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INDEX

Aseptic Processing Library

Aseptic Library	Available Languages
Basics of Cleanroom Operations (Aseptic01)	English
Sterile Dosage Forms Introduction (Aseptic02)	English
Principles of Restricted Access Barrier Systems and Isolators (Aseptic03)	English
Isolators for Aseptic Processing (Aspetic04)	English
RABS for Aseptic Processing (Aseptic05)	English
Media Fills for Aseptic Processing (Aseptic06)	English
Dos and Don'ts of Aseptic Environments (Aseptic07)	English
Cleanroom Cleaning, Sanitization, and Disinfection (Aseptic08)	English
Principles of Aseptic Processing (PHDV71)	English, Chinese Simplified

Clinical: Medical Device Library

Clinical: Medical Device Library	Available Languages
Overview of FDA's Bioresearch Monitoring Program (BIMO01)	English, Chinese Simplified
GCP/ICH Obligations of Sponsors, Monitors, and Investigators (GCP01)	English, Chinese Simplified
Obligations of Investigators in Conducting Medical Device Trials (GCP03)	English
GCP/ICH Obligations of Sponsors and Monitors (GCP04)	English, Chinese Simplified, Japanese
HIPAA — The Impact On Clinical Research (GCP05)	English, Chinese Simplified
Ethics as the Foundation to Clinical Research (GCP10)	English
Overview of the Clinical Research Process (GCP11)	English, Chinese Simplified
Selecting and Managing Clinical Contract Research Organizations (CROs)(GCP12)	English
Informed Consent (GCP13)	English, Chinese Simplified
Ethical Review Boards (GCP14)	English
European Union Clinical Trial Regulation (GCP16)	English
The Role of the Clinical Research Associate (GCP17)	English
The Role of the Clinical Research Coordinator (GCP18)	English
Medical Device Safety Reporting (GCP19)	English
ISO 14155: Obligations of Sponsors and Monitors (GCP20)	English, Chinese Simplified
Clinical Trial Audits and Consequences of Noncompliance (GCP21)	English, Chinese Simplified

INDEX

Clinical: Medical Device Library	Available Languages
Aspects of Regulatory History (GCP22)	English, Chinese Simplified
Financial Disclosure by Clinical Investigators (GCP24)	English
Laboratory Specimens for Clinical Research (GCP25)	English
Administrative Roles of the Clinical Research Associate (GCP26)	English
Administrative Roles of the Clinical Research Coordinator (GCP27)	English
The Clinical Development Process: Investigational Product, Plan, and Data Management (GCP28)	English
Recruitment and Retention of Study Patients (GCP29)	English
ISO 14155: Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice (GCP30)	English, Chinese Simplified, Korean
Good Clinical Practices (GCPs) for New Product Investigations (PHA36)	English, Chinese Simplified
Protection of Human Subjects in Clinical Trials (PHA46)	English, Chinese Simplified
A Tour of FDA (PHDV60)	English, Chinese Simplified, Portuguese (Brazil)
GxPs (PHDV61)	English, Chinese Simplified
A Tour of Health Canada (PHDV89)	English, French (Canadian)

Clinical: Pharmaceutical Library

Clinical: Pharmaceutical Library	Available Languages
Overview of FDA's Bioresearch Monitoring Program (BIMO01)	English, Chinese Simplified
GCP/ICH Obligations of Sponsors, Monitors, and Investigators (GCP01)	English, Chinese Simplified
GCP/ICH Obligations of Investigators Conducting Clinical Trials (GCP02)	English, Chinese Simplified, Japanese
GCP/ICH Obligations of Sponsors and Monitors (GCP04)	English, Chinese Simplified, Japanese
HIPAA — The Impact On Clinical Research (GCP05)	English, Chinese Simplified
Overview of the Preparation Requirements for the ICH Common Technical Document (GCP06)	English
Ethics as the Foundation to Clinical Research (GCP10)	English
Overview of the Clinical Research Process (GCP11)	English, Chinese Simplified
Selecting and Managing Clinical Contract Research Organizations (CROs)(GCP12)	English
Informed Consent (GCP13)	English, Chinese Simplified
Ethical Review Boards (GCP14)	English
Drug Safety and Adverse Event Reporting (GCP15)	English, Chinese Simplified, Japanese

INDEX

Clinical: Pharmaceutical Library	Available Languages
European Union Clinical Trial Regulation (GCP16)	English
The Role of the Clinical Research Associate (GCP17)	English
The Role of the Clinical Research Coordinator (GCP18)	English
Clinical Trial Audits and Consequences of Noncompliance (GCP21)	English, Chinese Simplified
Aspects of Regulatory History (GCP22)	English, Chinese Simplified
Investigational Product Development (GCP23)	English
Financial Disclosure by Clinical Investigators (GCP24)	English
Laboratory Specimens for Clinical Research (GCP25)	English
Administrative Roles of the Clinical Research Associate (GCP26)	English
Administrative Roles of the Clinical Research Coordinator (GCP27)	English
The Clinical Development Process: Investigational Product, Plan, and Data Management (GCP28)	English
Recruitment and Retention of Study Patients (GCP29)	English
Good Clinical Practices (GCPs) for New Product Investigations (PHA36)	English, Chinese Simplified
Protection of Human Subjects in Clinical Trials (PHA46)	English, Chinese Simplified
A Tour of FDA (PHDV60)	English, Chinese Simplified, Portuguese (Brazil)
GxPs (PHDV61)	English, Chinese Simplified
A Tour of Health Canada (PHDV89)	English, French (Canadian)

Data Integrity Library

Data Integrity Library	Available Languages
Introduction to Data Integrity (DATA01)	English, Chinese Simplified, Spanish (Spain)
Auditing of Computer System Validation to Ensure Data Integrity (DATA02)	English, Chinese Simplified
Data Integrity: The Role of Quality Assurance for Data Integrity (DATA03)	English, Chinese Simplified
Data Integrity for Quality Control Laboratories (DATA04)	English, Chinese Simplified, Spanish (Spain)
Data Integrity for Clinical Research Staff (DATA05)	English, Chinese Simplified

