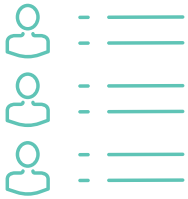
LIFE SCIENCE
TRAINING INSTITUTE

COURSE CATALOG

The Life Science Training Institute helps pharmaceutical, biotech, and medical device companies build knowledgeable, compliant workforces by providing training from drug discovery through commercialization. We are dedicated to advancing careers of those working to develop new therapies and to protect patient safety.

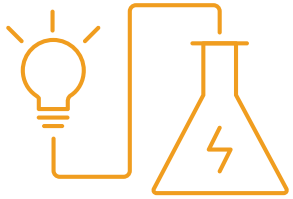
CLINICAL



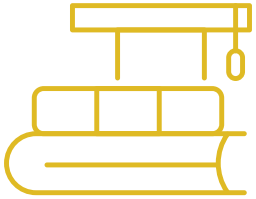
MANUFACTURING

REGULATORY & COMPLIANCE

RESEARCH & DEVELOPMENT



TRAINING & LEADERSHIP



LIFE SCIENCE TRAINING INSTITUTE

CLINICAL

The Investigator Meeting: Why Your Trial Will Succeed or Fail

Change Management Plan Development for Risk-Based Clinical Studies - From Site Monitoring to Vendor Management and Beyond

Leveraging Technology for Risk-Based Monitoring from Small Start-ups to Large Organizations

Clinical Regulatory Document Management Compliance Professional (CRDMCP)

Regulated Clinical Documentation And Content Purpose - Proper Handling And Metadata

Electronic Informed Consent: New Guidance-Implications & Implementation

It's Ten O'Clock...Do You Know Where Your Trial Master File Is?

Pediatric Clinical Trials - Special Considerations and Requirements

New FDA Draft Guidance: eCTD Is Coming to Promotional Submissions... Are You Ready

New Pharma Compliant Google Ad Formats: Implementation Tips For Success

Preparing eCTD Submissions - A Step-By-Step Guide

FDAs Mandate Requiring Conformance to SEND and SDTM for Pharma Submissions - What is the Vision?

Surviving a FDA GCP Inspection - Preparation Techniques for Success

Clinical Finance: Key Strategies to Stay in Control of Your Study Budget

The Power of Influencing - Achieving Patient-focused Outcomes to Guarantee Success

Five Critical Steps To a Executing a Successful Medical Device Clinical Strategy - Compliant Trial Design That Works

Partnership Strategies with CROs & Vendors - Create Relationships that Create Results

Strategic Clinical Project Management: Principles and Practical Applications

Medical Applications in 3-D Printing - Clinical Benefits Regulatory Issues & Manufacturing Challenges

Standard Operating Procedure Training - How to Write SOPs that are GCP Compliant

Understanding The New Final Rule NIH-HHS Final Rule On Clinical Trial Reporting - Tips For Compliance Success

Clinical Study Requirements - Understanding Differences Between the US and EU

Understanding & Implementing The New NIH FDA Draft Clinical Trial Protocol Template

LIFE SCIENCE TRAINING INSTITUTE

CLINICAL

Conducting the CRO Pre-qualification Audit for GCP Compliance - Key Risk Factors to Avoid

Good Clinical Practices (GCP) Overview for Clinical Research Professionals - A Global Primer

Quality by Design (QbD) in Clinical Trials - Build Bullet-Proof Protocols

Using Social Media for Patient Recruitment in Clinical Trials

Introduction to Biostatistics - Collecting and Summarizing Data

Applying Biostatistics to Clinical Trial Design

Introduction to Biostatistics Hypothesis Testing

Top IND Pitfalls How to Avoid Them

Electronic Informed Consent (eIC) - How The New FDAOHRP Final Guidance Affects You

Finally...Update to ICH GCP E6 (R2) - Critical Updates You Must Know!

Good Documentation Practices for Clinical Trials: Ensuring Air-Tight Results

FINAL Risk-based Monitoring Guidance: Updates Impact Analysis on Clinical Monitoring Systems

Remote Monitoring Implementation Post ICH E6 (R2) - A Practical Guide

CRO Oversight - Risk Assessment Action Planning

Monitoring Electronic Health Records (EHRs) - Frequently Asked Questions

CRA Oversight - A Risk-based Approach

Risk-based Monitoring Plan Development

Monitoring Informed Consent (IC) - Frequently Asked Questions

Remote Monitoring of Clinical Source Data - Why Not?

