

GPiLEARN™
SOLUTIONS FOR LIFE SCIENCES **Rx**



Life Sciences Courseware



Knowledge. Performance. Impact.

 **GP**
STRATEGIES™

Now there's a **flexible, affordable way** to achieve your compliance training goals.

In the Life Sciences industry, it's vital that your people are aligned with the processes they need to perform within regulations. Making that happen, however, can be a budgetary and logistical challenge. Fortunately, GP Strategies™ has a solution.



A company built around service.

Over the past 45 years, GP Strategies has built a reputation for going the extra mile for our clients. As a training, consulting, and engineering firm, we focus mainly on service and only develop products requested by our customers when their particular needs cannot be served by existing solutions. GPiLEARN Rx is one of those solutions. Built upon our existing learning portal infrastructure, GPiLEARN Rx was designed specifically to be a flexible, customizable, and affordable solution—completely unlike anything else offered in the industry. Our extensive experience in e-Learning and courseware development makes GPiLEARN Rx a natural extension of our consulting and training business. It has been tested, validated, and recommended for your use by the industry partners for whom it was originally developed.

FDA Regulated Product



You can now achieve your compliance training goals with GPiLEARN Rx, a flexible and affordable learning solution from GP Strategies. GPiLEARN Rx features a library of e-Learning modules centralized around Good Manufacturing, Good Clinical, and Good Laboratory Practices (GxP).

Interactive courseware designed to making learning stick.

GPiLEARN Rx was designed with the flexibility needed to meet the demands of life sciences companies of every size and organizational structure. Using our proven infrastructure, we built in flexible options for each organization to receive the level of solution they need to educate their people, meet their budgets, and ensure compliance:

- GP Strategies' library of e-Learning courses features modules based around GxP topics.
- GPiLEARN Rx offers an industry proven solution.
- Courseware is interactive with knowledge checks throughout and a summary exam at the finish.
- Choose from the whole library or a few specific courses.

The secret behind the industry's most affordable and effective solution.

The key to GPiLEARN Rx's affordability is its flexibility. GP Strategies built numerous options into the GPiLEARN Rx offering, so you can tailor your purchase to the right solution, at the right costs and reduce risk within your organization.

- Purchase our courseware or subscribe to individual courses through the GPiLEARN Rx portal.
- Fully customize course content according to your specifications and authoring environment.
- Host on GP Strategies' LMS or run on your own SCORM- or AICC- compliant LMS.
- Tailor the branding of courses and your portal to match your organization's brand.
- Track course results to your system or to our centralized LMS.

Good Laboratory Practices

Good Laboratory Practices

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Founded in 1966, GP Strategies is a global performance improvement solutions provider of sales and technical training, e-learning solutions, management consulting and engineering services. GP Strategies' solutions improve the effectiveness of organizations by delivering innovative and superior training, consulting and business improvement services, customized to meet the specific needs of its clients.

GP Strategies at a Glance

Customers include Fortune 500 companies, manufacturing, process and energy industries, and other commercial and government organizations. GP Strategies is headquartered in Elkridge, Maryland, USA. Additional information may be found at gpstrategies.com.



visit our web site: lifesciences.gpstrategies.com

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GP Strategies Vision and Mission

We have a vision to equip and enable people and businesses to perform at their highest potential. Our mission is to make a meaningful impact by providing the expertise and solutions needed to solve business challenges and attain ultimate performance results.

Your Total Solutions Partner

GP Strategies believes that successful companies are characterized by an unrelenting focus on effectively linking their people, processes, and technology—three interrelated elements that directly impact the achievement of an organization's performance, cost management, and compliance objectives. We believe that execution and effectiveness are key when it comes to training, training outsourcing, homeland security, engineering, and technical issues.

Measurable, sustainable improvements in profitability and efficiency prove the value of GP Strategies' work. Our diverse subject-matter expertise serves as the foundation for a true understanding of the issues surrounding workplace technologies, but it's our extensive experience that really makes the difference for our customers. Ultimately, it's your people that really drive productivity—GP Strategies unlocks their potential, putting it to work for your organization.