INDEX

Dietary Supplements Library

Dietary Supplements Library	Available Languages
Dietary Supplements - Packaging, Labeling, Holding, and Distribution (Dietary01)	English
Dietary Supplements - Introduction to Part 111 cGMPs (Dietary02)	English
Dietary Supplements - cGMPS for Manufacturing Facilities and Equipment (Dietary03)	English
Dietary Supplements - Production and Process Control System for Manufacturing Operations (Dietary04)	English
Dietary Supplements - cGMP Requirements for Quality Control (Dietary05)	English
Dietary Supplements - Requirements for Records and Recordkeeping (Dietary06)	English

EHS for Life Science - Basics Library

EHS for Life Science - Basics Library	Available Languages
Access to Employee Exposure and Medical Records (EHS01)	English
Asbestos Awareness (EHS04)	English
Basic Radiation Awareness (EHS05)	English
Benzene (EHS07)	English
Bloodborne Pathogens - General Industry (EHS08)	English, French (European), German, Spanish (Latin American)
Bloodborne Pathogens - Healthcare Workers (EHS09)	English, Chinese Simplified, French (European), German, Japanese, Spanish (Latin American)
Toxic Substance Control Act (TSCA) Reporting (EHS102)	English
Tuberculosis: Exposure Prevention and Control (EHS103)	English
Welding Safety (EHS06)	English
Driver Safety Program (DSP)(EHS110)	English
DOT Hazardous Materials Training -- Carrier Requirements (Highway) (EHS112)	English
DOT Hazardous Materials Training - Carrier Requirements (Air) (EHS114)	English
DOT Hazardous Materials Training - Security Awareness (EHS115)	English
Flammable Liquids (EHS12)	English
Handling Compressed Gases (EHS13)	English
Computer Workstation Safety (EHS14)	English
Confined Space Entry (EHS15)	English
DOT Employee Drug and Alcohol Awareness (EHS17)	English
DOT Hazardous Materials Training - General Awareness (EHS18)	English
DOT Hazardous Materials Training - Shipping Papers (EHS22)	English
Electrical Safety (EHS23)	English

INDEX

EHS for Life Science - Basics Library	Available Languages
Emergency Preparedness for Healthcare Workers (EHS24)	English
EPA Inspections (EHS25)	English
Fall Protection (EHS27)	English
Fire Extinguishers (EHS29)	English, German, Spanish (Latin American)
Fire Prevention (EHS30)	English
Fire Safety for Healthcare Workers (EHS31)	English, Spanish (Latin American)
Workplace Ergonomics: Factors to Prevent Injury (EHS33)	English
Forklift Safety (EHS34)	English
Hazard Communication (EHS37)	English, German, Spanish (Latin American)
Hazardous Waste Determination (EHS38)	English
Hazardous Waste Disposal (EHS39)	English
Hazardous Waste Drum Management (EHS40)	English
Uniform Hazardous Waste Manifest Completion (EHS41)	English
HAZWOPER Awareness (EHS42)	English
Heat Stress (EHS44)	English
Hoists and Rigging (EHS46)	English
Hot Work (EHS47)	English
Hydrogen Sulfide (H2S) (EHS48)	English
Infection Prevention and Control (EHS50)	English
Environmental Management Systems (EHS51)	English
Guidelines of Workplace Safety (EHS53)	English
Ladder Safety (EHS55)	English
Lead (EHS56)	English
Lockout/Tagout - Affected (EHS57)	English
Lockout/Tagout - Authorized (EHS58)	English
Office Safety (EHS65)	English
Personal Protective Equipment (EHS67)	English
PPE Assessment (EHS68)	English
Process Gauge Radiation (EHS69)	English
Safety Signs and Color Codes (EHS92)	English
Scaffold Safety (EHS93)	English
Walking and Working Surfaces - Affected Person (EHS98)	English
Safe Driving (PHDV41)	English
Preventing Back Injuries (PHDV52)	English
Laboratory Safety (PHDV67)	English, Chinese Simplified

INDEX

Ethics & Corporate Responsibilities Library

Ethics & Corporate Responsibilities Library	Available Languages
General Data Protection Regulation (DP01)	English, French (European), German, Spanish (Spain)
Active Listening Skills (EHS02)	English, Chinese Simplified
Computer Workstation Safety (EHS14)	English
Guidelines of Workplace Safety (EHS53)	English
Managing Conflict (EHS62)	English
Office Safety (EHS65)	English
Personal Leadership Power (EHS66)	English
Self-Motivation (EHS94)	English
Overcoming Negativity in the Workplace (EHS95)	English
Doing the Right Thing for Customers and Business Partners (ETHICS03)	English
Sarbanes-Oxley Act: An Overview (ETHICS07)	English
Doing the Right Thing: Anti-Bribery (ETHICS09	English
Handling Confidential Information (ETHICS10)	English, Chinese Simplified
Recognizing and Avoiding Conflicts of Interest (ETHICS11)	English, Chinese Simplified, Portuguese (Brazil)
Safeguarding Intellectual Property (ETHICS12)	English
Detecting and Preventing Fraud (ETHICS13)	English, Chinese Simplified, French (European), Italian, Japanese, Spanish (Latin American)
Global Anti-Bribery (ETHICS14)	English, Chinese Simplified, French (European), German, Italian, Japanese, Portuguese (Brazil), Spanish (Latin American), Spanish (Spain), Turkish
Privacy and Data Protection (ETHICS15)	English, Chinese Simplified, Portuguese (Brazil)
Foreign Corrupt Practices Act (FCPA) (ETHICS16)	English, Chinese Simplified, French (European), German, Japanese, Portuguese (Brazil), Spanish (Spain)
Making Ethical Decisions (ETHICS17)	English
Preventing Sexual Harassment (Ethics18)	English
Discrimination and Harassment Free Workplace (ETHICS19)	English
Email and Corporate Communications (ETHICS20)	English
Physical and Network Security (ETHICS21)	English, Chinese Simplified
Global Fair Competition Laws (ETHICS22)	English, Chinese Simplified, French (European), German, Portuguese (Brazil), Spanish (Spain)
Recognizing and Avoiding Insider Trading (ETHICS23)	English
Accurate Company Records (ETHICS24)	English
Work Secure: Security Measures for Employees (ETHICS25)	English
Doing Business with the USGovernment (ETHICS26)	English
US Trade Controls (ETHICS27)	English
Trade Secrets (ETHICS28)	English

