quality Policy & Management Responsibility			
1.101	Does top management establish, document, and communicate a quality policy appropriate to the organization?	820.20(a) / 211.22	
1.102	Is there a documented Quality Management System (QMS) with defined scope, processes, and objectives?	820.20 / 211.22(a)	
1.103	Does a Quality Assurance/Quality Unit exist as an independent organizational entity with documented authority?	820.20(b) / 211.22(a)	
1.104	Does the Quality Unit have sole authority to approve or reject all components, in-process materials, finished products, labeling, and packaging materials?	211.22(a)	
1.105	Are management review meetings conducted at defined intervals to assess QMS performance, CAPA effectiveness, and resource needs?	820.20(c)	
1.106	Are management review records retained and include corrective actions, quality objectives, and resource allocation decisions?	820.20(c)	
1.107	Are quality objectives established, measurable, and communicated at relevant organizational levels?	820.20(a)	
1.2 Personnel Qualifications & Training			
1.201	Are personnel performing quality-affecting activities qualified by education, background, training, and experience?	820.25 / 211.25	
1.202	Are job descriptions or equivalent documentation defining responsibilities maintained for all quality-related roles?	820.25(a) / 211.25	
1.203	Is a written training program in place covering cGMP regulations, SOPs, and job-specific functions?	820.25(b) / 211.25(a)	
1.204	Are training records maintained indicating employee name, training date, type of training, and trainer signature?	820.25(b) / 211.25	
1.205	Is training effectiveness verified, and are records retrievable by employee and by procedure/program?	820.25(b) / 211.25	
1.206	Are employees retrained when SOPs or critical procedures are significantly revised?	211.25(a)	
1.207	Are temporary employees and contractors given equivalent orientation and training before performing quality-affecting work?	211.25(a) / 211.34	
1.208	Are consultants' qualifications (education, training, experience) documented along with the services they provide?	211.34	
1.209	Are employees instructed to report health conditions that could adversely affect product safety or purity to supervisors?	820.25 / 211.28(d)	

1.3 Internal Audit Program			
1.301	Is a formal internal audit program established with written procedures defining scope, frequency, methods, and responsibilities?	820.22 / 211.22	
1.302	Are auditors independent of the areas being audited?	820.22	
1.303	Are audit findings documented and reviewed by responsible management?	820.22 / 211.22	
1.304	Are corrective actions resulting from audits tracked to completion and verified for effectiveness?	820.100 / 211.192	
1.305	Are audit records maintained in a confidential and retrievable manner?	820.22	

SECTION 2 – Document & Record Controls

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
2.1 Document Control			
2.101	Is a document control system in place covering creation, review, approval, distribution, revision, and obsolescence of documents?	820.40 / 211.68	
2.102	Are all quality-critical documents (SOPs, batch records, specifications, forms) approved by authorized personnel before use?	820.40(a) / 211.186	
2.103	Is a master list or equivalent maintained identifying current revision status and distribution of all controlled documents?	820.40(a)	
2.104	Are obsolete documents promptly removed from points of use and clearly identified if retained for reference?	820.40(b)	
2.105	Are changes to documents reviewed and approved by the same or equivalent functions that performed the original review?	820.40(b) / 211.100	
2.106	Is the reason for document changes identified in the document or supporting records?	820.40(b)	
2.2 Records Management			
2.201	Are quality records legible, identifiable, stored to prevent damage or deterioration, and retrievable?	820.180 / 211.68	
2.202	Is a defined retention period established for all record types, consistent with regulatory requirements?	820.180 / 211.180	
2.203	Are electronic records and electronic signatures, if used, compliant with applicable requirements (e.g., 21 CFR Part 11)?	820.40 / 211.68 / Part 11	
2.204	Are batch production and control records complete, accurate, and reviewed before product release?	211.186 / 211.192	

2.205	Are all entries in records made at the time of performance, signed or initialed, and dated?	211.186 / 211.188	
2.206	Are corrections to records made by drawing a single line through the error, entering the correction, and dating and initialing the change?	211.186	
2.3 Device History Record (DHR) – 820 Specific			
2.301	Is a Device History Record (DHR) maintained for each batch/lot of finished device demonstrating it was manufactured in accordance with the Device Master Record (DMR)?	820.184	
2.302	Does the DHR include dates of manufacture, quantity manufactured and released, acceptance records, and labeling/packaging used?	820.184	
2.303	Is a Device Master Record (DMR) maintained containing or referencing all procedures and specifications for each device type?	820.181	

