EAS CONSULTING GROUP

Specializing in FDA Regulatory Matters

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 (Devices) - QUALITY SYSTEM REGULATION
General Provisions	**Subpart A--General Provisions** § 110.3 - Definitions. § 110.5 - Current good manufacturing	**Subpart A--General Provisions** § 111.1 - Who is subject to this part? § 111.3 - What definitions apply to this part? § 111.5 - Do other statutory provisions and regulations apply?	**Subpart A--General Provisions** § 211.1 - Scope. § 211.3 - Definitions.	**Subpart A--General Provisions** § 820.1 - Scope. § 820.3 - Definitions.
Personnel		**Subpart B--Personnel** § 111.8 - What are the requirements under this subpart B for written procedures? § 111.10 - What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices? § 111.12 - What personnel qualification requirements apply? § 111.13 - What supervisor requirements apply? § 111.14 - Under this subpart B, what records must you make and keep?	**Subpart B--Organization and Personnel** § 211.22 - Responsibilities of quality control unit. § 211.25 - Personnel qualifications. § 211.28 - Personnel responsibilities. § 211.34 - Consultants.	**Subpart B--Quality System Requirements** § 820.20 - Management responsibility. § 820.25 - Personnel.
Building and Facility	**Subpart B--Buildings and Facilities** § 110.20 - Plant and grounds. § 110.35 - Sanitary operations. § 110.37 - Sanitary facilities and controls.	**Subpart C--Physical Plant and Grounds** § 111.15 - What sanitation requirements apply to your physical plant and grounds? § 111.16 - What are the requirements under this subpart C for written procedures? § 111.20 - What design and construction requirements apply to your physical plant? § 111.23 - Under this subpart C, what records must you make and keep?	**Subpart C--Buildings and Facilities** § 211.42 - Design and construction features. § 211.44 - Lighting. § 211.46 - Ventilation, air filtration, air heating and cooling. § 211.48 - Plumbing. § 211.50 - Sewage and refuse. § 211.52 - Washing and toilet facilities. § 211.56 - Sanitation. § 211.58 - Maintenance.	**Subpart G--Production and Process Controls** § 820.70(f)- Buildings
Equipment	**Subpart C--Equipment** § 110.40 - Equipment and utensils.	**Subpart D--Equipment and Utensils** § 111.25 - What are the requirements under this subpart D for written procedures? § 111.27 - What requirements apply to the equipment and utensils that you use? § 111.30 - What requirements apply to automated, mechanical, or electronic equipment? § 111.35 - Under this subpart D, what records must you make and keep?	**Subpart D--Equipment** § 211.63 - Equipment design, size, and location. § 211.65 - Equipment construction. § 211.67 - Equipment cleaning and maintenance. § 211.68 - Automatic, mechanical, and electronic equipment. § 211.72 - Filters.	**Subpart G--Production and Process Controls** § 820.70(g)- Equipment
Defect and Actions Levels	**Subpart G--Defect Action Levels** § 110.110 - Natural or unavoidable defects in food for human use that present no health hazard.			
REGULATIONS	**Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD**	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Production and Process Control	**Subpart E--Production and Process Controls** § 110.80 - Processes and controls.	Subpart E--Requirement to Establish a Production and Process Control System § 111.55 - What are the requirements to implement a production and process control system? § 111.60 - What are the design requirements for	Subpart E--Control of Components and Drug Product Containers and Closures § 211.80 - General requirements. § 211.82 - Receipt and storage of untested components, drug product containers, and closures.	Subpart C--Design Controls § 820.30 - Design controls.

EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750, Alexandria, Virginia 22314
(877) 327-9808 Toll Free • (571) 447-5500 Local • (703) 548-3270 Fax

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

	§ 110.93 - Warehousing and distribution.	the production and process control system? § 111.65 - What are the requirements for quality control operations? § 111.70 - What specifications must you establish? § 111.73 - What is your responsibility for determining whether established specifications are met? § 111.75 - What must you do to determine whether specifications are met? § 111.77 - What must you do if established specifications are not met? § 111.80 - What representative samples must you collect? § 111.83 - What are the requirements for reserve samples? § 111.87 - Who conducts a material review and makes a disposition decision? § 111.90 - What requirements apply to treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification established in accordance with 111.70 is not met? § 111.95 - Under this subpart E, what records must you make and keep?	§ 211.84 - Testing and approval or rejection of components, drug product containers, and closures. § 211.86 - Use of approved components, drug product containers, and closures. § 211.87 - Retesting of approved components, drug product containers, and closures. § 211.89 - Rejected components, drug product containers, and closures. § 211.94 - Drug product containers and closures.	
Document Controls				Subpart D--Document Controls § 820.40 - Document controls.
Purchasing Controls				Subpart E--Purchasing Controls § 820.50 - Purchasing controls.
Identification and Traceability				Subpart F--Identification and Traceability § 820.60 - Identification. § 820.65 - Traceability.

