COMPLIANCEWIRE® LEARNING SERVICES

FDA observations: Does your training stack up?

UL Solutions' content helps mitigate FDA observations for medical device companies

UL Solutions

Each year the U.S. Food and Drug Administration (FDA) may audit any medical device company unannounced to determine the organization's compliance with applicable regulations and the safety of their product(s). In addition, regulated companies are required to provide evidence of internal auditing per regulations.[1][2] While undergoing an internal or external audit may be stressful, the intent of both the agency and the internal auditors is public safety.

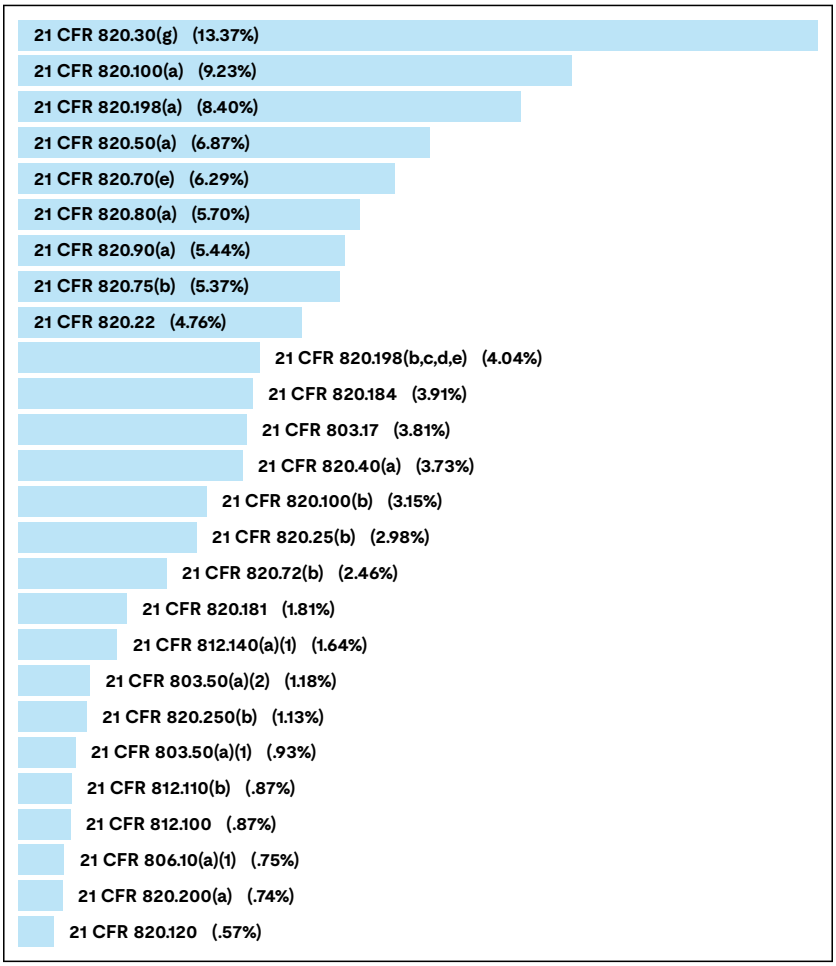
Training makes up an essential part of any audit or investigation, especially because of the escalating complexity and overlap of global quality regulations. This complexity is compounded when multiple manufacturing sites/locations are involved. Life science companies that serve many markets or rely on dispersed supply chains will commonly face compliance challenges from regulatory agencies, including the FDA and European Commission, as well as from international organizations, such as the International Committee on Harmonization (ICH), the International Standards Organization (ISO), and national governments.

The first items typically requested during an agency inspection are an organizational chart, followed by training records for key individuals at the company, including all individuals who are interviewed during the audit process. Having your internal organizational training programs secured in one place can assist you with inspection readiness and reduce stress, which in turn will allow your organization to focus on the key areas of the inspections.

Having a robust training program covering all critical regulations, guidelines, and procedures, while also executing internal audits, will help you gain efficiencies and prepare your company to be inspection-ready.