INDEX

Ethics & Corporate Responsibilities Library	Available Languages
HIPAA: General Awareness (HIPAA01)	English
Age Discrimination (LAV01)	English
Affirmative Action in the Workplace (For Employers) (LAV02)	English
Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA) (LAV03)	English
Hiring and Firing (LAV04)	English
Diversity and Inclusion in the Workplace (LAV05)	English
Americans with Disabilities Act (LAV07)	English
Sexual Harassment Awareness for Employees (LAV08)	English
Sexual Harassment Awareness for Managers (LAV09)	English
Substance Abuse (LAV10)	English
Violence in the Workplace (LAV11)	English
Code of Business Conduct (LAV15)	English
Confidentiality, Intellectual Property Protection, and Information Security (LAV19)	English
Harassment in the Workplace (LAV21)	English
Harassment Avoidance Training for California (LAV22)	English, Spanish (Latin American)
Sexual Harassment Awareness for New York Employees and Supervisors (LAV23)	English, Spanish (Latin American)
Sexual Harassment Awareness for California Employees (LAV24)	English, Spanish (Latin American)
Sexual Harassment Awareness for California Employees (LAV24)	English
Sexual Harassment Awareness for Employees and Supervisors (All States except California) (LAV25)	English

FDA BIMO Library	Available Languages
Overview of FDA's Bioresearch Monitoring Program (BIMO01)	English, Chinese Simplified
BIMO: General Inspection Assignment Process (BIMO02)	English, Chinese Simplified
BIMO: BIMO: Parts 50 & 56 - Protection of Human Subjects and Institutional Review Boards (IRBs) (BIMO03)	English, Chinese Simplified
BIMO: Clinical Investigator (CI) Responsibilities (BIMO04)	English, Chinese Simplified
BIMO: Sponsor/Monitor Responsibilities (BIMO05)	English, Chinese Simplified
BIMO: In Vitro Bioequivalence Program Part I (BIMO06)	English, Chinese Simplified
BIMO: In Vivo Bioequivalence Program Part II (BIMO07)	English, Chinese Simplified

INDEX

FDA Inspection and Enforcement Library

FDA Inspection and Enforcement Library	Available Languages
Quality Systems Inspection Technique (QSIT) (DEV42)	English, Chinese Simplified, Korean
Introduction to the Quality System (QS) Regulation (DEV43)	English, Chinese Simplified, French (European), Korean
Failure Investigations for Medical Device Manufacturers (DEV45)	English, Chinese Simplified, Korean
Computerized Systems Inspections in the Medical Device Industry (DEV59)	English, Chinese Simplified, Korean
A Guide to ISO 9001:2015 _ Quality Management Systems Requirements (DEV61)	English, Chinese Simplified, Korean
Food and Drug Law: FDA Jurisdictions (FDA01)	English, Chinese Simplified
Food and Drug Law: Prohibited Actions (FDA02)	English, Chinese Simplified
Food and Drug Law: Judicial Actions (FDA03)	English, Chinese Simplified
Food and Drug Law: Criminal Acts Violations (FDA04)	English, Chinese Simplified
Food and Drug Law: Imports and Exports (FDA05)	English, Chinese Simplified
FDA Good Guidance Practices (GGPs) (FDA21)	English, Chinese Simplified
Evidence and Proof (FDA22)	English, Chinese Simplified
Sample Collection (FDA23)	English, Chinese Simplified
Recalls of FDA-Regulated Products (FDA24)	English, Chinese Simplified
Special Investigations (FDA25)	English, Chinese Simplified
FDA Establishment Inspection Report Writing (FDA26)	English, Chinese Simplified
Interviewing Techniques (FDA27)	English, Chinese Simplified
Field Examinations (FDA28)	English, Chinese Simplified
Risk Management 1: Key Concepts and Definitions (FDA29)	English, Chinese Simplified, Korean
FDA 483s: Inspectional Observations (FDA30)	English, Chinese Simplified
Part 11: Electronic Records; Electronic Signatures (FDA31)	English, Chinese Simplified, Japanese, Korean
FDA Establishment Inspection (EI) (FDA32)	English, Chinese Simplified
Destruction and Reconditioning (FDA33)	English, Chinese Simplified
Import Operations 1: Background (FDA37)	English, Chinese Simplified, Korean
Basics of Inspections: Beginning an Inspection (FDA38)	English, Chinese Simplified
Basics of Inspections: Issues and Observations (FDA39)	English, Chinese Simplified
Import Operations 2: The Process (FDA42)	English, Chinese Simplified, Korean
Import Operations 3: Other Activities (FDA43)	English, Chinese Simplified, Korean
Courtroom Testimony (FDA46)	English, Chinese Simplified
QSIT 1 - Beginning the Inspection (FDA50)	English, Chinese Simplified
QSIT 2 - The Management Controls Subsystem (FDA51)	English, Chinese Simplified
QSIT 3 - The Design Controls Subsystem (FDA52)	English, Chinese Simplified
QSIT 4 - The Corrective and Preventive Actions Subsystem (FDA53)	English, Chinese Simplified