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Quality Control		**Subpart F--Production and Process Control System: Requirements for Quality Control** § 111.103 - What are the requirements under this subpart F for written procedures? § 111.105 - What must quality control personnel do? § 111.110 - What quality control operations are required for laboratory operations associated with the production and process control system? § 111.113 - What quality control operations are required for a material review and disposition decision? § 111.117 - What quality control operations are required for equipment, instruments, and controls? § 111.120 - What quality control operations are required for components, packaging, and labels before use in the manufacture of a dietary supplement? § 111.123 - What quality control operations are required for the master manufacturing record, the batch production record, and manufacturing operations? § 111.127 - What quality control operations are required for packaging and labeling operations? § 111.130 - What quality control operations are required for returned dietary supplements? § 111.135 - What quality control operations are required for product complaints? § 111.140 - Under this subpart F, what records must you make and keep?	**Subpart B--Organization and Personnel** § 211.22 - Responsibilities of quality control unit.	**Subpart A--General Provisions** § 820.5 - Quality system. **Subpart B--Quality System Requirements** § 820.22 - Quality audit.
Acceptance Activities				**Subpart H--Acceptance Activities** § 820.80 - Receiving, in-process, and finished device acceptance. § 820.86 - Acceptance status.
Nonconforming Products				**Subpart I--Nonconforming Product** § 820.90 - Nonconforming product.
Corrective and Preventive Action				**Subpart J--Corrective and Preventive Action** § 820.100 - Corrective and preventive action.

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Packaging and Labeling Controls Product Received for Packaging		**Subpart G--Production and Process Control System: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement** § 111.153 - What are the requirements under this subpart G for written procedures? § 111.155 - What requirements apply to components of dietary supplements? § 111.160 - What requirements apply to packaging and labels received? § 111.165 - What requirements apply to a product received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier)? § 111.170 - What requirements apply to rejected components, packaging, and labels, and to rejected products that are received for packaging or labeling as a dietary supplement? § 111.180 - Under this subpart G, what records must you make and keep?		
Production Process Control Master Document		**Subpart H--Production and Process Control System: Requirements for the Master Manufacturing Record** § 111.205 - What is the requirement to establish a master manufacturing record? § 111.210 - What must the master manufacturing record include?	**Subpart J--Records and Reports** § 211.186 - Master production and control records.	**Subpart M--Records** § 820.181 - Device master record.
Production and Process Batch Production		**Subpart I--Production and Process Control System: Requirements for the Batch Production Record** § 111.255 - What is the requirement to establish a batch production record? § 111.260 - What must the batch record include?	**Subpart J--Records and Reports** § 211.188 - Batch production and control records.	

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Production Process Laboratory Operations		**Subpart J--Production and Process Control System: Requirements for Laboratory Operations** § 111.303 - What are the requirements under this subpart J for written procedures? § 111.310 - What are the requirements for the laboratory facilities that you use? § 111.315 - What are the requirements for laboratory control processes? § 111.320 - What requirements apply to laboratory methods for testing and examination? § 111.325 - Under this subpart J, what records must you make and keep?	**Subpart I--Laboratory Controls** § 211.160 - General requirements. § 211.165 - Testing and release for distribution. § 211.166 - Stability testing. § 211.167 - Special testing requirements. § 211.170 - Reserve samples. § 211.173 - Laboratory animals. § 211.176 - Penicillin contamination.	
Production Process Controls – Manufacturing Operations		**Subpart K--Production and Process Control System: Requirements for Manufacturing Operations** § 111.353 - What are the requirements under this subpart K for written procedures? § 111.355 - What are the design requirements for manufacturing operations? § 111.360 - What are the requirements for sanitation? § 111.365 - What precautions must you take to prevent contamination? § 111.370 - What requirements apply to rejected dietary supplements? § 111.375 - Under this subpart K, what records must you make and keep?	**Subpart F--Production and Process Controls** § 211.100 - Written procedures; deviations. § 211.101 - Charge-in of components. § 211.103 - Calculation of yield. § 211.105 - Equipment identification. § 211.110 - Sampling and testing of in-process materials and drug products. § 211.111 - Time limitations on production. § 211.113 - Control of microbiological contamination. § 211.115 - Reprocessing.	**Subpart G--Production and Process Controls** § 820.70 - Production and process controls. § 820.72 - Inspection, measuring, and test equipment. § 820.75 - Process validation.
Production Process Control – Packaging and Labeling Operations		**Subpart L--Production and Process Control System: Requirements for Packaging and Labeling Operations** § 111.403 - What are the requirements under this subpart L for written procedures? § 111.410 - What requirements apply to packaging and labels? § 111.415 - What requirements apply to filling, assembling, packaging, labeling, and related operations? § 111.420 - What requirements apply to repackaging and relabeling? § 111.425 - What requirements apply to a packaged and labeled dietary supplement that is rejected for distribution? § 111.430 - Under this subpart L, what records must you make and keep?	**Subpart G--Packaging and Labeling Control** § 211.122 - Materials examination and usage criteria. § 211.125 - Labeling issuance. § 211.130 - Packaging and labeling operations. § 211.132 - Tamper-evident packaging requirements for over-the-counter (OTC) human drug products. § 211.134 - Drug product inspection. § 211.137 - Expiration dating.	**Subpart K--Labeling and Packaging Control** § 820.120 - Device labeling. § 820.130 - Device packaging.

