



## Purchasing Controls and Supply Chain Management

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# Course Outline

<b>Day One</b>	<b>Day Two</b>	<b>Day Three</b>
<i>Module 1</i> Introduction	<i>Module 4</i> Supplier Selection (cont'd)	<i>Module 8</i> Integrating Supplier Controls Throughout the Quality Management System
<i>Module 2</i> Definitions and Regulatory Requirements	<i>Module 5</i> Defining Supplier Controls	<i>Module 9</i> Supply Chain Management
<i>Module 3</i> Planning	<i>Module 6</i> Day-to-Day Operations	<i>Module 10</i> Submissions and Compliance
<i>Module 4</i> Supplier Selection	<i>Module 7</i> Communications and Improvements	

# Course Outline – Purchasing Controls and Supply Chain Management

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Day 1: 8:00 a.m. – 5:00 p.m. Instruction, with breaks and lunch

## **Topics Covered:**

### **About this Course**

### **Introduction to FDA Requirements and Terminology**

\*\*\* Only for courses outside the USA \*\*\*

#### **1. Introduction**

Suppliers, customers, supply chain  
Understanding business flow  
Safety risk & business risk  
Purchasing Controls and Acceptance Activities  
Situation Analysis

#### **2. Definitions and Regulatory Requirements**

Key definitions  
Regulatory requirements:

- Responsibilities for finished devices
- Purchasing Controls
- Acceptance Activities
- Life cycle approach to supplier controls

Situation analyses  
Class exercise

#### **3. Planning**

Deciding what to acquire and what to retain  
Scope of requirements that manufacturers should specify for suppliers  
Defining technical requirements  
Defining quality requirements  
Defining business requirements  
Considering safety risk and business risk in requirements  
Planning for acceptance activities  
Situation analyses  
Warning Letters  
Class exercise

#### **4. Supplier Selection (partial Day One, completed Day Two)**

Selection of suppliers

- Identification of potential suppliers
- Establish evaluation criteria
- Determine assessment methods
- Evaluate potential suppliers
- Quantify risk of each supplier
- Make selections

Situation analyses  
Warning Letters  
Class Exercise



## **Course Outline – Purchasing Controls and Supply Chain Management**

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**Day 2: 8:00 a.m. – 5:00 p.m. Instruction, with breaks and lunch**

### ***Topics Covered:***

**Note – Day Two starts with continuation of Module 4 – see previous page**

#### **5. Defining Supplier Controls**

- How risk affects supplier control decisions
- Supplier agreements
- Controls in supplier's QMS
- Internal suppliers
- Controls in manufacturer's QMS
- Situation Analysis
- Warning Letter

#### **6. Day-to-Day Operations**

- Placing an order
- Purchasing data
- Receiving and accepting products and services
- Monitoring supplier performance
- Class exercise
- Managing supplier performance
- Managing changes
- Situation Analysis
- Warning Letters

#### **7. Communication and Improvements**

- Feedback and communication with suppliers
- Situation Analysis
- When performance is inadequate
- Corrective and preventive action
- CAPA and suppliers
- Situation Analysis
- Supplier improvement
- Warning Letters



## **Course Outline – Purchasing Controls and Supply Chain Management**

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**Day 3: 8:00 a.m. – 12:00 p.m. Instruction, with breaks**

### ***Topics Covered:***

**8. Integrating Supplier Controls Throughout the QMS**

- Supplier Controls and Quality Management Systems
- Planning
- Establishing requirements
- Finalization of controls
- Monitoring supplier performance
- Warning Letters
- Class Exercise

**9. Supply Chain Management**

- Defining Supply Chain Management
- Supply logistics: Inventory
- Supply logistics: Delivery
- Relationships with suppliers
- Supply chain and risk management
- Situation Analysis

**10. Submissions and Compliance**

- Premarket Applications
- Compliance responsibility – Contracting significant activities
- Summary
- Course Wrap-Up