INDEX

FDA Inspection and Enforcement Library	Available Languages
QSIT 5 - The Production and Process Controls Subsystem (FDA54)	English, Chinese Simplified
Systems Based Drug Inspections (FDA55)	English, Chinese Simplified
Part 11: Electronic Records and Signatures - Enforcement Policy (FDA57)	English, Chinese Simplified
Part 11: Electronic Records and Signatures - Application (FDA61)	English, Chinese Simplified, Korean
MDR Regulation 1: Overview and General Provisions (FDA63)	English, Chinese Simplified, Korean
Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations (FDA64)	English, Chinese Simplified
MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements (FDA65)	English, Chinese Simplified, Korean
MDR Regulation 3: Requirements for Individual Adverse Event Reports (FDA66)	English, Chinese Simplified, Korean
Computerized Systems Inspections in the Pharmaceutical Industry (PHA81)	English, Chinese Simplified, Korean
Good Laboratory Practices (GLPs) (PHDV62)	English, Chinese Simplified
Handling an FDA Inspection (PHDV74)	English, Chinese Simplified, Korean, Spanish (Latin American)
EU Directives and Inspection Readiness (PHDV96)	English, German, Spanish (Spain)
QS Regulation 1: Overview and General Provisions (QSR01)	English, Chinese Simplified, Korean
QS Regulation 2: Quality System Requirements (QSR02)	English, Chinese Simplified, Korean
QS Regulation 3: Design Controls (QSR03)	English, Chinese Simplified, Korean
QS Regulation 4: Document and Purchasing Controls (QSR04)	English, Chinese Simplified, Korean
QS Regulation 5: Identification and Traceability; Production and Process Controls (QSR05)	English, Chinese Simplified, Korean
QS Regulation 6: Acceptance Activities; Nonconforming Product (QSR06)	English, Chinese Simplified, Korean
QS Regulation 7: Corrective and Preventive Action (QSR07)	English, Chinese Simplified, Korean
QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation (QSR08)	English, Chinese Simplified, Korean
QS Regulation 9: Records (QSR09)	English, Chinese Simplified, Korean
QS Regulation 10: Servicing; Statistical Techniques (QSR10)	English, Chinese Simplified, Korean
QS Regulation 11: Application and Inspection of QS Regulation Requirements (QSR11)	English, Chinese Simplified, Korean

INDEX

Global Regulatory Library

Global Regulatory Library	Available Languages
The Approval Process for New Medical Devices in the United States (DEV47)	English, Chinese Simplified, Korean
Medical Device Filings: 510(k), PMA, De Novo, and IDE (DEV53)	English
Global Regulatory Library Strategy and Planning Process (DEV54)	English, Chinese Simplified, Korean
Regulatory Requirements for Medical Devices in the Republic of Korea (DEV58)	English, Korean
Brazil's Technical Regulations for Medical Devices: RDC 665/2022, 67/2009, and 23/2012 (DEV63)	English, Portuguese (Brazil)
Canadian Medical Device Regulations (DEV64)	English
Overview of UKCA, UKNI, and CE Marking for Medical Devices (DEV66)	English
ICH Q7: Introduction and Quality Management (ICHreg01)	English, Chinese Simplified
ICH Q7: Resources and Materials Management (ICHreg02)	English
Documenting the Drug Development Process - ICH Q8(R2) (ICHreg03)	English
Validation of Analytical Laboratory Procedures (ICHreg04)	English
Q9: Quality Risk Management (ICHreg05)	English, Japanese
Quality Systems Approach (ICHreg06)	English
Q10 Pharmaceutical Quality System (ICHreg07)	English
EU Medical Device Regulation (MDR) (MDR01)	English, Chinese Simplified, Japanese, Korean
EU In Vitro Diagnostic Regulations (IVDR) (MDR02)	English, Chinese Simplified, Korean
CE Certification for Medical Devices (MDR03)	English, Chinese Simplified, French (European), German, Korean, Spanish (Spain)
Change Control (PHA35)	English, Chinese Simplified
Gowning for Sterile Manufacturing (PHA63)	English, Chinese Simplified
European Union Good Distribution Practices for Medicinal Products (PHA77)	English, Spanish (Spain)
European Union GMP Requirements (PHA78)	English, Chinese Simplified

INDEX

Healthcare: General Library

Healthcare: General Library	Available Languages
Bloodborne Pathogens -- Healthcare Workers (EHS09)	English, Chinese (Simplified), French (European), German, Japanese, Spanish (Latin America)
Fire Safety for Healthcare Workers (EHS31)	English, Spanish (Latin America)
Deficit Reduction Act: False Claims and Employee Protections Training (GCP01)	English
HP: Compliance Program General Session (GCP02)	English
Fraud and Abuse Awareness (GCP04)	English
Code of Conduct (GCP015)	English

HIPPA Library

HIPPA Library	Available Languages
HIPAA: General Awareness (HIPAA01)	English
HIPAA: Privacy Standards (HIPAA02)	English
Business Practices to Protect Personal Health Information (HIPAA05)	English
HIPAA Privacy: Role-Based Training I (Incidental PHI Contact) (HIPAA06)	English
HIPAA Privacy: Role-Based Training II (Internal Uses of PHI)(HIPAA07)	English
HIPAA Privacy: Role-Based Training III (Uses and Disclosures of PHI) (HIPAA08)	English
HIPAA Privacy: Role-Based Training IV (Managers, Supervisors, and Compliance Staff) (HIPAA09)	English
Information Security (HIPAA10)	English

HR Compliance & Risk Management Library

HR Compliance & Risk Management Library	Available Languages
Active Listening Skills (EHS02)	English, Chinese Simplified
Basics of Business Finance (EHS06)	English
Building Customer Loyalty (EHS11)	English
Computer Workstation Safety (EHS14)	English
Improving Productivity (EHS49)	English
Guidelines of Workplace Safety (EHS53)	English
Making Meetings Work I: Purpose and Preparation (EHS60)	English

