COMPLIANCEWIRE® LEARNING SERVICES

FDA observations: Does your training stack up?

UL Solutions content helps mitigate FDA observations for pharma companies

UL Solutions

Each year, the U.S. Food and Drug Administration (FDA) may audit any pharmaceutical 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 audit may be stressful, the intent of both the agency and the internal auditors is public safety.

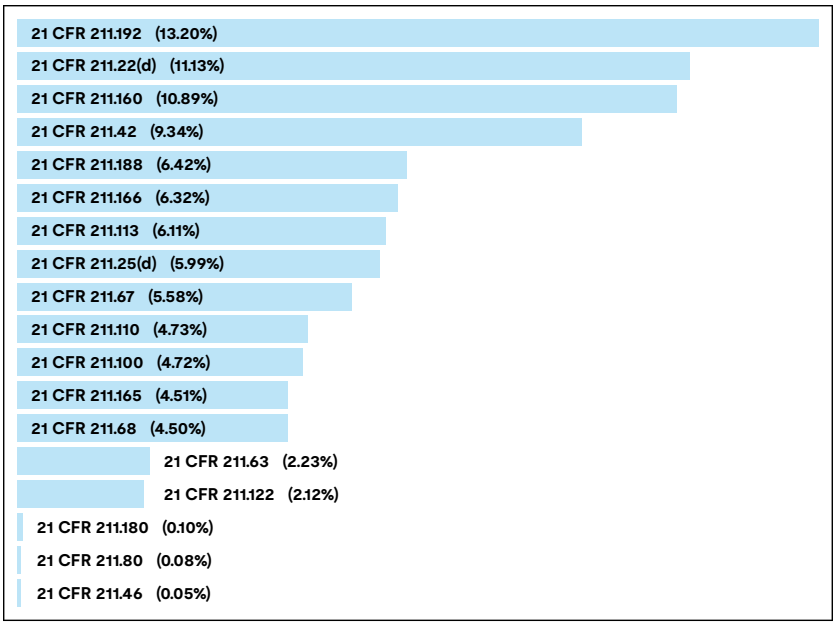
Training makes up an essential part of any audit or investigation, especially because of the escalating complexity and overlap of global quality regulations. This complexity is compounded when multiple manufacturing sites/locations are involved. Life science companies that serve many markets or rely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

The first item typically requested during an agency inspection is 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 an 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 13,054** audit observations for pharmaceutical companies from **2013-2022** and summarized the **18 MOST** cited areas.



1. *Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations*
2. *§ 21 CFR Part 211 Subpart B - Organization and Personnel 211.22 - Responsibilities of quality control unit.*

The 18 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 any time. To support your success, UL Solutions subject matter experts have reviewed the FDA's 13,054 audit observations from field audits of pharmaceutical companies conducted from 2013 to 2022 and summarized the 18 most cited areas. They are, in order of most cited:

Regulation	Description	Observations, Percentage
21 CFR 211.192	Production record review	1,723 observations, 13.20%
21 CFR 211.22(d)	Responsibilities of quality control unit	1,453 observations, 11.13%
21 CFR 211.160	Laboratory controls, general requirements	1,421 observations, 10.89%
21 CFR 211.42	Design and construction	219 observations, 9.34%
21 CFR 211.188	Batch production and control records	838 observations, 6.42%
21 CFR 211.166	Stability testing	825 observations, 6.32%
21 CFR 211.113	Control of microbiological contamination	797 observations, 6.11%
21 CFR 211.25(d)	Personnel qualifications	782 observations, 5.99%
21 CFR 211.67	Equipment cleaning and maintenance	728 observations, 5.58%
21 CFR 211.110	Sampling and testing of in-process materials and drug products	617 observations, 4.73%
21 CFR 211.100	Written procedures, deviations	616 observations, 4.72%
21 CFR 211.165	Testing and release for distribution	589 observations, 4.51%
21 CFR 211.68	Automatic, mechanical and electronic equipment	587 observations, 4.50%
21 CFR 211.63	Equipment design, size and location	291 observations, 2.23%
21 CFR 211.122	Packaging and labeling control	277 observations, 2.12%
21 CFR 211.180	General records	129 observations, 0.10%
21 CFR 211.80	Control of components and drug product containers and closures	102 observations, 0.08%
21 CFR 211.46	Ventilation, air filtration, air heating and cooling	60 observations, 0.05%