Another component that should be considered as part of the inspection readiness plan is a review of any observations from the past. This data is publicly available to the industry via the FDA website, which provides insight into the FDA's focus.

We reviewed **THE FDA'S 38,302** audit observations for medical device companies from **2013-2022** and summarized the **26 MOST** cited areas.



1. Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
2. § 21CFR Part 820 Subpart B - Quality System Requirements: 820.22 Quality audit

The 26 most cited observation areas

UL Solutions experts at ComplianceWire® are in the business of mitigating risk by helping support your critical areas with effective training programs. This will help prepare your company to be audit-ready for an FDA or other agency inspection at any time. To support your success, our subject matter experts have reviewed the FDA's 38,302 audit observations from field audits of medical device companies conducted from 2013 to 2022 and summarized the 26 most cited areas. They are, in order of most cited, the following:

Regulation	Description	Observations, percentage
21 CFR 820.30(g)	Design validation – risk analysis not performed/inadequate	5,120 observations, 13.37%
21 CFR 820.100(a)	Lack of adequate procedures	3,537 observations, 9.23%
21 CFR 820.198(a)	Lack of adequate complaint procedures	3,216 observations, 8.40%
21 CFR 820.50(a)	Evaluation of supplies, contractors, etc., requirements	2,630 observations, 6.87%
21 CFR 820.70(e)	Contamination control, lack of, or inadequate, procedures	2,408 observations, 6.29%
21 CFR 820.80(a)	Lack of adequate procedures – acceptance activities	2,183 observations, 5.70%
21 CFR 820.90(a)	Nonconforming product, lack of, or inadequate, procedures	2,082 observations, 5.44%
21 CFR 820.75(b)	Lack/inadequate procedure – monitoring/ control of validation process	2,058 observations, 5.37%
21 CFR 820.22	Quality audits – defined intervals	1,822 observations, 4.76%
21 CFR 820.198 (b,c,d,e)	Investigation of device failure, records, procedures investigation	1,546 observations, 4.04%
21 CFR 820.184	Lack of, or inadequate, DHS procedures	1,497 observations, 3.91%
21 CFR 803.17	Lack of written MDR procedures	1,460 observations, 3.81%
21 CFR 820.40(a)	Not approved or obsolete document retrieval	1,430 observations, 3.73%
21 CFR 820.100(b)	Documentation, procedures	1,206 observations, 3.15%
21 CFR 820.25(b)	Training – Lack of, or inadequate, procedures	1,142 observations, 2.98%
21 CFR 820.72(b)	Calibration procedures – content	943 observations, 2.46%
21 CFR 820.181	DMR – not, or inadequately, maintained	694 observations, 1.81%
21 CFR 812.140(a)(1)	Investigator device correspondence accountability records inadequate	629 observations, 1.64%
21 CFR 803.50(a)(2)	Individual report of malfunction	451 observations, 1.18%
21 CFR 820.250(b)	Sampling methods – Lack of, or inadequate, procedures	433 observations, 1.13%
21 CFR 803.50(a)(1)	Report of death or serious injury	357 observations, .93%
21 CFR 812.110(b)	Investigator noncompliance with agreement/plans/regulations	335 observations, .87%
21 CFR 812.100	Investigators compliance with agreement/ plans/regulations	333 observations, .87%
21 CFR 806.10(a)(1)	Report of risk to health	289 observations, .75%
21 CFR 820.200(a)	Servicing – Lack of, or inadequate, procedures	283 observations, .74%
21 CFR 820.120	Lack of, or inadequate, procedures for labeling	218 observations, .57%

ComplianceWire® e-learning course mappings

We then mapped our ComplianceWire® content catalog offerings to these areas of focus from the FDA to produce the resulting chart. By implementing these e-learning courses into your training programs annually or more frequently, you can have confidence that you are providing the necessary training requirements in areas where the FDA has focused in the past.