INDEX

HR Compliance & Risk Management Library	Available Languages
Making Meetings Work II: Leadership (EHS61)	English
Managing Conflict (EHS62)	English
Managing Job Stress (EHS63)	English
Managing Transition to Teams (EHS64)	English
Office Safety (EHS65)	English
Personal Leadership Power (EHS66)	English
Self-Motivation (EHS94)	English
Overcoming Negativity in the Workplace (EHS95)	English
SMART Goal Setting (EHS99)	English
Work Secure: Security Measures for Employees (ETHICS25)	English
Age Discrimination (LAV01)	English
Affirmative Action in the Workplace (For Employers) (LAV02)	English
Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA) (LAV03)	English
Hiring and Firing (LAV04)	English
Diversity and Inclusion in the Workplace (LAV05)	English
Family and Medical Leave Act (FMLA) (LAV06)	English
Americans with Disabilities Act (LAV07)	English
Sexual Harassment Awareness for Employees (LAV08)	English
Sexual Harassment Awareness for Managers (LAV09)	English
Substance Abuse (LAV10)	English
Violence in the Workplace (LAV11)	English
Antitrust Law and Competitor Relationships (LAV14)	English
Code of Business Conduct (LAV15)	English
Confidentiality, Intellectual Property Protection, and Information Security (LAV19)	English
Harassment in the Workplace (LAV21)	English
Harassment Avoidance Training for California (LAV22)	English, Spanish (Latin American)
Sexual Harassment Awareness for New York Employees and Supervisors (LAV23)	English, Spanish (Latin American)
Sexual Harassment Awareness for California Employees (LAV24)	English, Spanish (Latin American)
Sexual Harassment Awareness for Employees and Supervisors (All States except California) (LAV25)	English

INDEX

HR Compliance & Risk Management Library	Available Languages
Affirmative Action in the Workplace (For Employers) (LAV02)	English
Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA) (LAV03)	English
Hiring and Firing (LAV04)	English
Diversity and Inclusion in the Workplace (LAV05)	English
Family and Medical Leave Act (FMLA) (LAV06)	English
Americans with Disabilities Act (LAV07)	English

MDSAP Library

MDSAP Library	Available Languages
Introduction to the Medical Device Single Audit Program (MDSAP)(DEV62)	English, French (European), German, Portuguese (Brazil), Spanish (Spain)
Australia Therapeutic Goods Administration (TGA) MDSAP Specific (MDSAP_Australia)	English
Brazil Agência Nacional de Vigilância Sanitária (ANVISA) — MDSAP Country-Specific Tasks (MDSAP_Brazil)	English
Health Canada - MDSAP Country-Specific Tasks (MDSAP_Canada)	English
Japan Ministry of Health, Labour and Welfare (MHLW) — MDSAP Country-Specific Tasks (MDSAP_Japan)	English
United States Food and Drug Administration (FDA) MDSAP Country-Specific Tasks (MDSAP_US)	English
Overview of the Medical Device Single Audit Program (MDSAP) Chapter Structure (MDSAP00)	English
MDSAP Chapter 1 Process Management (MDSAP01)	English
MDSAP Chapter 2 — Process: Device Marketing Authorization and Facility Registration (MDSAP02)	English
MDSAP Chapter 3 - Process: Measurement, Analysis, and Improvement (MDSAP03)	English
MDSAP Chapter 4 — Process: Medical Device Adverse Events and Advisory Notices (MDSAP04)	English
MDSAP Chapter 5 — Process: Design and Development (MDSAP05)	English
MDSAP Chapter 6: Process - Production and Service Controls - Part 1 (MDSAP06_01)	English
MDSAP Chapter 6: Process - Production and Service Controls - Part 2 (MDSAP06_02)	English
MDSAP Chapter 7 — Process: Purchasing (MDSAP07)	English

INDEX

Medical Device - Sales & Marketing

Medical Device - Sales & Marketing	Available Languages
Basic Radiation Awareness (EHS05)	English
Bloodborne Pathogens - Healthcare Workers (EHS09)	English, Chinese Simplified, French (European), German, Japanese, Spanish (Latin American)
HIPAA: General Awareness (HIPAA01)	English
Basics of the AdvaMed Code (MDSM01)	English, Chinese Simplified, French (European), German, Spanish (Latin American)
Reporting Adverse Events for Medical Devices (MDSM02)	English
Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) and Similar State-Level Requirements (MDSM03)	English
MedTech Europe Code of Ethical Business Practice (MDSM04)	English, Chinese Simplified, French (European), German, Spanish (European)
Introduction to Medical Device Health Care Compliance (MDSM05)	English
National Patient Safety Goals: HCIR Credentialing (MDSM07)	English
OIG Compliance Program Guidance for Medical Device Manufacturers - Field Force (OIG03)	English
Operating Room Conduct and Protocol (PHA68)	English, Chinese Simplified, Spanish (Latin American)
Physician Payment Sunshine Act (PHSM11)	English, Chinese Simplified, French (European), German
HIPAA and Privacy Guidelines for Medical Device Sales Representatives (PRIVACY01)	English
Overview of UKCA, UKNI, and CE Marking for Medical Devices (DEV66)	English

Medical Device GMPs Library

Medical Device GMPs Library	Available Languages
Design Control Regulations for Medical Device Manufacturers (DEV40)	English, Chinese Simplified
Medical Device Packaging, Labeling, and Distribution (DEV41)	English, Chinese Simplified
Introduction to the Quality System (QS) Regulation (DEV43)	English, Chinese Simplified, French (European), Korean
Review of Basic Statistical Techniques (DEV44)	English, Chinese Simplified
Failure Investigations for Medical Device Manufacturers (DEV45)	English, Chinese Simplified, Korean
Complaint Management for Medical Device Manufacturers (DEV46)	English, Chinese Simplified
An Introduction to ISO 13485 - The Quality Management System for Medical Devices (DEV48)	English, Chinese Simplified, French (European), German, Spanish (Spain)
A Guide to ISO 13485 - The Quality Management System for Medical Devices (DEV50)	English, Chinese Simplified, French (European), German, Japanese, Spanish (Spain)