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 211.25(d) – Personnel qualifications

All courses listed below pertain to 21 CFR 211.25(d)

21 CFR 211.22(d) – Responsibilities of the quality control unit

DATA01	Introduction to Data Integrity	**PHA40**	DEA Compliance
DATA02	Auditing of Computer System Validation to Ensure Data Integrity	**PHA41**	Care and Handling of Drug Product Components, Labeling, Containers, and Closures
DATA03	Data Integrity: The Role of Quality Assurance for Data Integrity	**PHA42**	Meeting Process Requirements for Returned and Salvaged Drug Products
DATA04	Data Integrity for Quality Control Laboratories	**PHA43**	How to Meet Drug Retention and Stability Testing Requirements
DATA05	Data Integrity for Clinical Research Staff	**PHA45**	Conducting Annual Product Reviews
DEV42	Quality Systems Inspection Technique (QSIT)	**PHA48**	Writing and Reviewing SOPs
DEV43	Introduction to the Quality System (QS) Regulation	**PHA50**	Resolving Out Of Specification Test Results
FDA01	Food and Drug Law: FDA Jurisdictions	**PHA51**	Writing Validation Protocols
FDA02	Food and Drug Law: Prohibited Actions	**PHA53**	Batch Record Reviews
FDA03	Food and Drug Law: Judicial Actions	**PHA55**	Documenting Validation Activities
FDA04	Food and Drug Law: Criminal Acts Violations	**PHA59**	Failure Investigations for Pharmaceutical Manufacturers
FDA05	Food and Drug Law: Imports and Exports	**PHA60**	GMP Principles for Batch Records
FDA21	FDA Good Guidance Practices (GGPs)	**PHA64**	GMP Principles of SOPs
FDA22	Evidence and Proof	**PHA65**	Awareness of FDA Inspections for Pharmaceutical Manufacturers
FDA24	Recalls of FDA-Regulated Products	**PHA67**	FDA Training and Qualification Requirements
FDA25	Special Investigations	**PHA70**	Corrective and Preventive Actions
FDA26	FDA Establishment Inspection Report Writing	**PHA71**	Complaint Management for Pharmaceutical Manufacturers
FDA27	Interviewing Techniques	**PHA72**	Risk Management in Pharmaceutical Manufacturing
FDA28	Field Examinations	**PHA73**	Tools and Techniques for Effective CAPA Systems
FDA29	Risk Management 1: Key Concepts and Definitions	**PHA74**	Principles of Good Documentation
FDA30	FDA 483s: Inspectional Observations	**PHA75**	Pre- and Post-Approval FDA Drug Inspections
FDA32	FDA Establishment Inspection (EI)	**PHA76**	Role of the Qualified Person
FDA33	Destruction and Reconditioning	**PHA81**	Computerized Systems Inspections in the Pharmaceutical Industry
FDA37	Import Operations 1: Background	**PHA82**	cGMP Refresher: Pharmaceutical Quality System and Quality Culture
FDA55	Systems Based Drug Inspections	**PHDV101**	Management Responsibility for Quality: What FDA Expects
FDA57	Part 11: Electronic Records and Signatures – Enforcement Policy	**PHDV102**	Requirements for Computerized Systems Validation and Compliance
FDA61	Part 11: Electronic Records and Signatures – Application	**PHDV103**	Approach to Computerized Systems Validation and Compliance
FDA64	Enforcement of the Post-Marketing Adverse Drug Experience Reporting Regulations	**PHDV61**	GxPs
ICHreg01	ICH Q7: Introduction and Quality Management	**PHDV63**	Understanding GMPs for Facilities and Equipment
ICHreg02	ICH Q7: Resources and Materials Management	**PHDV64**	Handling a Product Recall
ICHreg03	Documenting the Drug Development Process – ICH Q8(R2)	**PHDV69**	Principles of Auditing
ICHreg04	Validation of Analytical Laboratory Procedures	**PHDV70**	Effectively Responding to FDA 483s and Warning Letters
ICHreg05	Q9: Quality Risk Management	**PHDV73**	Orientation to GMP Compliance
ICHreg06	Quality Systems Approach	**PHDV74**	Handling an FDA Inspection
ICHreg07	Q10 Pharmaceutical Quality System	**PHDV76**	Meeting GMP Training Requirements
PHA35	Change Control	**PHDV78**	Application of cGMPs to Analytical Laboratories
PHA37	Principles of Cleaning Validation	**PHDV80**	The Design and Development of Software Used in Automated Process Controls
PHA38	Introduction to cGMPs	**PHDV92**	GMP Updates: Supply Chain Quality and Emerging Compliance Concerns
PHA39	Packaging and Labeling of Finished Pharmaceuticals		