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21 CFR 820.30(g) – Design validation – risk analysis not performed/inadequate

DEV40	Design Control Regulations for Medical Device Manufacturers	**PHDV103**	Approach to Computerized Systems Validation and Compliance
DEV42	Quality Systems Inspection Technique (QSIT)	**PHDV63**	Understanding GMPs for Facilities and Equipment
DEV43	Introduction to the Quality System (QS) Regulation	**PHDV77**	Key Concepts of Process Validation
DEV50	A Guide to ISO 13485 – The Quality Management System for Medical Devices	**PHDV78**	Application of cGMPs to Analytical Laboratories
FDA29	Risk Management 1: Key Concepts and Definitions	**PHDV79**	A Step-by-Step Approach to Process Validation
PHA50	Resolving Out Of Specification Test Results	**PHDV87**	Environmental Control and Monitoring
PHA51	Writing Validation Protocols	**PHDV88**	Implementing an Equipment Qualification Program
PHA55	Documenting Validation Activities	**QSR03**	QS Regulation 3: Design Controls
PHDV102	Requirements for Computerized Systems Validation and Compliance		

21 CFR (820.100(a)) – Lack of adequate procedures

DATA01	Introduction to Data Integrity	**MDR03**	CE Certification for Medical Devices
DATA02	Auditing of Computer System Validation to Ensure Data Integrity	**PHA47**	Understanding the Principles and Practices of Process Controls
DATA03	Data Integrity: The Role of Quality Assurance for Data Integrity	**PHA48**	Writing and Reviewing SOPs
DATA04	Data Integrity for Quality Control Laboratories	**PHA64**	GMP Principles of SOPs
DEV40	Design Control Regulations for Medical Device Manufacturers	**PHA67**	FDA Training and Qualification Requirements
DEV42	Quality Systems Inspection Technique (QSIT)	**PHDV101**	Management Responsibility for Quality: What FDA Expects
DEV45	Failure Investigations for Medical Device Manufacturers	**PHDV75**	Essentials of an Effective Calibration Program
DEV46	Complaint Management for Medical Device Manufacturers	**QSR04**	QS Regulation 4: Document and Purchasing Controls
GCP29	Recruitment and Retention of Study Patients	**QSR09**	QS Regulation 9: Records
ICHreg04	Validation of Analytical Laboratory Procedures		

21 CFR 820.198(a) – Lack of adequate complaint procedures

DEV46	Complaint Management for Medical Device Manufacturers

21 CFR 820.50(a) – Evaluation of supplies, contractors, etc., requirements

Aseptic01	Basics of Cleanroom Operations	**PHA38**	Introduction to cGMPs
FDA27	Interviewing Techniques	**PHA55**	Documenting Validation Activities
FDA28	Field Examinations	**PHA67**	FDA Training and Qualification Requirements
GCP01	GCP/ICH Obligations of Sponsors, Monitors, and Investigators	**QSR04**	QS Regulation 4: Document and Purchasing Controls
GCP29	Recruitment and Retention of Study Patients		

21 CFR 820.70 (e) – Contamination control, lack of, or inadequate, procedures

Aseptic01	Basics of Cleanroom Operations	**DEV43**	Introduction to the Quality System (QS) Regulation
Aseptic05	RABS for Aseptic Processing	**PHA47**	Understanding the Principles and Practices of Process Controls
Aseptic07	Dos and Don'ts of Aseptic Environments	**QSR03**	
Aseptic08	Cleanroom Cleaning, Sanitization, and Disinfection		

21 CFR 820.90(a) – Nonconforming product, lack of, or inadequate, procedures

Aseptic01	Basics of Cleanroom Operations	**PHDV63**	Understanding GMPs for Facilities and Equipment
DEV40	Design Control Regulations for Medical Device Manufacturers	**PHDV77**	Key Concepts of Process Validation
DEV43	Introduction to the Quality System (QS) Regulation	**PHDV78**	Application of cGMPs to Analytical Laboratories
FDA61	Part 11: Electronic Records and Signatures – Application	**PHDV79**	A Step-by-Step Approach to Process Validation
PHA47	Understanding the Principles and Practices of Process Controls	**PHDV87**	Environmental Control and Monitoring
PHDV102	Requirements for Computerized Systems Validation and Compliance	**PHDV88**	Implementing an Equipment Qualification Program
PHDV103	Approach to Computerized Systems Validation and Compliance	**QSR03**	QS Regulation 3: Design Controls