SECTION 3 – Design Controls (21 CFR 820 – Device Specific)

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
3.1 Design Planning & Input			
3.101	Is a design and development plan established for each new or significantly modified device, defining stages, responsibilities, and review requirements?	820.30(b)	
3.102	Are design inputs (physical, performance, safety, regulatory requirements) documented and reviewed for adequacy?	820.30(c)	
3.103	Are incomplete, ambiguous, or conflicting design input requirements resolved before design work proceeds?	820.30(c)	
3.2 Design Output, Review & Verification			
3.201	Are design outputs documented and expressed in terms that can be verified against design inputs?	820.30(d)	
3.202	Are formal design reviews conducted at appropriate stages, with results documented and retained?	820.30(e)	
3.203	Is design verification performed to confirm outputs meet input requirements, and are results documented?	820.30(f)	
3.204	Is design validation performed to ensure devices conform to user needs and intended uses under actual or simulated use conditions?	820.30(g)	
3.205	Are design transfers to manufacturing controlled and documented to ensure specifications are correctly translated into production procedures?	820.30(h)	

3.3 Design Changes			
3.301	Are design changes identified, documented, reviewed, verified, validated (as appropriate), and approved before implementation?	820.30(i)	
3.302	Is the impact of design changes on previously validated configurations assessed and documented?	820.30(i)	

SECTION 4 – Facilities & Environmental Controls

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
4.1 Facility Design & Maintenance			
4.101	Is the facility of suitable size, construction, and location to facilitate cleaning, maintenance, and operations?	820.70(f) / 211.42	
4.102	Is there adequate space to prevent mix-ups and contamination between different products, materials, and activities?	820.70(f) / 211.42(b)	
4.103	Are facilities maintained in a clean, orderly, and sanitary condition with a documented housekeeping program?	820.70(f) / 211.56	
4.104	Is the facility free from infestation by rodents, birds, insects, and vermin, with a written pest control program?	211.56(a)(b)	
4.105	Are all areas of the facility maintained in a good state of repair?	820.70(f) / 211.58	
4.106	Is sewage, trash, and other refuse disposed of safely, sanitarily, and at sufficient frequency?	211.52	
4.2 Environmental Controls			
4.201	Are environmental conditions (temperature, humidity, air pressure, cleanliness) controlled and monitored as required for the product(s) manufactured?	820.70(c) / 211.44–211.46	
4.202	Is adequate ventilation provided with appropriate air filtration, with written procedures for filter inspection and replacement?	820.70(c) / 211.46	
4.203	Are separate air handling systems in place as required to prevent contamination (mandatory if penicillin is present)?	211.42(d)	
4.204	Is lighting adequate in all areas including manufacturing, testing, and storage?	211.44	
4.205	Are environmental monitoring results trended and reviewed, with defined alert and action limits?	820.70(c)	
4.3 Contamination Control			
4.301	Are procedures in place to prevent contamination of product by cleaning agents, lubricants, or other substances?	820.70(e) / 211.67	

4.302	Are written procedures for the use of rodenticides, insecticides, fungicides, and fumigants maintained, using only registered/approved agents?	211.56(c)	
4.303	Are contractor and temporary personnel required to comply with all sanitation and GMP procedures?	211.56(d)	

SECTION 5 – Equipment Controls

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
5.1 Equipment Design, Installation & Qualification			
5.101	Is all production and quality control equipment of appropriate design, adequate size, and suitably located for its intended use?	820.70(g) / 211.63	
5.102	Are equipment surfaces that contact materials or products non-reactive, non-absorptive, and non-additive so as not to affect product quality?	820.70(g) / 211.65(a)	
5.103	Are lubricants, coolants, and operating substances prevented from contacting drug components or finished product?	211.65(b)	
5.104	Is equipment qualified (IQ/OQ/PQ or equivalent) before use in production or quality testing, with documented results?	820.70(g) / 211.63	
5.105	Have fiber-releasing or asbestos-containing filters been eliminated from all production processes?	211.72	
5.2 Equipment Identification & Maintenance			
5.201	Is each piece of equipment clearly and durably identified with a unique identifier traceable to maintenance and calibration records?	820.70(g) / 211.105	
5.202	Are written preventive maintenance procedures and schedules established and followed for all critical equipment?	820.70(g) / 211.67(b)	
5.203	Are maintenance records (including date, type of maintenance, parts replaced, and personnel) maintained on or near each piece of equipment?	820.70(g) / 211.67(c)	
5.204	Is idle or out-of-service equipment clearly marked to prevent unintended use?	211.105	
5.3 Equipment Cleaning & Changeover			
5.301	Are written cleaning procedures established for each piece of equipment, including disassembly, cleaning agents, and reassembly instructions?	820.70(g) / 211.67(b)	
5.302	Has cleaning validation been performed to demonstrate residual contamination levels are within acceptable limits?	211.67 / 820.70	
5.303	Is clean equipment labeled with a cleaning date and protected from contamination prior to use?	820.70(g) / 211.67(b)(5)	