21 CFR 211.42 – Design and Construction

Aseptic01	Basics of Cleanroom Operations	**DEV43**	Introduction to the Quality System (QS) Regulation
Aseptic02	Sterile Dosage Forms Introduction	**ICHreg01**	ICH Q7: Introduction and Quality Management
Aseptic03	Principles of Restricted Access Barrier Systems and Isolators	**ICHreg02**	ICH Q7: Resources and Materials Management
Aseptic05	RABS for Aseptic Processing	**ICHreg03**	Documenting the Drug Development Process – ICH Q8(R2)
Aseptic06	Media Fills for Aseptic Processing	**PHA47**	Understanding the Principles and Practices of Process Controls
Aseptic07	Dos and Don'ts of Aseptic Environments	**PHA49**	Understanding Post-Approval Changes
Aseptic08	Cleanroom Cleaning, Sanitization, and Disinfection	**PHA63**	Gowning for Sterile Manufacturing

21 CFR 211.63 – Equipment design, size and location

Aseptic01	Basics of Cleanroom Operations	**PHDV71**	Principles of Aseptic Processing
PHA44	Maintenance and Cleaning of Drug Manufacturing Equipment		

21 CFR 211.67 – Equipment cleaning and maintenance

Aseptic02	Sterile Dosage Forms Introduction	**PHA63**	Gowning for Sterile Manufacturing
Aseptic04	Isolators for Aseptic Processing	**PHDV63**	Understanding GMPs for Facilities and Equipment
Aseptic05	RABS for Aseptic Processing	**PHDV71**	Principles of Aseptic Processing
Aseptic08	Cleanroom Cleaning, Sanitization, and Disinfection	**PHDV81**	Principles of Sterilization
PHA37	Principles of Cleaning Validation	**PHDV87**	Environmental Control and Monitoring
PHA44	Maintenance and Cleaning of Drug Manufacturing Equipment	**PHDV88**	Implementing an Equipment Qualification Program
PHA54	Collecting Samples and Establishing Limits for Cleaning Validation		

21 CFR 211.68 – Automatic, mechanical, and electronic equipment

Aseptic05	RABS for Aseptic Processing	**PHDV63**	Understanding GMPs for Facilities and Equipment
FDA31	Part 11: Electronic Records; Electronic Signatures	**PHDV75**	Essentials of an Effective Calibration Program
FDA57	Part 11: Electronic Records and Signatures – Enforcement Policy	**PHDV88**	Implementing an Equipment Qualification Program
FDA61	Part 11: Electronic Records and Signatures – Application		

21 CFR 211.80 – Control of components and drug product containers and closures

Aseptic06	Media Fills for Aseptic Processing	**PHA39**	Packaging and Labeling of Finished Pharmaceuticals
FDA23	Sample Collection	**PHA40**	DEA Compliance
FDA24	Recalls of FDA-Regulated Products	**PHA41**	Care and Handling of Drug Product Components, Labeling, Containers, and Closures
FDA33	Destruction and Reconditioning	**PHA42**	Meeting Process Requirements for Returned and Salvaged Drug Products
FDA55	Systems Based Drug Inspections	**PHA47**	Understanding the Principles and Practices of Process Controls
ICHreg01	ICH Q7: Introduction and Quality Management	**PHA75**	Pre- and Post-Approval FDA Drug Inspections
ICHreg02	ICH Q7: Resources and Materials Management	**PHDV71**	Principles of Aseptic Processing
ICHreg03	Documenting the Drug Development Process – ICH Q8(R2)		

