This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

CUMPARISON CHART

1996 QUALITY SYSTEM REGULATION VERSUS 1978 GOOD MANUFACTURING PRACTICES REGULATION VERSUS ANSI/ISO/ASQC Q9001-1994 AND ISO/DIS 13485:1996

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	Q9001- and ISO/DI	
§ 820.1 Scope	§ 820.1 Scope	9001. 13485	1 Scope
		9001	2 Normative references
		13485	2 Normative References
§ 820.3 Definitions	§ 820.3 Definitions	9001	3 Definitions
		13485	3 Definitions
§ 820.5 Quality system	§ 820.5 Quality assurance program	9001	4 Quality system requirements
		9001	4.2 Quality system
		9001	4.2.1 General
		13485	4.2.1 General
§ 820.20 Management		9001	4.1
responsibility		-	Management responsibility
§ 820.20(a) Quality policy		9001	4.1.1 Quality policy

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.20(b) Organization	§ 820.20 Organization	9001 4.1.2 Organization
§ 820.20(b)(1) Responsibility and authority	§ 820.20 Organization	9001 4.1.2.1 Responsibility and authority
§ 820.20(b)(2) Resources	§ 820.20 Organization	9001 4.1.2.2 Resources
§ 820.20(b)(3) Management representative	§ 820.20 Organization § 820.20(a)(4) Quality	9001 4.1.2.3 Management representative
	assurance program requirements	9001 4.2.2(b) Quality- system procedures
§ 820.20(c) Management review		9001 4.1.3 Management review
§ 820.20(d) Quality planning		9001 4.2.3 Quality planning
§ 820.20(e) Quality system procedures		9001 4.2.2 Quality- system procedures
		9001 4.2.1 General
§ 820.22 Quality audit	§ 820.20(b) Audit procedures	9001 4.17 Internal quality audits
§ 820.25 Personnel		9001 4.18 Training
§ 820.25(a) General	§ 820.25 Personnel	9001 4.1.2.2 Resources
§ 820.25(b) Training	§ 820.25(a) Personnel training	9001 4.18 Training

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.30 Design controls		9001 4.4 Design Control
§ 820.30(a) General		9001 4.4.1 General
§ 820.30(b) Design and development planning		9001 4.4.2 Design and development planning
		9001 4.4.3 Organizational and technical interfaces
§ 820.30(c) Design input		9001 4.4.4 Design input
§ 820.30(d) Design output		9001 4.4.5 Design output
§ 820.30(e) Design review		9001 4.4.6 Design review
§ 820.30(f) Design verification		9001 4.4.7 Design verification
§ 820.30(g) Design validation	§ 820.160 Finished device inspection	9001 4.4.8 Design validation
	(simulated use testing)	13485 4.4.1 General
		13485 4.4.8 Design validation
§ 820.30(h) Design transfer	§ 820.100 Manufacturing specifications and processes § 820.100(a)(1) Specification controls	9001 4.2.3(c) Quality planning 9001 4.4.1 General

Quality System Regulation - 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.30(i) Design changes	§ 820.100(a)(2) Specification controls	9001 4.4.9 Design changes
§ 820.30(j) Design history file		9001 4.16 Control of quality records
§ 820.40 Document controls		9001 4.5 Document and data control
		9001 4.5.1 General
§ 820.40(a) Document approval and distribution	§ 820.180 General requirements	9001 4.5.2 Document and data approval and issue
		13485 4.5.2 Document and data approval and issue
§ 820.40(b) Document changes	§ 820.180 General requirements	9001 4.5.3 Document and data changes
§ 820.50 Purchasing		9001 4.6 Purchasing
controls		9001 4.6.1 General
§ 820.50(a) Evaluation of suppliers, contractors, and consultants	§ 820.81(a) Acceptance of critical components	9001 4.6.2 Evaluation of subcontractors
§ 820.50(b) Purchasing data	§ 820.80(b) Critical component supplier	9001 4.3 Contract review
	agreement	9001 4.6.3 Purchasing data
		13485 4.6.3 Purchasing data

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.60 Identification	§ 820.80 Components	9001 4.8 Product identification and traceability 13485 4.8(A) Product
		identification and traceability
§ 820.65 Traceability	§ 820.151 Critical device, distribution records	9001 4.8 Product identification and traceability
		13485 4.8(B) Product identification and traceability
§ 820.70 Production and process controls		9001 4.9 Process control
§ 820.70(a) General	§ 820.100 Manufacturing specifications and processes	9001 4.9 (a)(c)(d)(e) and (f) Process control
	§ 820.100(b)(1) and (2) Processing controls	
§ 820.70(b) Production and process changes	§ 820.100(b)(3) Processing controls	9001 4.4.9 Design changes
§ 820.70(c) Environmental control	§ 820.46 Environmental control	9001 4.9(b) Process control
		9001 4.11.2(g) Control procedure
		13485 4.9(B) Environmental control in manufacture