Cultivating Success

GP Strategies is well recognized as a provider of training and performance improvement solutions to many Fortune 500 companies. We offer a wide range of services across all functional areas of life sciences. Our success is based on a commitment to develop long-term, mutually beneficial working partnerships with our clients. This commitment, coupled with GP Strategies' diverse experience, provides the opportunity to incorporate best practices from various industries into GP Strategies' services, helping us provide effective and flexible solutions to meet customers' needs, regardless of their industry and size.

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1 THE FDA AND GOOD MANUFACTURING PRACTICES (GMPs)

55 minutes

- Explain what the FDA is.
- Describe how the FDA came about.
- Explain what GMPs are.
- Describe how GMPs came about.
- Describe the terms and definitions as explained by the FDA.
- Explain 21 CFR Part 11 Electronic Records, Electronic Signatures.
- Explain 21 CFR Part 211 Current GMP for Finished Pharmaceuticals.
- Explain 21 CFR Part 820 Quality System Regulation.
- Explain 21 CFR Part 210 Current GMP in Manufacturing, Processing, Packing, or Holding of Drugs.

2 GOOD LABORATORY PRACTICES (GLPs)

35 minutes

- Explain the background for GLPs.
- Describe the organization and personnel involved in nonclinical laboratory studies.
- Describe the facilities of GLPs.
- Describe the equipment design, maintenance, and calibration.
- Explain the testing facilities operation of 21 CFR Part 58.
- Explain test and control articles of GLPs.
- Describe the protocol and conduct of a nonclinical laboratory study.
- Explain records and reports for GLPs.

3 GOOD CLINICAL PRACTICES (GCPs)

50 minutes

- Explain the background of GCPs.
- Describe the standards of ethical behavior.
- Explain the protection of human subjects.
- Describe the financial disclosure required by clinical investigators.
- Describe the Institutional Review Boards (IRBs).
- Explain the Investigation New Drug (IND) application.
- Describe clinical research responsibilities.

4 PRINCIPLES OF GOOD DOCUMENTATION

25 minutes

- Explain the background of good documentation.
- Describe the types of documents.
- Explain how to enter information.
- Explain entry errors and entry omissions.
- Explain rewriting documents and transcribing data.
- Describe approvals, photocopies, and falsification of documents.

5 WRITING AND REVIEWING STANDARD OPERATING PROCEDURES (SOPs)

25 minutes

- Describe what constitutes a SOP.
- Explain the SOP process.
- Explain the general format of the SOP.
- Describe where SOPs are needed according to current GxP regulations.

6 PRINCIPLES OF AUDITING

25 minutes

- Explain the background of the FDA audit.
- Describe the inspection types associated with the FDA audit.
- Explain the auditing quality standard.

7 MEETING GxP TRAINING REQUIREMENTS

20 minutes

- Define training.
- Describe the principles of effective training.
- Explain the FDA regulations regarding GxP training.
- Explain the role of training in a GxP program.
- Describe the requirements for any type of GxP training program.
- Define the responsibilities of those involved in a GxP training program.
- Compare the types of training.
- Describe how training is documented and monitored.

8 RISK MANAGEMENT I: KEY CONCEPTS AND DEFINITIONS

20 minutes

- Describe quality risk management.
- Describe the quality risk management process.
- Explain the definitions associated with risk management.

9 CHANGE CONTROL

20 minutes

- Define change in the pharmaceutical industry.
- Describe the benefits of change control.
- List the impacts of uncontrolled change.
- Explain the FDA regulations regarding change control.
- Identify the types of changes addressed in a change control program.
- Explain how to address emergency and temporary changes.
- Describe how changes are documented and tracked.
- Describe the potential challenges of a change control program.
- List best practices in implementing an effective change control program.

10 VENDOR CERTIFICATION

20 minutes

- Describe quality standard guidelines.
- Explain how to manage supplier quality.
- Explain why it is important to manage the quality of suppliers' products and services.

11 UNDERSTANDING PRINCIPLES/ PRACTICES OF PROCESS CONTROLS

20 minutes

- Explain the general requirements for production and process controls.
- Describe production and process manufacturing controls.
- Describe 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals, Subpart F – Production and Process Controls.