21 CFR 820.22 – Quality audits – defined intervals

DEV42	Quality Systems Inspection Technique (QSIT)	**FDA39**	Basics of Inspections: Issues and Observations
DEV50	A Guide to ISO 13485 – The Quality Management System for Medical Devices	**MDSAP00**	Overview of the Medical Device Single Audit Program (MDSAP) Chapter Structure
DEV60	An Introduction to ISO 9001:2015 – The Quality Management System Requirements	**MDSAP01**	MDSAP Chapter 1 Process Management
DEV61	A Guide to ISO 9001:2015 – Quality Management Systems Requirements	**MDSAP02**	MDSAP Chapter 2 – Process: Device Marketing Authorization and Facility Registration
DEV62	Introduction to the Medical Device Single Audit Program (MDSAP)	**PHA38**	Introduction to cGMPs
FDA26	FDA Establishment Inspection Report Writing	**PHDV101**	Management Responsibility for Quality: What FDA Expects
FDA27	Interviewing Techniques	**PHDV69**	Principles of Auditing
FDA28	Field Examinations	**PHDV74**	Handling an FDA Inspection
FDA32	FDA Establishment Inspection (EI)	**QSR02**	QS Regulation 2: Quality System Requirements
FDA38	Basics of Inspections: Beginning an Inspection		

21 CFR 820.198 (b,c,d,e) – Investigation of device failure, records, procedures investigation

DEV41	Medical Device Packaging, Labeling, and Distribution	**DEV46**	Complaint Management for Medical Device Manufacturers
DEV42	Quality Systems Inspection Technique (QSIT)	**PHA50**	Resolving Out Of Specification Test Results
DEV44	Review of Basic Statistical Techniques	**QSR06**	QS Regulation 6: Acceptance Activities; Nonconforming Product
DEV45	Failure Investigations for Medical Device Manufacturers	**QSR07**	QS Regulation 7: Corrective and Preventive Action

21 CFR 820.184 – Lack of, or inadequate, DHS procedures

PHA35	Change Control	**QSR07**	QS Regulation 7: Corrective and Preventive Action

21 CFR 803.17 – Lack of written MDR procedures

FDA63	MDR Regulation 1: Overview and General Provisions	**MDR03**	CE Certification for Medical Devices
FDA65	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements	**MDSM02**	Reporting Adverse Events for Medical Devices
FDA66	MDR Regulation 3: Requirements for Individual Adverse Event Reports	**PHDV101**	Management Responsibility for Quality: What FDA Expects
GCP19	Medical Device Safety Reporting	**QSR02**	QS Regulation 2: Quality System Requirements
MDR01	EU Medical Device Regulation (MDR)	**QSR09**	QS Regulation 9: Records

21 CFR 820.100(b) – Documentation, procedures

Aseptic05	RABS for Aseptic Processing	**FDA64**	Enforcement of the Post-Marketing Adverse Drug Experience Reporting Regulations
Aseptic07	Dos and Don'ts of Aseptic Environments	**FDA65**	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements
Aseptic08	Cleanroom Cleaning, Sanitization, and Disinfection	**FDA66**	MDR Regulation 3: Requirements for Individual Adverse Event Reports
DATA01	Introduction to Data Integrity	**GCP03**	Obligations of Investigators in Conducting Medical Device Trials
DATA02	Auditing of Computer System Validation to Ensure Data Integrity	**GCP10**	Ethics as the Foundation to Clinical Research
DATA03	Data Integrity: The Role of Quality Assurance for Data Integrity	**GCP11**	Overview of the Clinical Research Process
DATA04	Data Integrity for Quality Control Laboratories	**ICHreg04**	Validation of Analytical Laboratory Procedures
DEV40	Design Control Regulations for Medical Device Manufacturers	**MDR03**	CE Certification for Medical Devices
DEV42	Quality Systems Inspection Technique (QSIT)	**PHA35**	Change Control
DEV45	Failure Investigations for Medical Device Manufacturers	**PHA38**	Introduction to cGMPs
DEV46	Complaint Management for Medical Device Manufacturers	**PHA47**	Understanding the Principles and Practices of Process Controls
DEV48	An Introduction to ISO 13485 – The Quality Management System for Medical Devices	**PHA48**	Writing and Reviewing SOPs
DEV50	A Guide to ISO 13485 – The Quality Management System for Medical Devices	**PHA51**	Writing Validation Protocols