INDEX

Medical Device GMPs Library	Available Languages
Medical Device Filings: 510(k), PMA, De Novo, and IDE (DEV53)	English
Global Regulatory Library Strategy and Planning Process (DEV54)	English, Chinese Simplified, Korean
ISO 14971: Risk Management for Medical Devices (DEV55)	English
Good Documentation Practices for Medical Device Manufacturers (DEV56)	English, Chinese Simplified, Japanese, Spanish (Latin American)
Computerized Systems Inspections in the Medical Device Industry (DEV59)	English, Chinese Simplified, Korean
An Introduction to ISO 9001:2015 _ The Quality Management System Requirements (DEV60)	English, Chinese Simplified, French (European), German, Spanish (Spain)
A Guide to ISO 9001:2015 _ Quality Management Systems Requirements (DEV61)	English, Chinese Simplified, Korean
Introduction to the Medical Device Single Audit Program (MDSAP) (DEV62)	English, French (European), German, Portuguese (Brazil), Spanish (Spain)
Brazil's Technical Regulations for Medical Devices: RDC 665/2022, 67/2009, and 23/2012 (DEV63)	English, Portuguese (Brazil)
Canadian Medical Device Regulations (DEV64)	English
cGMP Refresher: Medical Device Quality System and Quality Culture (DEV65)	English, Chinese Simplified
Overview of UKCA, UKNI, and CE Marking for Medical Devices (DEV66)	English
EU Medical Device Regulation (MDR)(MDR01)	English, Chinese Simplified, Japanese, Korean
EU In Vitro Diagnostic Regulations (IVDR) (MDR02)	English, Chinese Simplified, Korean
CE Certification for Medical Devices (MDR03)	English, Chinese Simplified, French (European), German, Korean, Spanish (Spain)
Change Control (PHA35)	English, Chinese Simplified
Introduction to cGMPs (PHA38)	English, Chinese Simplified, French (European), German, Japanese, Portuguese (Brazil), Spanish (Spain)
Care and Handling of Drug Product Components, Labeling, Containers, and Closures (PHA41)	English, Chinese Simplified
Conducting Annual Product Reviews (PHA45)	English, Chinese Simplified
Understanding the Principles and Practices of Process Controls (PHA47)	English, Chinese Simplified, Japanese
Writing and Reviewing SOPs (PHA48)	English, Chinese Simplified
Understanding Post-Approval Changes (PHA49)	English
Resolving Out Of Specification Test Results (PHA50)	English, Chinese Simplified
Writing Validation Protocols (PHA51)	English, Chinese Simplified
Batch Record Reviews (PHA53)	English, Chinese Simplified
Documenting Validation Activities (PHA55)	English, Chinese Simplified
GMP Principles for Batch Records (PHA60)	English, Chinese Simplified
Gowning for Sterile Manufacturing (PHA63)	English, Chinese Simplified

INDEX

Medical Device GMPs Library	Available Languages
GMP Principles of SOPs (PHA64)	English, Chinese Simplified, Korean
FDA Training and Qualification Requirements (PHA67)	English, Chinese Simplified, Korean
Role of the Qualified Person (PHA76)	English
European Union Good Distribution Practices for Medicinal Products (PHA77)	English, Spanish (Spain)
European Union GMP Requirements (PHA78)	English, Chinese Simplified
Management Responsibility for Quality: What FDA Expects (PHDV101)	English, Chinese Simplified
Requirements for Computerized Systems Validation and Compliance (PHDV102)	English, Chinese Simplified, Korean
Approach to Computerized Systems Validation and Compliance (PHDV103)	English, Chinese Simplified, Japanese, Korean
Australian Therapeutic Goods _ Medical Device Regulations Overview (PHDV105)	English
A Tour of FDA (PHDV60)	English, Chinese Simplified, Portuguese (Brazil)
Good Laboratory Practices (GLPs) (PHDV62)	English, Chinese Simplified
Understanding GMPs for Facilities and Equipment (PHDV63)	English, Chinese Simplified
Handling a Product Recall (PHDV64)	English, Chinese Simplified, Korean
Principles of Auditing (PHDV69)	English, Chinese Simplified, Korean
Effectively Responding to FDA 483s and Warning Letters (PHDV70)	English, Chinese Simplified, Japanese
Principles of Aseptic Processing (PHDV71)	English, Chinese Simplified
Orientation to GMP Compliance (PHDV73)	English, Chinese Simplified, Spanish (Latin American)
Handling an FDA Inspection (PHDV74)	English, Chinese Simplified, Korean, Spanish (Latin American)
Essentials of an Effective Calibration Program (PHDV75)	English, Chinese Simplified, Korean
Meeting GMP Training Requirements (PHDV76)	English, Chinese Simplified
Key Concepts of Process Validation (PHDV77)	English, Chinese Simplified
Application of cGMPs to Analytical Laboratories (PHDV78)	English, Chinese Simplified, Spanish (Spain)
A Step-by-Step Approach to Process Validation (PHDV79)	English, Chinese Simplified, Korean
The Design and Development of Software Used in Automated Process Controls (PHDV80)	English, Chinese Simplified
Principles of Sterilization (PHDV81)	English, Chinese Simplified
High Purity Water Systems (PHDV82)	English, Chinese Simplified
Pharmaceutical and Medical Device Supplier Quality Management (PHDV85)	English, Chinese Simplified
Testing for Bacterial Endotoxins (PHDV86)	English
Environmental Control and Monitoring (PHDV87)	English, Chinese Simplified, Korean
Implementing an Equipment Qualification Program (PHDV88)	English, Chinese Simplified
GMP Updates: Supply Chain Quality and Emerging Compliance Concerns (PHDV92)	English, Chinese Simplified

