



LIBRARY GUIDE:

# Pharmaceutical GMPs

TITLES ONLY





UL Pure Learning's Good Manufacturing Practices (GMP) Library is designed for professionals in the Biotechnology and Pharmaceutical industries, and is comprised of courses that cover underlying concepts and specific, advanced global information for professionals in regulatory affairs. The global curriculum includes courses describing Food and Drug Administration (FDA) regulations, European Union (EU) directives, and International Conference on Harmonisation (ICH) guidance; many feature course content provided by the FDA.

Content is continually updated to reflect changes in these regulations. Using innovative technology, all content is fully customizable to meet the specific needs of your employees and organization.

### FDA Partnership

UL's Cooperative Research and Development Agreement (CRADA) with the FDA has enabled the FDA to meet its significant training and documentation challenge – and also resulted in course content provided or reviewed and used by the FDA itself and available to FDA-regulated Life Science companies – all delivered in a valid and 21 CFR Part 11-compliant environment. The CRADA was recently renewed through 2019 and expanded to include new technologies.

When the **FDA CRADA** symbol appears within the course description, it indicates that the content for the course was provided by the US Food and Drug Administration as a result of a CRADA between the FDA and UL.



## Courses Listed by Functional Area:

### Core Knowledge

Awareness of FDA Inspections for Pharmaceutical Manufacturers .....	PHA65
Biotechnology: An Overview of Compliance Considerations .....	PHDV68
Change Control .....	PHA35
GMPs for API Bulk Manufacturers .....	PHA52
GxPs .....	PHDV61
Introduction to GMPs .....	PHA38
Key Concepts of Process Validation .....	PHDV77
Orientation to GMP Compliance .....	PHDV73
Part 11 – Electronic Records; Electronic Signatures .....	FDA31
Principles of Good Documentation .....	PHDV65
Understanding Post-Approval Changes .....	PHA49

### Production

Care and Handling of Drug Product Components, Labeling, Containers and Closures .....	PHA41
DEA Compliance .....	PHA40
Environmental Control and Monitoring .....	PHDV87
GMP Principles for Batch Records .....	PHA60
Gowning for Sterile Manufacturers .....	PHA63
Maintenance and Cleaning of Drug Manufacturing Equipment .....	PHA44
Packaging and Labeling of Finished Pharmaceuticals .....	PHA39
Principles of Aseptic Processing .....	PHDV71
Understanding GMPs for Facilities and Equipment .....	PHDV63
Understanding the Principles and Practices of Process Controls .....	PHA47
Vendor Certification for Pharmaceutical Manufacturers .....	PHDV85

### Maintenance and Facilities

DEA Compliance .....	PHA40
Environmental Control and Monitoring .....	PHDV87
Essentials of an Effective Calibration Program .....	PHDV75
Gowning for Sterile Manufacturers .....	PHA63
High Purity Water Systems .....	PHDV82
Implementing an Equipment Qualification Program .....	PHDV88
Maintenance and Cleaning of Drug Manufacturing Equipment .....	PHA44
Understanding GMPs for Facilities and Equipment .....	PHDV63

### Warehousing & Distribution

Care and Handling of Drug Product Components, Labeling, Containers and Closures .....	PHA41
Meeting Process Requirements for Returned and Salvaged Drug Products .....	PHA42

### QC Labs

Application of GMPs to Analytical Laboratories .....	PHDV78
Application of GMPs to Microbial Laboratories .....	PHDV72
Collecting Samples and Establishing Limits for Cleaning Validation .....	PHA54
Documenting Validation Activities .....	PHA55
Environmental Control and Monitoring .....	PHDV87
Failure Investigations for Pharmaceutical Manufacturers .....	PHA59
Gowning for Sterile Manufacturers .....	PHA63
How to Meet Drug Retention and Stability Testing Requirements .....	PHA43
Principles of Aseptic Processing .....	PHDV71
Resolving Out-of-Specification Test Results .....	PHA50
Testing for Bacterial Endotoxins .....	PHDV86



## IT Validation

A Step-by-Step Approach to Process Validation .....	PHDV79
Approach to Computerized Systems Validation and Compliance .....	ISPE02
Documenting Validation Activities .....	PHA55
Implementing an Equipment Qualification Program .....	PHDV88
Part 11: Electronic Records and Signatures – Changes in Enforcement Policy .....	FDA57
Principles of Cleaning Validation .....	PHA37
Requirements for Computerized Systems Validation and Compliance .....	ISPE01
The Design and Development of Software Used in Automated Process Controls .....	PHDV80
Understanding the Principles and Practices of Process Controls .....	PHA47
Writing Validation Protocols .....	PHA51

