About the Instructor:

Jim Colyn is the President and Principle Consultant of Jim Colyn & Associates Quality Consultants. He is a Lead Assessor of Quality Systems (RAB) with eighteen (18) years of experience in Quality Management...establishing and maintaining Quality Management Systems in a variety of industries, including human tissues, medical devices, plastics, elastomers, and oil service tools. Jim has extensive background in Quality and Regulatory compliance with Current Good Tissue Practice (cGTP) regulations—21 CFR 1270/1271, Quality System Regulations (QSRs) - 21 CFR 820, as the international Quality System Standards—ISO 9001 and ISO 13485. Working in both FDA and non-FDA regulated industries, he has led in the successful ISO registration of six (6) separate facilities.

As the Director of Quality and Compliance for a leading human tissue processor, Jim Colyn and his team of Quality professionals developed and maintained the Quality Program for Human Tissue Intended for Transplantation (21 CFR 1270) and Current Good Tissue Practices (21 CFR 1271), as well as the Medical Device Regulations (21 CFR 820) which resulted in an enviable compliance history.

Over the years, Jim has established strong

Listen to what participants in Our Courses designed for regulated industries have to say…

- *"The course was very well organized. The topics were interesting. I definitely will recommend it to my colleagues."*
- *"Excellent presentations, very experienced speaker. He kept my interest throughout the entire course."*
- *"I learned a lot! The course was presented as an on-site course, and our entire Quality organization benefited greatly!"*
- *"I was able to get answers to questions that*

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…advancing to a culture of performance!"
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Current Good Tissue Practice Training Series

cGTP Quality Auditor Training

Attend one of our Courses—or schedule an On-Site Course at your facility today!

This course will provide guidance on:

- The Principles of Auditing
- Managing Audit Programs *[including assigning responsibilities, establishing audit program objectives, coordinating auditing activities, and providing sufficient audit team resources]*
- Conducting Audits of Quality Management Systems [with special emphasis on auditing HCTP requirements]
- Competence needed by the Auditor

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Auditing is both an art and a science. A basic knowledge of quality systems and specifications is certainly necessary...but not always enough.

What is in This Course?

The Auditor Training course consists of eleven modules designed to communicate the following:

⇒ General knowledge about the establishment and maintenance of Quality Management Systems

⇒ Difference between Quality Assurance and Quality Control

⇒ Quality Management System Documentation

⇒ Basic requirements of the cGTP Quality Program (21 CFR 1271)

⇒ Body of Knowledge – Quality Management Systems Auditing (ISO 19011:2002 – *Guidelines for Quality and/or Environmental Management Systems Auditing*), including

- Audit Program Objectives
- Audit Program Implementation
- Audit Program Records
- Conduction Document Review (The Desktop Audit)
- Preparing for and Conducting On-Site Audit Activities
- Preparing, Approving, and Distribution the Audit Report
- Conducting

⇒ Conduction Audit Meetings

⇒ Auditing techniques and skills important to the audit process

⇒ Sampling Plans

Learning Objectives

At the conclusion of the workshop, participants will be able to:

♦ Describe the elements of a sound comprehensive Quality Management System under 21 CFR 1271 (i.e., cGTP Quality Program).

♦ Illustrate the role of Quality Assurance in the development of Quality Standards.

♦ Explain the audit evidence necessary to comply with good auditing practices.

♦ Using ISO 19011:2002 as a guide, describe:

♦ The entire audit life-cycle, including pre-audit activities

♦ How to conduct internal audits

♦ How to conduct post-audit surveillance and follow-up activities.

♦ Outline how to prepare for an internal audit and effectively manage resources.

♦ Explain how to collect audit evidence and document observations, including techniques for effective interviewing and listening.

♦ Describe how to document audits, including:

♦ Nonconformities

♦ Corrective actions

♦ Audit reports.

♦ Illustrate how to:

♦ Verify the effectiveness of corrective action

♦ Close out an audit

♦ Conduct follow-up surveillances.

Who Should Attend this Course?

⇒ This course is designed for Quality professionals with responsibilities for conducting internal audits, and supplier audits.

⇒ Since requirements prohibit auditing areas over which one has direct responsibilities, organizations should consider cross-functionally training auditors to ensure independent, objective audits of all operations

At the end of the course, participants will be able to take a two-hour examination on the elements contained in the course. Individuals receiving a passing score will receive a Jim Colyn & Associates Quality Consultants, LLC Qualified Auditor Certificate.

To schedule one of our courses at your facility...or to attend on off-site course, e-mail or phone our Training Coordinator:
David.JColynConsulting@gmail.com
Or call: (336) 601-0957