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.70(d) Personnel	§ 820.25(b) Personnel health and cleanliness § 820.56(a) Personnel sanitation § 820.56(c) Personnel practices	9001 4.9(b) Process control 13485 4.9(A) Personnel
§ 820.70(e) Contamination control	§ 820.56(b) Contamination control § 820.56(d) Sewage and refuse disposal	9001 4.9(b) Process control 13485 4.9(C) Cleanliness of product
§ 820.70(f) Buildings	§ 820.40 Buildings	9001 4.9(b) Process control
§ 820.70(g) Equipment	§ 820.60(a)(b) and (c) Equipment	9001 4.9(b) and (g) Process control 13485 4.9(D) Maintenance
§ 820.70(h) Manufacturing material	§ 820.60(d) Manufacturing material	9001 4.9(b) Process control
§ 820.70(i) Automated processes	§ 820.61 Measurement equipment § 820.195 Critical devices, automated data processing	9001 4.4.8 Design validation 13485 4.9(F) Computer software used in process control
§ 820.72 Inspection, measuring, and test equipment	§ 820.61 Measurement equipment	9001 4.11 Control of inspection, measuring, and test equipment

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.75 Process validation	§ 820.100(a)(1) Specification controls	9001 4.9 Process control
	§ 820.101 Critical devices, manufacturing specifications, and processes	13485 4.9 Process control
§ 820.80 Receiving, in- process, and finished device acceptance		9001 4.10 Inspection and testing
§ 820.80(a) General	§ 820.80 Components	9001 4.10.1 General
	·	9001 4.6.4 Verification of purchased product
		9001 4.7 Control of customer- supplied product
§ 820.80(b) Receiving acceptance activities	§ 820.80(a) Acceptance of components	9001 4.10.2 Receiving inspection and testing
§ 820.80(c) In-process acceptance activities		9001 4.10.3 In-process inspection and testing
§ 820.80(d) Final acceptance activities	§ 820.160 Finished device inspection	9001 4.10.4 Final inspection and testing
§ 820.80(e) Acceptance records	§ 820.20(a)(2) Quality assurance program requirements	9001 4.10.5 Inspection and test records
	§ 820.161 Critical devices finished device inspection	13485 4.10.5 Inspection and test records

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.86 Acceptance status	§ 820.80(b) Storage and handling of components § 820.160 Finished device inspection	9001 Inspection and test status
§ 820.90 Nonconforming product		9001 4.13 Control of Nonconforming Product
§ 820.90(a) Control of nonconforming product	§ 820.161 Critical devices, finished device inspection	9001 4.13.1 General
§ 820.90(b) Nonconforming review and disposition	§ 820.115 Reprocessing of devices or components § 820.116 Critical devices, reprocessing of devices or components	9001 4.13.2 Review and disposition of nonconforming product 13485 4.13.2 Review and disposition of nonconforming product
§ 820.100 Corrective and preventive action	§ 820.20(a)(3) Quality assurance program requirements	9001 4.14 Corrective and preventive action
	§ 820.162 Failure investigation	13485 4.14 Corrective and preventive action
§ 820.120 Device labeling	§ 820.120 Device labeling § 820.121 Critical devices, device labeling	9001 4.15.1 General 9001 4.15.4 Packaging 13485 4.15.4 Packaging
§ 820.130 Device packaging	§ 820.130 Device packaging	9001 4.15.1 General 9001 4.15.4 Packaging

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.140 Handling	§ 820.80(b) Storage and handling of components	9001 4.15.1 General 9001 4.15.2 Handling 13485 4.15.1 General
§ 820.150 Storage	§ 820.80(b) Storage and handling of components	9001 4.15.1 General 9001 4.15.3 Storage 9001 4.15.5 Preservation 13485 4.15.1 General
§ 820.160 Distribution	§ 820.150 Distribution § 820.151 Critical devices, distribution records	9001 4.15.1 General 9001 4.15.6 Delivery 9001 4.3 Contract review 13485 4.15.6 Delivery 13485 4.8(B) Traceability
§ 820.170 Installation	§ 820.152 Installation	9001 4.9 Process control 13485 4.9(E) Installation
§ 820.180 General requirements	§ 820.180 General requirements	9001 4.16 Control of quality records 9001 4.5 Document and data control 9001 4.5.1 General 13485 4.16 Control of quality records

Quality System Regulation 1996: 21 CFR § 820	Good Manufacturing Practices (GMP) Regulation 1978: 21 CFR § 820	ANSI/ISO/ASQC Q9001-1994 and ISO/DIS 13485:April 1996
§ 820.181 Device master record	§ 820.181 Device master record § 820.182 Critical devices, device master record	9001 4.16 Control of quality records 9001 4.2.2 Quality-system procedures 13485 4.2.3 Quality planning
§ 820.184 Device history record § 820.186 Quality system record	§ 820.184 Device history record § 820.185 Critical devices, device history record § 820.20(a)(1) Quality assurance program requirements	9001 4.16 Control of quality records 13485 4.16 Control of quality records 9001 4.16 Control of quality records 9001 4.2.2
§ 820.198 Complaint files	§ 820.198 Complaint files	Quality-system procedures 9001 4.14.1 General 9001 4.14.2 Corrective action 9001 4.14.3 Preventive action 13485 4.14.1 General
§ 820.200 Servicing	§ 820.20(a)(3) Quality assurance program requirements	9001 4.19 Servicing
§ 820.250 Statistical techniques	§ 820.81(a) Acceptance of critical components § 820.160 Finished device inspection	9001 4.20 Statistical techniques