## Management/Supervision

A Tour of the FDA .....	PHDV60
Batch Record Reviews .....	PHA53
Managing FDA Inspections for Pharmaceutical Manufacturers .....	PHA66
Meeting GMP Training Requirements .....	PHDV76
Part 11: Electronic Records; Electronic Signatures – Changes in Enforcement Policy .....	FDA57
Pre- and Post-Approval FDA Inspections .....	PHDV66
Principles of Auditing .....	PHDV69
Principles of FDA Inspections for Pharmaceutical Manufacturers .....	PHA61
Writing and Reviewing SOPs .....	PHA48

## R&D/Design Controls

Review of Basic Statistical Techniques .....	DEV44
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## QA – Manufacturing Process

Batch Record Reviews .....	PHA53
Care and Handling of Drug Product Components, Labeling, Containers, and Closures .....	PHA41
Corrective and Preventive Actions .....	PHA70
Environmental Control and Monitoring .....	PHDV87
Essentials of an Effective Calibration Program .....	PHDV75
Failure Investigations for Pharmaceutical Manufacturers .....	PHA59
Gowning for Sterile Manufacturers .....	PHA63
High Purity Water Systems .....	PHDV82
ICH Q7A: Introduction and Quality Management .....	ISPE05
ICH Q7A: Resources and Materials Management .....	ISPE06
Implementing an Equipment Qualification Program .....	PHDV88
Maintenance and Cleaning of Drug Manufacturing Equipment .....	PHA44
Packaging and Labeling of Finished Pharmaceuticals .....	PHA39
Principles of Aseptic Processing .....	PHDV71
Principles of Auditing .....	PHDV69
Understanding GMPs for Facilities and Equipment .....	PHDV63
Understanding the Principles and Practices of Process Controls .....	PHA47
Vendor Certification for Pharmaceutical Manufacturers .....	PHDV85

## QA – Validation

A Step-by-Step Approach to Process Validation .....	PHDV79
Approach to Computerized Systems Validation and Compliance .....	ISPE02
Documenting Validation Activities .....	PHA55
Implementing an Equipment Qualification Program .....	PHDV88
Part 11: Electronic Records and Signatures – Changes in Enforcement Policy .....	FDA57
Principles of Cleaning Validation .....	PHA37
Requirements for Computerized Systems Validation and Compliance .....	ISPE01
The Design and Development of Software Used in Automated Process Controls .....	PHDV80
Understanding the Principles and Practices of Process Controls .....	PHA47
Writing Validation Protocols .....	PHA51

## Inspections

Handling an FDA Inspection .....	PHDV74
Managing FDA Inspections for Pharmaceutical Interviewing Techniques .....	FDA27
Manufacturers .....	PHA66
Pre- and Post-Approval FDA Inspections .....	PHDV66
Principles of FDA Inspections for Pharmaceutical Manufacturers .....	PHA61

## QA – Compliance

A Tour of the FDA .....	PHDV60
Batch Record Reviews .....	PHA53
DEA Compliance .....	PHA40
Effectively Responding to FDA 483s and Warning Letters .....	PHDV70
Handling a Product Recall .....	PHDV64
Part 11: Electronic Records and Signatures – Changes in Enforcement Policy .....	FDA57
Principles of Auditing .....	PHDV69
Managing FDA Inspections for Pharmaceutical Manufacturers .....	PHA66
Meeting GMP Training Requirements .....	PHDV76
Meeting Process Requirements for Returned and Salvaged Drug Products .....	PHA42
Vendor Certification for Pharmaceutical Manufacturers .....	PHDV85
Writing and Reviewing SOPs .....	PHA48

## QA – Quality Systems

Conducting Annual Product Reviews .....	PHA45
FDA Training and Qualification Requirements .....	PHA67
How to Meet Drug Retention and Stability Testing Requirements .....	PHA43
Meeting GMP Training Requirements .....	PHDV76
Risk Management in Pharmaceutical Manufacturing .....	PHA72
Writing and Reviewing SOPs .....	PHA48

## Combination Products

cGMP's for Combination Products .....	PHDV93
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## About UL Pure Learning

Since 1980, UL PURE Learning has been providing computer-based instruction, compliance management solutions, and advisory services to corporate and government customers with a strong focus on the needs of Life Sciences, Health Care, Energy, and Industrial sectors. Currently, more than one million active users around the world rely on our technology and courses, recording over 20 million training item completions annually.

Our unique partnership with the FDA provides online training tools to train and certify more than 35,000 federal, state, local and global FDA investigators in the areas of quality and compliance. UL and the FDA jointly develop content and deliver it via ComplianceWire.

PURE Learning is a part of UL, a premier global independent safety science company that has championed progress for 120 years. Its more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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