5.304	Is equipment inspected immediately prior to use for cleanliness and removal of previous batch/product identification?	820.70(g) / 211.67(b)(5)	
5.4 Calibration			
5.401	Is a calibration program established for all measuring and test equipment that could affect product quality or acceptance?	820.72 / 211.68	
5.402	Are calibration procedures, intervals, and acceptance criteria documented, and traceable to national or international standards?	820.72(b) / 211.68	
5.403	Are calibration records maintained and is out-of-tolerance equipment removed from service, investigated, and corrective action documented?	820.72 / 211.68	
5.404	Are computerized or automated systems used in production or quality testing validated?	820.70(i) / 211.68(b)	

SECTION 6 – Purchasing & Supplier Controls

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
6.1 Supplier Qualification & Approval			
6.101	Is a formal supplier qualification program in place requiring evaluation and approval of suppliers/vendors before use?	820.50 / 211.84	
6.102	Are purchasing requirements (specifications, quality requirements, regulatory requirements) defined in writing for each purchased component or service?	820.50(b) / 211.80	
6.103	Are approved supplier lists maintained and reviewed periodically?	820.50(a) / 211.80	
6.104	Are supplier audits or assessments conducted at defined intervals for critical suppliers, with results documented?	820.50(a) / 211.84	
6.2 Receiving, Inspection & Testing			
6.201	Are incoming materials, components, containers, closures, and labeling placed in quarantine pending acceptance testing?	820.80(b) / 211.82 / 211.84	
6.202	Are written sampling and inspection procedures in place based on acceptable quality levels and statistical criteria?	820.80(b) / 211.82	
6.203	Is at least one identity test performed on each incoming lot of active pharmaceutical ingredient or critical material, even when a Certificate of Analysis is accepted?	211.84(d)(1)	
6.204	Are containers sampled according to written procedures, and are containers from which samples are taken appropriately marked?	211.84(c)	
6.205	Are rejected materials clearly identified, segregated, and controlled to prevent unauthorized use?	820.80(b) / 211.89	

6.206	Are microbiological tests performed on incoming materials where required?	211.84(d)(6)	
6.3 Material Storage & Inventory Control			
6.301	Are all materials and components stored under appropriate conditions (temperature, humidity, light) to prevent degradation?	820.150 / 211.142	
6.302	Are materials stored off the floor, spaced to allow for cleaning and inspection, and in a manner that prevents contamination and mix-ups?	820.150 / 211.80	
6.303	Is a FIFO (first in, first out) inventory system in place to ensure oldest approved materials are used first?	820.150 / 211.150(a)	
6.304	Are retested or resampled materials clearly identified and re-released through the quality system before use?	211.87	
6.305	Is destruction of rejected or obsolete materials documented with date and identity of materials destroyed?	211.184(e)	

SECTION 7 – Production & Process Controls			
Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
7.1 Process Validation & Change Control			
7.101	Are all production processes validated (or justified as not requiring validation) prior to routine commercial production?	820.75 / 211.100(a)	
7.102	Does each validated process have an approved validation protocol defining acceptance criteria, sampling plans, and test methods?	820.75 / 211.100	
7.103	Are revalidation activities triggered by changes in process, equipment, materials, or environment that may affect product quality?	820.75(b) / 211.100	
7.104	Is a formal change control system in place requiring documented review and approval of all changes to processes, materials, equipment, or facilities?	820.70(b) / 211.100	
7.105	Does the change control process evaluate the need for revalidation, stability studies, or regulatory notification before implementation?	820.70(b) / 211.100	
7.2 Batch/Production Records			
7.201	Does each batch have a complete production record (master batch record + executed batch record) reviewed and approved before release?	820.184 / 211.188	
7.202	Does the master batch record specify the theoretical yield, with allowable deviations, at each critical processing step?	211.186	