21 CFR 820.100(b) – Documentation, procedures – continued			
DEV55	ISO 14971: Risk Management for Medical Devices	**PHDV69**	Principles of Auditing
DEV56	Good Documentation Practices for Medical Device Manufacturers	**PHDV74**	Handling an FDA Inspection
DEV60	An Introduction to ISO 9001:2015 – The Quality Management System Requirements	**PHDV75**	Essentials of an Effective Calibration Program
DEV61	A Guide to ISO 9001:2015 – Quality Management Systems Requirements	**PHDV76**	Meeting GMP Training Requirements
DEV62	Introduction to the Medical Device Single Audit Program (MDSAP)	**PHDV77**	Key Concepts of Process Validation
FDA22	Evidence and Proof	**PHDV79**	A Step-by-Step Approach to Process Validation
FDA23	Sample Collection	**PHSM11**	Physician Payment Sunshine Act
FDA26	FDA Establishment Inspection Report Writing	**QSR02**	QS Regulation 2: Quality System Requirements
FDA27	Interviewing Techniques	**QSR04**	QS Regulation 4: Document and Purchasing Controls
FDA28	Field Examinations	**QSR05**	QS Regulation 5: Identification and Traceability; Production and Process Controls
FDA32	FDA Establishment Inspection (EI)	**QSR06**	QS Regulation 6: Acceptance Activities; Nonconforming Product
FDA39	Basics of Inspections: Issues and Observations	**QSR07**	QS Regulation 7: Corrective and Preventive Action
FDA61	Part 11: Electronic Records and Signatures – Application	**QSR08**	QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation
FDA63	MDR Regulation 1: Overview and General Provisions	**QSR09**	QS Regulation 9: Records
21 CFR 820.25(b) – Training – Lack of, or inadequate, procedures			
PHA47	Understanding the Principles and Practices of Process Controls	**PHA67**	FDA Training and Qualification Requirements
PHA48	Writing and Reviewing SOPs	**PHDV76**	Meeting GMP Training Requirements
21 CFR 820.72(b) – Calibration procedures – content			
ICHreg04	Validation of Analytical Laboratory Procedures	**PHDV63**	Understanding GMPs for Facilities and Equipment
PHA47	Understanding the Principles and Practices of Process Controls	**PHDV75**	Essentials of an Effective Calibration Program
PHDV102	Requirements for Computerized Systems Validation and Compliance	**PHDV78**	Application of cGMPs to Analytical Laboratories
PHDV103	Approach to Computerized Systems Validation and Compliance	**QSR05**	QS Regulation 5: Identification and Traceability; Production and Process Controls
21 CFR 820.181 – DMR – not, or inadequately, maintained			
DEV40	Design Control Regulations for Medical Device Manufacturers	**FDA63**	MDR Regulation 1: Overview and General Provisions
DEV41	Medical Device Packaging, Labeling, and Distribution	**QSR09**	QS Regulation 9: Records
DEV42	Quality Systems Inspection Technique (QSIT)		
21 CFR 812.140(a)(1) – Investigator device correspondence accountability records inadequate			
BIMO01	Overview of FDA's Bioresearch Monitoring Program	**GCP01**	GCP/ICH Obligations of Sponsors, Monitors, and Investigators
BIMO02	BIMO: General Inspection Assignment Process	**GCP03**	Obligations of Investigators in Conducting Medical Device Trials
BIMO03	BIMO: BIMO: Parts 50 & 56 – Protection of Human Subjects and Institutional Review Boards (IRBs)	**GCP10**	Ethics as the Foundation to Clinical Research
BIMO04	BIMO: Clinical Investigator (CI) Responsibilities	**GCP11**	Overview of the Clinical Research Process
BIMO05	BIMO: Sponsor/Monitor Responsibilities	**GCP30**	ISO 14155: Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
DATA05	Data Integrity for Clinical Research Staff	**PHA36**	Good Clinical Practices (GCPs) for New Product Investigations
DEV47	The Approval Process for New Medical Devices in the United States		
21 CFR 803.50(a)(2) – Individual report of malfunction			
FDA65	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements	**MDSM02**	Reporting Adverse Events for Medical Devices
FDA66	MDR Regulation 3: Requirements for Individual Adverse Event Reports		