Root Cause Analysis for Clinical Research Professionals

Source Data Review (SDR) vs Source Data Verification (SDV) - A Site Monitoring Best Practices Update

HIPAA Source Data Access - Dispelling the Myths

Performing Risk Assessment Within GCP

Writing Clinical Monitoring Reports - Using the Liquid Report Writing Method

CRO Selection and Oversight A Risk-Based Approach

A Risk-based Study Management Approach for Clinical Sites

MANUFACTURING

Best Practices in CMC Dossier Preparation: Facing Tough Challenges

The Nuts and Bolts of a Quality Manual: Avoiding Pitfalls and Ensuring Compliance

The Vendor GMP Qualification Audit: Ensure Your Vendors Meet Your Compliance Standard

Applying Quality Risk Management (QRM) in Manufacturing - A Proactive Approach

Effective Batch Record Review - Getting It Right The First Time

Best Practices for Deviation Investigations Cost-effective Problem Correction

Understanding Aseptic Technique and Cleanroom Behavior Avoiding Human Error

Understanding Cleanroom Microbiology Building A Foundation For Compliance

FDA GMP Inspections - Proven Preparation Survival Techniques

Project Management Execution for Pharma/Biotech Manufacturing Facilities - A Step-by-Step Guide

Serialization and Product Traceability - Global Regulatory Requirements

Improving Biological Facility Design - 11 Critical Tips for Compliance

Compliance Validation Requirements for Serialization - Keys to Success

Bioprocess Facility Design - Layout Rules and Configurations

Aging Aseptic and Biological Manufacturing Facilities - Renovation for Survival

Quality by Design (QbD): Making Sense of the ICH Q8, Q9, Q10 Puzzle

Authoring and Implementing Standard Operating Procedures (SOPs) - Best Practices for Success

Quality Agreements & FDA - What You Must Know to Comply

Effective Investigations Root Cause Analysis - A Step-by-Step Guide for Manufacturers

Aseptic Processing Preparing Staff and Programs For Compliance

Data Integrity Manufacturing - Detecting Mitigating Risk

The Top Method Validation Mistakes - And How to Avoid Them

ANDAs FDA Guidance on Stability Testing of Generic Products

Risk-Based Approaches To Establishing Sample Sizes For Process Validation

Good Manufacturing Practices (GMP) An Introduction

MANUFACTURING

Bad Standard Operating Procedures (SOPs) = Bad Training: Garbage In, Garbage Out

Renovating Pharmaceutical Manufacturing Facilities to Accommodate Aseptic Fill/Finish - Critical Planning Execution Compliance Tips

The Seven Characteristics Of A World Class Supply Chain

Selecting a CMO/CDMO 11 Best Practices For Sourcing The Right Partner

Vendor Qualification and Compliance - What Sponsors & CMOs Must Know

Cleaning Validation -- Lessons Learned in the Trenches

FDA's New Guidance on Comparability Protocols - What You Need to Know

Process Validation Training - Ensuring Compliance With Multiple Standards

Reacting to "Human Error" - Moving Beyond "Retraining" As A Response

Reducing Human Error in Life Sciences Manufacturing

LIFE SCIENCE TRAINING INSTITUTE

REGULATORY & COMPLIANCE

The Investigational New Drug (IND) Submission - Tips to Win the First Time

Successful FDA Interactions: Practical Approaches to Ensure Positive Outcomes

The Global Development Plan (GDP): Your Roadmap To Drug-Device Development

Electronic Data Integrity in a GxP Environment - Managing the Data Lifecycle for Compliance

Cloud Computing In A GxP Environment - Three Key Success Factors

NEW FDA Data Integrity Draft Guidance Key Points to Understand

Auditing Validated Computer Systems In A GxP Environment

Using FMEA For Risk-Based Approach To Computer Systems Validation

Regenerative Medicine - Understanding the Regulatory Landscape

Project Management Best Practices for Validation & Regulatory Projects

Regulatory Affairs for Biologics - A Compliance Primer

Using the ACE Program for FDA Imports - Ensuring Compliance Speedy Product Delivery

User Requirements Specifications: A Compliance Primer

Communicating Beyond the Label - FDA's Latest Guidance Updates

FDA Guidance on Social Media - Questions Answered and Unanswered

Medical Device Compliant Handling and MDR Reporting

Risk Management for Medical Devices Converting to EN ISO 14971-2012

Risk Management for Medical Devices: A Compliance Primer

Design Controls 101: A Practical Crash Course

Shed the Weight! Developing Standard Operating Procedures According to Lean Principles