INDEX

Medical Device GMPs Library	Available Languages
Combination Products - cGMP Requirements (PHDV93)	English, Chinese Simplified
QS Regulation 1: Overview and General Provisions (QSR01)	English, Chinese Simplified, Korean
QS Regulation 2: Quality System Requirements (QSR02)	English, Chinese Simplified, Korean
QS Regulation 3: Design Controls (QSR03)	English, Chinese Simplified, Korean
QS Regulation 4: Document and Purchasing Controls (QSR04)	English, Chinese Simplified, Korean
QS Regulation 5: Identification and Traceability; Production and Process Controls (QSR05)	English, Chinese Simplified, Korean
QS Regulation 6: Acceptance Activities; Nonconforming Product (QSR06)	English, Chinese Simplified, Korean
QS Regulation 7: Corrective and Preventive Action (QSR07)	English, Chinese Simplified, Korean
QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation (QSR08)	English, Chinese Simplified, Korean
QS Regulation 9: Records (QSR09)	English, Chinese Simplified, Korean
QS Regulation 10: Servicing; Statistical Techniques (QSR10)	English, Chinese Simplified, Korean
QS Regulation 11: Application and Inspection of QS Regulation Requirements (QSR11)	English, Chinese Simplified, Korean

Medicare Advantage Library

Medicare Advantage Library	Available Languages
Medicare Advantage: Administration and Management (MA27)	English
Medicare Advantage: Membership Services (MA28)	English
Medicare Advantage: Overview of the Medicare Program (MA29)	English
Medicare Advantage: Provider Compliance (MA34)	English
MAPD: Risk Adjustment and Data Validation (MA35)	English
Medicare Advantage: Plan Benefit Package and Bid Pricing Tool (MA36)	English
Medicare Advantage: Claims Processing (MA38)	English
Medicare Advantage: Provider Networks (MA40)	English
Medicare Advantage: Quality Management and Utilization Management (MA41)	English
Medicare Advantage Health Plan and PDP: Fraud, Waste, and Abuse (MAPD01)	English

INDEX

Medicare Advantage Library	Available Languages
MAPD: Enrollment (MAPD02)	English
MAPD/PDP: Communications and Marketing (MAPD03)	English
MAO/PDP: Compliance Program Guidelines (MAPD04)	English
Special Needs Plans: Model of Care (MAPD05)	English
MAPD: Disenrollment (MAPD06)	English

Medicare Broker/Agent Training Library

Medicare Broker/Agent Training Library	Available Languages
Medicare Plan: Broker and Agent Training - Broker/Agent Requirements (MSales01)	English
Medicare Plan: Broker and Agent Training - Medicare Basics (MSales02)	English
Medicare Advantage and Part D Plan: Broker and Agent Training -- MA-PD, PDP, and Cost Plan Enrollment and Disenrollment (MSales03)	English
Medicare Plan: Broker and Agent Training - Beneficiary Protections (MSales04)	English
Medicare Plan: Broker and Agent Training - Marketing Communication and Compensation (MSales05)	English
Medicare Plan Broker and Agent Training Exam (MSales06)	English

Medicare Part D Library

Medicare Part D Library	Available Languages
Medicare Advantage (Part C) and Part D Grievances (MAPARTD01)	English
Parts C and D Coverage Decisions (MAPARTD02)	English
Parts C and D Appeals (MAPARTD03)	English
Medicare Advantage Health Plan and PDP: Fraud, Waste, and Abuse (MAPD01)	English
MAPD: Enrollment (MAPD012)	English
MAPD/PDP: Communications and Marketing (MAPD03)	English
MAO/PDP: Compliance Program Guidelines (MAPD04)	English
Special Needs Plans: Model of Care (MAPD05)	English
MAPD: Disenrollment (MAPD06)	English
Medicare Part D: Administration and Management (PARTD01)	English

INDEX

Medicare Part D Library	Available Languages
Medicare Part D: Bid Pricing Tool and Plan Benefit Package (PARTD03)	English
Medicare Part D: PDP Enrollment (PARTD05)	English
Medicare Part D: Pharmacy Network (PARTD07)	English
Medicare Part D: Medication Therapy Management and Quality Improvement Program (PARTD08)	English
Medicare Part D: Coordination of Benefits and True Out-of-Pocket Facilitation (PARTD10)	English
Medicare Part D: PDP Disenrollment and Transaction Processing (PARTD11)	English

Pharmaceutical - Sales & Marketing Library

Pharmaceutical - Sales & Marketing Library	Available Languages
Bloodborne Pathogens - Healthcare Workers (EHS09)	English, Chinese Simplified, French (European), German, Japanese, Spanish (Latin American)
HIPAA: General Awareness (HIPAA01)	English
Basics of PhRMA Code (PHSM01)	English
Contracting with and Providing Medical Education for Healthcare Professionals (PHSM03)	English
Promotion of Pharmaceutical Products - In House (PHSM04)	English
Promotion of Pharmaceutical Products - Field Facing (PHSM05)	English
Interactions with Healthcare Professionals - In-House (PHSM06)	English
Interactions with Healthcare Professionals - Field (PHSM07)	English
Postmarketing Reporting of Adverse Drug Experiences (PHSM08)	English
Introduction to Pharmaceutical Compliance (PHSM09)	English
Introduction to the Regulation of Prescription Drug and Biologic Promotions (PHSM10)	English
Physician Payment Sunshine Act (PHSM11)	English, Chinese Simplified, French (European), German
HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives (PRIVACY02)	English