21 CFR 820.250(b) – Sampling methods – Lack of, or inadequate, procedures

DATA04	Data Integrity for Quality Control Laboratories	**ICHreg04**	Validation of Analytical Laboratory Procedures
FDA23	Sample Collection	**PHA47**	Understanding the Principles and Practices of Process Controls
FDA28	Field Examinations		

21 CFR 803.50(a)(1) – Report of death or serious injury

FDA64	Enforcement of the Post-Marketing Adverse Drug Experience Reporting Regulations	**GCP19**	Medical Device Safety Reporting
FDA65	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements	**MDSM02**	Reporting Adverse Events for Medical Devices
FDA66	MDR Regulation 3: Requirements for Individual Adverse Event Reports		

21 CFR 812.110(b) – Investigator noncompliance with agreement/plans/regulations

BIMO01	Overview of FDA's Bioresearch Monitoring Program	**GCP01**	GCP/ICH Obligations of Sponsors, Monitors, and Investigators
BIMO02	BIMO: General Inspection Assignment Process	**GCP03**	Obligations of Investigators in Conducting Medical Device Trials
BIMO03	BIMO: BIMO: Parts 50 & 56 – Protection of Human Subjects and Institutional Review Boards (IRBs)	**GCP10**	Ethics as the Foundation to Clinical Research
BIMO04	BIMO: Clinical Investigator (CI) Responsibilities	**GCP11**	Overview of the Clinical Research Process
BIMO05	BIMO: Sponsor/Monitor Responsibilities	**GCP30**	ISO 14155: Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
DATA05	Data Integrity for Clinical Research Staff	**PHA36**	Good Clinical Practices (GCPs) for New Product Investigations
DEV47	The Approval Process for New Medical Devices in the United States		

21 CFR 812.100 – Investigators compliance with agreements/plans/regulations

BIMO01	Overview of FDA's Bioresearch Monitoring Program	**GCP01**	GCP/ICH Obligations of Sponsors, Monitors, and Investigators
BIMO02	BIMO: General Inspection Assignment Process	**GCP03**	Obligations of Investigators in Conducting Medical Device Trials
BIMO03	BIMO: BIMO: Parts 50 & 56 – Protection of Human Subjects and Institutional Review Boards (IRBs)	**GCP10**	Ethics as the Foundation to Clinical Research
BIMO04	BIMO: Clinical Investigator (CI) Responsibilities	**GCP11**	Overview of the Clinical Research Process
BIMO05	BIMO: Sponsor/Monitor Responsibilities	**GCP30**	ISO 14155: Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
DATA05	Data Integrity for Clinical Research Staff	**PHA36**	Good Clinical Practices (GCPs) for New Product Investigations
DEV47	The Approval Process for New Medical Devices in the United States	**PHSM11**	Physician Payment Sunshine Act

21 CFR 806.10(a)(1) – Report of risk to health

DEV55	ISO 14971: Risk Management for Medical Devices	**FDA66**	MDR Regulation 3: Requirements for Individual Adverse Event Reports
FDA64	Enforcement of the Post-Marketing Adverse Drug Experience Reporting Regulations	**GCP19**	Medical Device Safety Reporting
FDA65	MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements	**MDSM02**	Reporting Adverse Events for Medical Devices

21 CFR 820.120 – Lack of, or inadequate, procedures for labeling

DEV41	Medical Device Packaging, Labeling, and Distribution	**QSR08**	QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation

21 CFR 820.200(a) – Servicing – Lack of, or inadequate, procedures

PHDV63	Understanding GMPs for Facilities and Equipment