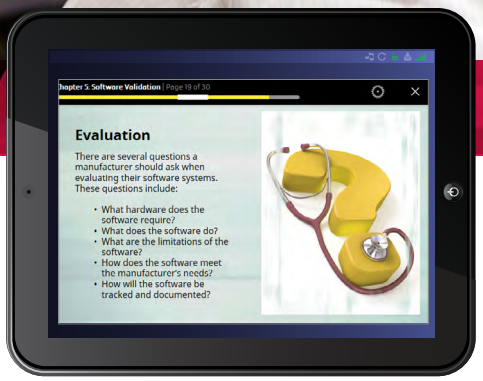
# GMP/QSR Essentials for Medical Device Organizations




"As a GMP trainer, I have dozens of training programs to develop and conduct each year. It would be more efficient for our team to rely on an eLearning source to deliver training on core GMP and QSR regulatory topics."

## Quality & Compliance Essentials

More than 200 QA and GMP training teams currently rely on UL Compliance to Performance's online courses to deliver "foundational" GMP training to their employees in operations, QA, management and more.

Written by industry and regulatory experts, our GMP online courses have been used to educate more than 200,000 Life Sciences professionals since 2011. As a best practice, many QA training teams include these core regulatory courses into "continuous education programs" – combining eLearning with more in-depth company procedure training that includes SOPs, work instructions and mentoring programs. The eLearning courses also serve as "digital repositories" that employees can return to when they have questions or concerns about core GMP regulations.

Our new Quality & Compliance Essentials program enables many more Life Sciences organizations to gain affordable access to five of the most popular courses in our GMP Library – for a single price.

QA teams can deliver these courses to as many learners as possible, so they can stretch their training budget and eliminate the need to develop this regulatory training content on their own, without sacrificing the quality of the training activity.

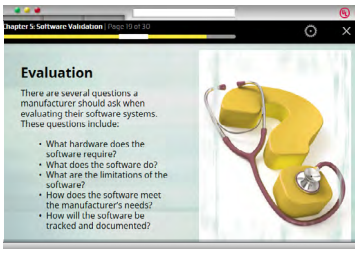
### The GMP Medical Device program includes these five courses:

- Introduction to QSR
- Orientation to GMP Compliance
- Good Documentation Practices for Medical Device Manufacturers
- Understanding GMPs for Facilities and Equipment
- Introduction to ISO 13485

## Introduction to QSR — DEV43

This course focuses on GMPs that help protect medical devices and medical device users. This course describes the GMPs for medical devices as specified in the Quality System Regulation (QSR).

Topics in this course span Quality System, Design Control, Software Validation and Responsibility. After completing this course, learners will be able to identify the components of a quality system, design controls and software validation.




## Orientation to GMP Compliance — PHDV73

This course removes the mystery of GMP regulations by introducing learners to the GMP regulations and how they are applied and interpreted.

Learners will better understand how the FDA and your own company's compliance professionals interpret and apply these important regulations.


## Good Documentation Practices for Medical Device Manufacturers — DEV56

This course presents the critical importance of creating and maintaining good documents for medical device manufacturers.

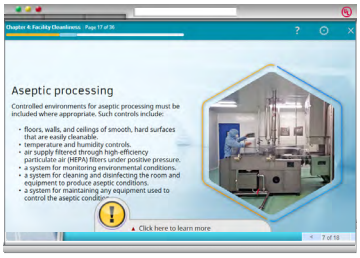
Learners will identify the stages of the Documentation Life Cycle, recognize important types of documents, recognize how documentation is controlled, and identify the important requirements of keeping accurate records.


## Understanding GMPs for Facilities and Equipment — PHDV63

This course explains how facilities and equipment GMP requirements impact many aspects of plant operation — from setup to maintenance and cleaning.

The course introduces the general layout and equipment used within a manufacturing plant.

Learners will understand the value of requirements centered on cleanliness, process flow, equipment, maintenance, calibration and cleaning.




## Introduction to ISO 13485 — DEV48

This course provides an overview of ISO 13485:2016, which is the international quality management system standard for medical device manufacturers.

The course compares ISO 13485 with its predecessor ISO 9001:2015 and discusses the "process approach" to quality management, including risk-based thinking. The course also explains the important clauses of ISO 13485 and how an organization can ensure compliance with the standard.


## An Engaging Learning Experience

To ensure the learners retain the material, each course contains "interactive quizzes" that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

In addition, courses contain a number of interactive activities that engage learners. These interactions also "chunk" critical information, which has been proven to improve retention in adult learners.

## Affordable Pricing

Pricing for the set is based on an organization's employee size. For a firm with 500 employees, for example, the subscription cost works out to approximately $20 per learner. Courses can be delivered in one of three methods:

- **SCORM:** Course files are provided in SCORM, so they can be delivered via your organization's SCORM-compliant learning management system. Optional maintenance fees are available, in the event that the courses are updated to reflect new regulations.
- **AICC:** Course files are delivered as AICC, so they can be delivered via your organization's AICC-compliant learning management system.
- **ComplianceWire®:** Courses can be delivered through UL Compliance to Performance's ComplianceWire learning management system for an additional fee.

## Get Started

To learn more about the GMP/QSR courses, or view a demo, please contact Pat Thunell at pat.thunell@ul.com.