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	CURRENT GOOD MANUFACTURING IN MANUFACTURING, PACKAGING, OR HOLDING OPERATIONS FOR SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Holding and Distribution	**Subpart E--Production and Process Controls** § 111.93 – Warehousing and Distribution	**Subpart M--Holding and Distributing** § 111.453 - What are the requirements under this subpart for M written procedures? § 111.455 - What requirements apply to holding components, dietary supplements, packaging, and labels? § 111.460 - What requirements apply to holding in-process material? § 111.465 - What requirements apply to holding reserve samples of dietary supplements? § 111.470 - What requirements apply to distributing dietary supplements? § 111.475 - Under this subpart M, what records must you make and keep?	**Subpart H--Holding and Distribution** § 211.142 - Warehousing procedures. § 211.150 - Distribution procedures.	**Subpart L--Handling, Storage, Distribution, and Installation** § 820.140 - Handling. § 820.150 - Storage. § 820.160 - Distribution. § 820.170 - Installation.
Returned and Salvaged Products		**Subpart N--Returned Dietary Supplements** § 111.503 - What are the requirements under this subpart N for written procedures? § 111.510 - What requirements apply when a returned dietary supplement is received? § 111.515 - When must a returned dietary supplement be destroyed, or otherwise suitably disposed of? § 111.520 - When may a returned dietary supplement be salvaged? § 111.525 - What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing? § 111.530 - When must an investigation be conducted of your manufacturing processes and other batches? § 111.535 - Under this subpart N, what records must you make and keep?	**Subpart K--Returned and Salvaged Drug Products** § 211.204 - Returned drug products. § 211.208 - Drug product salvaging.	
Product Complaints		**Subpart O--Product Complaints** § 111.553 - What are the requirements under this subpart O for written procedures? § 111.560 - What requirements apply to the review and investigation of a product complaint? § 111.570 - Under this subpart O, what records must you make and keep?	**Subpart J--Records and Reports** § 211.198 - Complaint files.	**Subpart M--Records** § 820.198 - Complaint files.

Side-by-Side Comparison – 21 CFR, Parts 110, 111, 211 and 820

REGULATIONS	Part 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD	Part 111 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS	Part 210, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS	Part 820 - QUALITY SYSTEM REGULATION
Records, Reports, and recordkeeping		**Subpart P--Records and Recordkeeping** § 111.605 - What requirements apply to the records that you make and keep? § 111.610 - What records must be made available to FDA?	**Subpart J--Records and Reports** § 211.180 - General requirements. § 211.182 - Equipment cleaning and use log. § 211.184 - Component, drug product container, closure, and labeling records. § 211.186 - Master production and control records. § 211.188 - Batch production and control records. § 211.192 - Production record review. § 211.194 - Laboratory records. § 211.196 - Distribution records.	**Subpart M--Records** § 820.180 - General requirements. § 820.181 - Device master record. § 820.184 - Device history record. § 820.186 - Quality system record.

Presented by:

Dean Cirotta
President and CEO
EAS Consulting Group, LLC
1700 Diagonal Road
Suite 750
Alexandria, VA 22314
571-447-5502