INDEX

Pharmaceutical GMPs Library

Pharmaceutical GMPs Library	Available Languages
Review of Basic Statistical Techniques (DEV44)	English, Chinese Simplified
Interviewing Techniques (FDA27)	English, Chinese Simplified
ICH Q7: Introduction and Quality Management (ICHreg01)	English, Chinese Simplified
ICH Q7: Resources and Materials Management (ICHreg02)	English
Change Control (PHA35)	English, Chinese Simplified
Principles of Cleaning Validation (PHA37)	English
Introduction to cGMPs (PHA38)	English, Chinese Simplified, French (European), German, Japanese, Portuguese (Brazil), Spanish (Spain)
Packaging and Labeling of Finished Pharmaceuticals (PHA39)	English, Chinese Simplified
DEA Compliance (PHA40)	English, Chinese Simplified
Care and Handling of Drug Product Components, Labeling, Containers, and Closures (PHA41)	English, Chinese Simplified
Meeting Process Requirements for Returned and Salvaged Drug Products (PHA42)	English, Chinese Simplified
How to Meet Drug Retention and Stability Testing Requirements (PHA43)	English, Chinese Simplified
Maintenance and Cleaning of Drug Manufacturing Equipment (PHA44)	English, Chinese Simplified, Japanese
Conducting Annual Product Reviews (PHA45)	English, Chinese Simplified
Understanding the Principles and Practices of Process Controls (PHA47)	English, Chinese Simplified, Japanese
Writing and Reviewing SOPs (PHA48)	English, Chinese Simplified
Understanding Post-Approval Changes (PHA49)	English
Resolving Out Of Specification Test Results (PHA50)	English, Chinese Simplified
Writing Validation Protocols (PHA51)	English, Chinese Simplified
Batch Record Reviews (PHA53)	English, Chinese Simplified
Collecting Samples and Establishing Limits for Cleaning Validation (PHA54)	English, Chinese Simplified
Documenting Validation Activities (PHA55)	English, Chinese Simplified
Failure Investigations for Pharmaceutical Manufacturers (PHA59)	English, Chinese Simplified, Spanish (Spain)
GMP Principles for Batch Records (PHA60)	English, Chinese Simplified
Gowning for Sterile Manufacturing (PHA63)	English, Chinese Simplified
GMP Principles of SOPs (PHA64)	English, Chinese Simplified, Korean
Awareness of FDA Inspections for Pharmaceutical Manufacturers (PHA65)	English, Chinese Simplified
FDA Training and Qualification Requirements (PHA67)	English, Chinese Simplified, Korean
Corrective and Preventive Actions (PHA70)	English, Chinese Simplified
Complaint Management for Pharmaceutical Manufacturers (PHA71)	English

INDEX

Pharmaceutical GMPs Library	Available Languages
Risk Management in Pharmaceutical Manufacturing (PHA72)	English
Tools and Techniques for Effective CAPA Systems (PHA73)	English
Principles of Good Documentation (PHA74)	English, Chinese Simplified, Japanese, Spanish (Latin American)
Pre- and Post-Approval FDA Drug Inspections (PHA75)	English, Chinese Simplified, Korean
Role of the Qualified Person (PHA76)	English
cGMP Refresher: Pharmaceutical Quality System and Quality Culture (PHA82)	English, Chinese Simplified, French (European), German, Japanese, Portuguese (Brazil), Spanish (Latin American)
Industry 4.0 for Pharmaceutical Manufacturing (PHA83)	English
Management Responsibility for Quality: What FDA Expects (PHDV101)	English, Chinese Simplified
Requirements for Computerized Systems Validation and Compliance (PHDV102)	English, Chinese Simplified, Korean
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A Tour of FDA (PHDV60)	English, Chinese Simplified, Portuguese (Brazil)
GxPs (PHDV61)	English, Chinese Simplified
Good Laboratory Practices (GLPs) (PHDV62)	English, Chinese Simplified
Understanding GMPs for Facilities and Equipment (PHDV63)	English, Chinese Simplified, Spanish (European)
Handling a Product Recall (PHDV64)	English, Chinese Simplified, Korean
Biotechnology: An Overview of Compliance Considerations (PHDV68)	English, Chinese Simplified
Principles of Auditing (PHDV69)	English, Chinese Simplified, Korean
Effectively Responding to FDA 483s and Warning Letters (PHDV70)	English, Chinese Simplified, Japanese
Principles of Aseptic Processing (PHDV71)	English, Chinese Simplified
Application of GMPs to Microbiology Laboratories (PHDV72)	English, Chinese Simplified, French (European)
Orientation to GMP Compliance (PHDV73)	English, Chinese Simplified, Spanish (Spain)
Handling an FDA Inspection (PHDV74)	English, Chinese Simplified, Spanish (Latin American)
Essentials of an Effective Calibration Program (PHDV75)	English, Chinese Simplified, Korean
Meeting GMP Training Requirements (PHDV76)	English, Chinese Simplified
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The Design and Development of Software Used in Automated Process Controls (PHDV80)	English, Chinese Simplified
Principles of Sterilization (PHDV81)	English, Chinese Simplified

INDEX

Pharmaceutical GMPs Library	Available Languages
High Purity Water Systems (PHDV82)	English, Chinese Simplified
Pharmaceutical and Medical Device Supplier Quality Management (PHDV85)	English, Chinese Simplified
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GMP Updates: Supply Chain Quality and Emerging Compliance Concerns (PHDV92)	English, Chinese Simplified
Combination Products - cGMP Requirements (PHDV93)	English, Chinese Simplified
European Union GMP Requirements for Computerised Systems (PHDV95)	English

PPACA Library

PPACA Library	Available Languages
Introduction to Medicaid (PPACA03)	English
Section 1557 of the Affordable Care Act (PPACA04)	English

Pharmacovigilance Library

Pharmacovigilance Library	Available Languages
Drug Safety and Pharmacovigilance: Assessing (PCV01_A)	English
Drug Safety and Pharmacovigilance: Reporting (PCV01_B)	English
Pharmacovigilance: Global Requirements — Regulations and Guidance (PCV02_A)	English
Pharmacovigilance: Global Requirements — Systems (PCV02_B)	English
Pharmacovigilance Audit and Inspection: Preparation (PCV03_A)	English
Pharmacovigilance Audit and Inspection: Dos and Don'ts (PCV03_B)	English
Assessing Data: Pharmacovigilance Signaling (PCV04_A)	English
Assessing Data: Data Mining and Risk Management (PCV04_B)	English
Device Safety and Vigilance: Assessing (PCV05_A)	English
Device Safety and Vigilance: Reporting (PCV05_B)	English

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INDEX

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