Effective Complaint Handling and Management for Medical Devices

The Future Of Biosimilars: Addressing Regulatory Challenges

FDA Quality Metrics Draft Guidance: What You Need to Know to be Prepared for Implementation

Preparing Personnel to Interact with Regulatory Inspectors

Preparing for - and Surviving - a FDA Medical Device Inspection

Analyzing and Understanding ISO 13485 Proposed Changes

REGULATORY & COMPLIANCE

Device Compliance Audit Management - Best Practices to Meet Global Regulations and Notified Body Expectations

The New Medical Device Single Audit Program (MDSAP) for Manufacturers - Analyzing Rewards and Challenges

Medical Device Regulatory Compliance Changes Managing Unannounced Visits from Notified Bodies

Effective Risk Management & Quality System Implementation for Medical Devices

Medical Device Regulatory Affairs 101 - Regulatory Affairs For Non-Regulators

De Novo Path to Device Approvals - Tips for Speedy Successful Outcomes

Reprocessing Medical Devices Final Guidance: How To Meet New Validation Requirements

Design Controls 101: Beyond Regulatory Requirements

Quantifying Risk In Medical Device Development - Uncovering Many Forms Of Risk In Innovative Ways

Competitive Medical Device Regulatory Strategy: Creating Market Barriers for your Competition

Understanding the Medical Device Classification System: Best Practices for Selecting the Best Fit

Communication With FDA - What Do We Say And How Do We Say It

The Premarket Notification- 510k Submission: Using Substantial Equivalence to your Advantage!

How To Take Advantage Of The Companion Diagnostics Opportunity

The Premarket Approval Pathway - Ensure Successful Regulatory Submissions

Adverse Event Reporting - Avoiding Common Pitfalls

Computerized Systems and Data Integrity - Avoiding The Top Five Regulatory Pitfalls

Risk-Based Approach to GAMP5 Computer Validation - The Practical Guide

FDA Inspection Readiness: A Compliance Primer

Responding Effectively To FDA Form 483 Observations - Strategies To Ensure Compliance

The New Medical Device Reporting (MDR) Guidance: An Easily Digestible Compliance Breakdown

Medical Device Recalls: A Step-By-Step Guide for Risk-Averse Success

How to Prepare for an FDA Inspection of Medical Devices

REGULATORY & COMPLIANCE

CE Marking of Medical Devices: A Step-by-Step Guide for Compliance

21 CFR Part 11 - Understanding the ERES Regulation for Compliance Success

Got a Date with the FDA? Conducting Successful Meetings

Monitoring Medical Device Trials Using the ISO 14155-2011 GCP Standard

Medical Device GCP: ISO 14155 Standard Investigator Training

Cost-Efficient/Cost-Effective Validation Protocols

FDA's New Final Guidance On Method Development And Validation - What You Must Know

Quality Assurance and Quality Control - Differences in FDA vs EU Regulations

LIFE SCIENCE TRAINING INSTITUTE

RESEARCH & DEVELOPMENT

Drug Development 101 - How A Drug Is Made

An Introduction to Good Laboratory Practices (GLP)

Design Change Analysis: Top Considerations

Surviving A FDA Good Laboratory Practices (GLP) Inspection - Critical Tips For Compliance

Lyophilization - An Introduction to the Scientific Principles

Lyophilization Cycle Design - A Practical Guide to Process Optimization

Lyophilization - Thermal Characterization as Part of an Empirical Process for Developing Optimized Formulations and Lyo Cycles

Laboratory Data Integrity Current Expectations for OOS Result Investigations

Stability Programs - Key Factors in Meeting FDAICH Regulations

LEADERSHIP & TRAINING

Building Accountability on Your Clinical Teams

Coping With Change - A Primer for Staff and Managers

Building An Effective GMP Training System - A Risk-Based Approach

Instructional Design for GMP Training - Improve Effectiveness and Measurability

Making Training Stick - Ensuring Your GMP & Task Training Is Effective

Powering Up Your GMP Training - Make Training Fun!

Competency-Based Training in a GMP Environment - Results Based on Roles and Responsibilities

Qualifying Your Life Science Trainers - What Do They Need for Your Training to Be Effective?

Identifying and Closing the Training Gap in Clinical Research

Onboarding Employees In A GMP Environment - Best Practices For Foundational Employee Success

Using Learning Management Systems (LMS) to Develop Pharma Training - Rewards & Challenges

Effective Clinical Investigator GCP Training - Getting It Right The First Time

Effective Problem Solving for Life Science Professionals