12 RECORDS MANAGEMENT

20 minutes

- Describe records, including electronic, confidential proprietary, and sensitive records.
- Describe Records Management and the requirements of a Records Management Program.
- Explain what is meant by the retention periods of records.
- Explain the responsibilities involved in Records Management.
- Describe records retention, holds, and guidelines.
- Describe records destruction.

13 DRUG SAFETY

35 minutes

- Explain the drug safety activities of the FDA.
- Explain the function of the Drug Safety Oversight Board (DSB).
- Define related drug safety terms.
- Describe product labeling, Public Health Advisories, Patient Information Sheets, Healthcare Professional Sheets, and Alerts.
- Describe adverse drug experiences for new drugs, investigational new drug applications, and post-marketing reports.
- Describe complaints for finished pharmaceuticals, medicated feeds, and quality system regulation.
- Explain how the FDA communicates drug safety information.

14 CONTROLLED SUBSTANCES AND THE DEA

40 minutes

- Explain the Controlled Substances Act (CSA).
- Define controlled substances and the associated terminology.
- Describe the role and mission of the DEA, Bureau of Narcotics and Dangerous Drugs (BNDD), and the Office of Diversion Control.

15 APPROACH TO COMPUTER SYSTEMS VALIDATION

30 minutes

- Describe a computer system.
- Describe the regulations behind computer systems validation.
- Explain the responsibilities involved in computer systems validation.
- Describe how to develop a Validation Master Plan and Protocol.
- Describe the Standard Operating Procedures (SOPs).
- Describe how to identify what systems needs to be validated.
- Explain the steps involved in the validation process.
- Explain the types of qualification activities that can be performed.

16 GMP PRINCIPLES OF BATCH RECORDS

20 minutes

- Describe the general requirements for records and reports for finished pharmaceuticals.
- Explain active pharmaceutical ingredients (APIs) documentation and records.

17 RESOLVING OUT-OF-SPECIFICATION TEST RESULTS

30 minutes

- Describe the background of out-of-specifications test results.
- Describe the out-of-specification investigation.
- Explain laboratory investigation responsibilities.

18 FAILURE INVESTIGATIONS FOR PHARMACEUTICAL MANUFACTURES

25 minutes

- Describe the regulatory requirements of failure investigations.
- State how to conduct a failure investigation.
- Define CAPA.

19 COMPUTERIZED SYSTEMS INSPECTIONS FOR THE PHARMACEUTICAL INDUSTRY

40 minutes

- Describe computerized systems.
- Explain system hardware.
- Describe system software.
- Define computerized operations.

20 ESSENTIALS OF CALIBRATION

30 minutes

- Describe the essentials of calibration.
- State the calibration requirements.
- Explain calibration schedules.
- List calibration standards.
- Describe the auditing of calibrations systems.

21 RECALLS OF FDA-REGULATED PRODUCTS

30 minutes

- Describe the background of recalling of FDA-regulated products.
- List the guidelines.
- Explain the recall.
- Explain the handling of recalls.

22 MAINTENANCE AND CLEANING DRUG MANUFACTURING EQUIPMENT

25 minutes

- Explain the cleaning process for drug manufacturing equipment.
- State the requirements for maintenance and cleaning of drug manufacturing equipment.

23 UNDERSTANDING GMPs FOR FACILITIES AND EQUIPMENT

30 minutes

- State the requirements for buildings and facilities.
- Describe the requirements for lighting, ventilation, and plumbing.
- List the requirements for equipment.

24 CARE AND HANDLING OF DRUG PRODUCT COMPONENTS, LABELING, CONTAINERS, AND CLOSURES

50 minutes

- Describe the current Good Manufacturing Practices (GMP) for finished pharmaceuticals for an organization and its personnel.
- Explain the control of components and drug product containers and closures.
- State the packaging and labeling controls.

25 RISK MANAGEMENT 2: QUALITY RISK MANAGEMENT

30 minutes

- Describe efficient risk management.
- Explain quality risk management.
- State the FDA's risk-based approach.

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