21 CFR 211.100 – Written procedures, deviations

DATA01	Introduction to Data Integrity	**PHA64**	GMP Principles of SOPs
DATA02	Auditing of Computer System Validation to Ensure Data Integrity	**PHA65**	Awareness of FDA Inspections for Pharmaceutical Manufacturers
DATA03	Data Integrity: The Role of Quality Assurance for Data Integrity	**PHA70**	Corrective and Preventive Actions
DATA04	Data Integrity for Quality Control Laboratories	**PHA71**	Complaint Management for Pharmaceutical Manufacturers
DATA05	Data Integrity for Clinical Research Staff	**PHA72**	Risk Management in Pharmaceutical Manufacturing
DEV42	Quality Systems Inspection Technique (QSIT)	**PHA73**	Tools and Techniques for Effective CAPA Systems
DEV43	Introduction to the Quality System (QS) Regulation	**PHA74**	Principles of Good Documentation
DEV44	Review of Basic Statistical Techniques	**PHA81**	Computerized Systems Inspections in the Pharmaceutical Industry

21 CFR 211.100 – Written procedures, deviations — continued

FDA23	Sample Collection	**PHDV102**	Requirements for Computerized Systems Validation and Compliance
FDA24	Recalls of FDA-Regulated Products	**PHDV103**	Approach to Computerized Systems Validation and Compliance
FDA25	Special Investigations	**PHDV61**	GxPs
FDA29	Risk Management 1: Key Concepts and Definitions	**PHDV69**	Principles of Auditing
FDA31	Part 11: Electronic Records; Electronic Signatures	**PHDV70**	Effectively Responding to FDA 483s and Warning Letters
FDA32	FDA Establishment Inspection (EI)	**PHDV71**	Principles of Aseptic Processing
FDA55	Systems Based Drug Inspections	**PHDV72**	Application of GMPs to Microbiology Laboratories
ICHreg03	Documenting the Drug Development Process – ICH Q8(R2)	**PHDV73**	Orientation to GMP Compliance
PHA35	Change Control	**PHDV74**	Handling an FDA Inspection
PHA43	How to Meet Drug Retention and Stability Testing Requirements	**PHDV75**	Essentials of an Effective Calibration Program
PHA47	Understanding the Principles and Practices of Process Controls	**PHDV76**	Meeting GMP Training Requirements
PHA48	Writing and Reviewing SOPs	**PHDV80**	The Design and Development of Software Used in Automated Process Controls
PHA51	Writing Validation Protocols	**PHDV81**	Principles of Sterilization
PHA53	Batch Record Reviews	**PHDV82**	High Purity Water Systems
PHA54	Collecting Samples and Establishing Limits for Cleaning Validation	**PHDV87**	Environmental Control and Monitoring
PHA59	Failure Investigations for Pharmaceutical Manufacturers	**PHDV92**	GMP Updates: Supply Chain Quality and Emerging Compliance Concerns
PHA60	GMP Principles for Batch Records		

21 CFR 211.110 – Sampling and testing of in-process materials and drug products

Aseptic06	Media Fills for Aseptic Processing	**PHA41**	Care and Handling of Drug Product Components, Labeling, Containers, and Closures
FDA23	Sample Collection	**PHA43**	How to Meet Drug Retention and Stability Testing Requirements
ICHreg03	Documenting the Drug Development Process – ICH Q8(R2)	**PHA54**	Collecting Samples and Establishing Limits for Cleaning Validation

21 CFR 211.113 – Control of microbiological contamination

ICHreg03	Documenting the Drug Development Process – ICH Q8(R2)	**PHDV72**	Application of GMPs to Microbiology Laboratories
PHA40	DEA Compliance		

