



# Quality System Regulation (QSR)



***“We need to help our QA team, CAPA team, auditing team, and operations managers understand each subpart of 21 CFR Part 820.”***

***“After they complete the training, we would like to make this content available for them as a digital reference tool.”***

## Quality & Compliance Essentials

More than 200 QA and GMP training teams leverage UL's online courses to deliver QSR training to employees within operations, QA, IT, management and more.

Through our new Quality & Compliance Essentials program, Medical Device organizations can deliver an engaging educational experience on each QSR SubPart, (A through O), as courses correspond to each SubPart.

### The Quality System Regulation set includes 11 courses:

- QS Regulation 1: Introduction to QSR
- QS Regulation 2: Quality System Requirements
- QS Regulation 3: Design Controls
- QS Regulation 4: Document and Purchasing Controls
- QS Regulation 5: Identification, Traceability; Production and Process Controls
- QS Regulation 6: Acceptance Activities; Nonconforming Product
- QS Regulation 7: Corrective and Preventive Action
- QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation
- QS Regulation 9: Records
- QS Regulation 10: Servicing; Statistical Techniques
- QS Regulation 11: Application and Inspection of QS Regulation Requirements

See reverse side for course details



## General Provisions, Requirements

The QSR01 course introduces the Quality System (QS) Regulation (21 CFR Part 820), and SubPart A, including requirements, scope, and key terms. The course also discusses the manufacturer's responsibility for a quality system under 21 CFR Part 820.

The QSR02 course focuses on SubPart B, the management responsibility, quality auditing, and personnel requirements.

## QSR01 & QSR02



## An Engaging Learning Experience

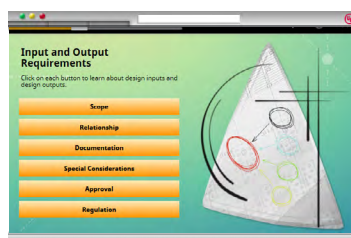
To ensure the learners retain the material, each course contains “interactive quizzes” that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

## Design Controls, Purchasing Controls

The QSR03 course addresses design controls requirements of SubPart C, including: Design Plan, Input/Output & Design Review.

The QSR04 course focuses on the Document Controls requirements of SubPart D, and the SubPart E, Purchasing Controls requirements.

## QSR03 & QSR04



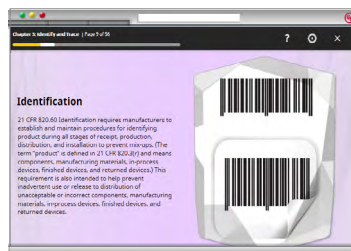
In addition, courses contain a number of interactive buttons that learners must click before continuing to the next page. This idea of “chunking” information has been proven to improve retention in adult learners.

## Process Controls, Acceptance Activities

The QSR05 course focuses on SubPart F, Identification and Traceability; Production and Process Controls.

The QSR06 course focuses on SubPart H, Acceptance Activities and SubPart I, Nonconforming Product.

## QSR05 & QSR06



## 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. These 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.

## CAPA, Labeling and Packaging

The QSR07 course focuses on SubPart J, Corrective and Preventive Action.

The QSR08 course focuses on SubPart K, Labeling and Package Control, and SubPart L, Handling, Storage, Distribution, and Installation.

## QSR07 & QSR08



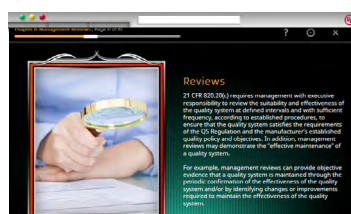
## Records, Servicing, Inspection

The QSR09 course focuses on SubPart M, Records, such as Device Master Records.

The QSR10 course focuses on SubPart N, Servicing and SubPart O, Statistical Techniques.

The QSR11 course focuses on the application and inspection of QSR requirements.

## QSR09 to QSR11



- **ComplianceWire®:** Courses can be delivered through UL's ComplianceWire learning management system for an additional fee.

## Get Started

To learn more about the QSR set, or arrange a demo, please contact Pat Thunell at [pat.thunell@ul.com](mailto:pat.thunell@ul.com).