7.203	Are actual yields calculated and compared to theoretical yields, with unexplained discrepancies investigated?	211.192 / 211.103	
7.204	Is the addition of each component to a batch documented at the time of addition by the person performing the operation, with independent second-person verification?	211.101(c)(d)	
7.205	Are all weighing and measuring operations performed by one qualified person and independently verified by a second person with dual signatures?	211.101(c) / 211.103	

7.3 In-Process Controls & Testing

7.301	Are in-process controls and sampling points defined in production procedures with established acceptance criteria?	820.70(a) / 211.110	
7.302	Are in-process materials tested at appropriate stages to ensure conformance with specifications (identity, strength, quality, purity)?	820.80(c) / 211.110(c)	
7.303	Are in-process results documented, reviewed, and any rejects or deviations captured in the batch record with investigation?	820.80(c) / 211.192	
7.304	Are label issuance, reconciliation, and destruction procedures in place to prevent label mix-ups and ensure accountability?	211.125	
7.305	Are line clearance procedures performed and documented before each new batch or product to prevent mix-ups and cross-contamination?	820.70(a) / 211.67	

7.4 Reprocessing & Rework

7.401	Are written procedures in place for reprocessing or reworking batches/lots that do not meet specifications?	820.90(b) / 211.115	
7.402	Is Quality Unit review and approval required before any rework or reprocessing is performed?	820.90(b) / 211.115(b)	
7.403	Are reworked/reprocessed batches tested to confirm they meet original specifications before release?	820.90(b) / 211.115(b)	

SECTION 8 – Identification, Traceability & Nonconforming Product

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
8.1 Identification & Traceability			
8.101	Are all materials, components, in-process materials, and finished products uniquely identified throughout the manufacturing process?	820.60 / 211.80	
8.102	Is traceability established from finished product back through all components, materials, and production steps?	820.65 / 211.188	
8.103	Are batch/lot numbers assigned and documented to enable full traceability in the event of a recall?	820.65 / 211.188	

8.104	Is the acceptance status of product clearly indicated at all stages (e.g., quarantine, released, rejected)?	820.86 / 211.84	
8.2 Nonconforming Product Control			
8.201	Is a documented procedure in place for identifying, segregating, evaluating, and dispositioning nonconforming products?	820.90 / 211.192	
8.202	Are nonconforming products clearly labeled and physically segregated to prevent unintended use or distribution?	820.90 / 211.89	
8.203	Is disposition of nonconforming products (accept, rework, reject, return) documented with justification and authorized approvals?	820.90(a) / 211.192	
8.204	Are nonconformances investigated to determine root cause and are CAPAs generated when warranted?	820.90 / 820.100	
8.205	Are nonconformance records retained as quality records and trended periodically for systemic issues?	820.90 / 820.100	

SECTION 9 – Finished Product Controls, Testing & Release			
Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
9.1 Acceptance Testing & Release			
9.101	Are written acceptance criteria and test methods established for all finished product attributes (identity, strength, quality, purity)?	820.80(d) / 211.165	
9.102	Is finished product held in quarantine until all required testing is complete and Quality Unit has authorized release?	820.80(d) / 211.142	
9.103	Are stability studies conducted per written protocols for each drug product, covering all relevant storage conditions?	211.166	
9.104	Are reserve samples retained in quantities sufficient for at least two full retests (twice the amount needed for release testing)?	820.180 / 211.170	
9.105	Are sterility and pyrogen tests performed as required for parenteral and ophthalmic products?	211.167(a)	
9.106	Are controlled/sustained-release products tested to confirm conformance to release time specifications?	211.167(c)	
9.107	Are expiration dates stamped or printed on labels, linked to stability data and applicable storage conditions?	211.137	
9.2 Labeling & Packaging Controls			
9.201	Are specifications established for all labeling and packaging components, and are these verified against approved copy before use?	820.120 / 211.122	