21 CFR 211.122 – Packaging and labeling control

FDA24	Recalls of FDA-Regulated Products	**PHA42**	Meeting Process Requirements for Returned and Salvaged Drug Products
FDA33	Destruction and Reconditioning	**PHA53**	Batch Record Reviews
PHA39	Packaging and Labeling of Finished Pharmaceuticals	**PHA77**	European Union Good Distribution Practices for Medicinal Products
PHA41	Care and Handling of Drug Product Components, Labeling, Containers, and Closures	**PHDV64**	Handling a Product Recall

21 CFR 211.160 – Laboratory controls, general requirements

FDA55	Systems Based Drug Inspections	**PHDV72**	Application of GMPs to Microbiology Laboratories
ICHreg04	Validation of Analytical Laboratory Procedures	**PHDV78**	Application of cGMPs to Analytical Laboratories
PHA53	Batch Record Reviews	**PHDV86**	Testing for Bacterial Endotoxins

21 CFR 211.165 – Testing and release for distribution

FDA24	Recalls of FDA-Regulated Products	**PHA77**	European Union Good Distribution Practices for Medicinal Products
FDA33	Destruction and Reconditioning	**PHDV64**	Handling a Product Recall
PHA39	Packaging and Labeling of Finished Pharmaceuticals	**PHDV78**	Application of cGMPs to Analytical Laboratories
PHA41	Care and Handling of Drug Product Components, Labeling, Containers, and Closures	**PHDV86**	Testing for Bacterial Endotoxins
PHA53	Batch Record Reviews		

21 CFR 211.166 – Stability testing

PHA41	Care and Handling of Drug Product Components, Labeling, Containers, and Closures	**PHDV86**	Testing for Bacterial Endotoxins
PHA43	How to Meet Drug Retention and Stability Testing Requirements		

21 CFR 211.180 – General records

FDA22	Evidence and Proof	**PHA54**	Collecting Samples and Establishing Limits for Cleaning Validation
FDA24	Recalls of FDA-Regulated Products	**PHA55**	Documenting Validation Activities
ICHreg04	Validation of Analytical Laboratory Procedures	**PHA59**	Failure Investigations for Pharmaceutical Manufacturers
ICHreg07	Q10 Pharmaceutical Quality System	**PHA60**	GMP Principles for Batch Records
PHA39	Packaging and Labeling of Finished Pharmaceuticals	**PHA67**	FDA Training and Qualification Requirements
PHA41	Care and Handling of Drug Product Components, Labeling, Containers, and Closures	**PHA70**	Corrective and Preventive Actions
PHA42	Meeting Process Requirements for Returned and Salvaged Drug Products	**PHA73**	Tools and Techniques for Effective CAPA Systems
PHA44	Maintenance and Cleaning of Drug Manufacturing Equipment	**PHA74**	Principles of Good Documentation
PHA48	Writing and Reviewing SOPs	**PHA76**	Role of the Qualified Person
PHA51	Writing Validation Protocols	**PHA77**	European Union Good Distribution Practices for Medicinal Products
PHA53	Batch Record Reviews		

21 CFR 211.188 – Batch production and control records

FDA33	Destruction and Reconditioning	**PHA60**	GMP Principles for Batch Records
FDA55	Systems Based Drug Inspections	**PHA73**	Tools and Techniques for Effective CAPA Systems
ICHreg07	Q10 Pharmaceutical Quality System	**PHA75**	Pre- and Post-Approval FDA Drug Inspections
PHA41	Care and Handling of Drug Product Components, Labeling, Containers, and Closures	**PHA76**	Role of the Qualified Person
PHA49	Understanding Post-Approval Changes	**PHA77**	European Union Good Distribution Practices for Medicinal Products
PHA53	Batch Record Reviews	**PHDV64**	Handling a Product Recall

21 CFR 211.192 – Production record review

FDA25	Special Investigations	**PHA72**	Risk Management in Pharmaceutical Manufacturing
ICHreg07	Q10 Pharmaceutical Quality System	**PHA73**	Tools and Techniques for Effective CAPA Systems
PHA50	Resolving Out Of Specification Test Results	**PHDV72**	Application of GMPs to Microbiology Laboratories
PHA59	Failure Investigations for Pharmaceutical Manufacturers	**PHDV78**	Application of cGMPs to Analytical Laboratories
PHA70	Corrective and Preventive Actions		