9.202	Is labeling stored separately by product/strength with restricted access, and are issuance and reconciliation of labels documented?	820.120 / 211.122(d) / 211.125	
9.203	Are label examination procedures in place to detect errors in labels, including correct labeling for the product, strength, quantity, and expiration date?	820.120 / 211.130	
9.204	Are all finished products visually examined upon completion of packaging to verify correct labeling?	211.134(a)	
9.205	Are excess labels bearing lot numbers or expiration dates reconciled, and are unneeded labels destroyed and documented?	820.120 / 211.125(d)	

SECTION 10 – Corrective & Preventive Action (CAPA)

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
10.1 CAPA System			
10.101	Is a documented CAPA procedure in place that defines sources of data, investigation requirements, effectiveness checks, and management review?	820.100 / 211.192	
10.102	Are CAPA sources documented and include complaints, nonconformances, audit findings, process data, and field reports?	820.100(a) / 211.192	
10.103	Is root cause analysis performed for all significant quality events before corrective action is determined?	820.100(b) / 211.192	
10.104	Are preventive actions initiated based on trend analysis or risk assessment to address potential quality issues before they occur?	820.100(a)(7) / 211.192	
10.105	Are CAPA actions implemented within a defined timeframe with responsible ownership assigned?	820.100 / 211.192	
10.106	Is the effectiveness of implemented CAPAs verified before closure, and are records maintained?	820.100(b)(7) / 211.192	
10.107	Are CAPA trends reported to management review as a standing agenda item?	820.100(c) / 820.20	

SECTION 11 – Complaints, Adverse Events & Field Actions

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
11.1 Complaint Handling			
11.101	Is a formal complaint handling procedure in place that ensures all complaints (oral and written) are documented and evaluated?	820.198 / 211.198	

11.102	Does the Quality Unit review all complaints on a timely basis to determine whether they require investigation and regulatory reporting?	820.198(b) / 211.198(a)	
11.103	Are complaints investigated with documented findings, root cause (where applicable), and corrective actions?	820.198(c) / 211.198(b)	
11.104	Are decisions not to investigate a complaint documented with justification and the name of the responsible person?	820.198(d) / 211.198(b)(3)	
11.105	Are complaint files maintained in a centralized system and trended for systemic quality signals?	820.198 / 211.198	

11.2 MDR / Adverse Drug Reporting & Recalls

11.201	Are procedures in place to identify and evaluate events that may require Medical Device Reporting (MDR) or adverse drug event reporting?	820.198 / 314.81	
11.202	Are reportable events submitted to FDA within required timeframes (e.g., 30-day MDR, 5-day MDR for certain device events)?	820.198 / 803	
11.203	Is a formal written recall/field corrective action procedure in place that enables traceable recall of products through distribution records?	820.160 / 211.150 / 7 CFR 7	
11.204	Are distribution records maintained in sufficient detail to support a targeted and timely product recall?	820.160 / 211.150	

SECTION 12 – Distribution, Handling & Returned Goods

Item #	Requirement / Question	CFR Reference	Yes / No / NA / Obs.
12.1 Distribution Controls			
12.101	Are distribution procedures written and followed to ensure only released product is shipped, using a documented FIFO system?	820.160 / 211.150	
12.102	Are distribution records maintained that include product identity, lot/batch number, quantity, and shipping destination to support a recall?	820.160 / 211.150	
12.103	Are shipping and storage conditions defined and verified to prevent product degradation during distribution?	820.150 / 211.142	
12.2 Returned Goods			
12.201	Are returned goods quarantined, uniquely identified, and evaluated before any decision on disposition is made?	820.90 / 211.204	
12.202	Is reprocessing or re-release of returned goods subject to Quality Unit review and approval, including testing to confirm conformance?	820.90 / 211.204	
12.203	Are records of returned goods maintained, including identity, quantity, date returned, and disposition?	820.90 / 211.204	

AUDIT SUMMARY & OVERALL FINDINGS

Section	Total Items	Conforming (✓)	Nonconforming (X)	Observations (O)
1 – QMS & Org. Controls				
2 – Document & Record Controls				
3 – Design Controls (820)				
4 – Facilities & Environmental				
5 – Equipment Controls				
6 – Purchasing & Supplier Controls				
7 – Production & Process Controls				
8 – ID, Traceability & Nonconforming				
9 – Finished Product & Testing				
10 – CAPA				
11 – Complaints & Field Actions				
12 – Distribution & Returned Goods				
TOTAL				

KEY FINDINGS & OBSERVATIONS:

AUDITOR SIGN-OFF:

Lead Auditor Signature:	Date:	Audit Report #: