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 have been brought up on the job regularly."*

Jim Colyn & Associates
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…advancing to a culture of performance!"
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Current Good Tissue Practice Training Series

cGTP Regulations Basic Training

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

21 CFR 1271

- Quality Program Requirements
- Process Validation Requirements
- Software Validation Requirements
- Electronic Records Requirements
- Quality System Documentation and Records Controls
- Facilities and Equipment Controls
- Environmental Control Requirements

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Learn the fundamentals of establishing and maintaining a Quality Program *"that must be designed to prevent, detect, and correct deficiencies that may lead to an increased risk of the introduction, transmission, or spread of communicable diseases."*

Course Outline

Session 1: Overview of the Regulation

- The Big Picture: 21 CFR Part 1271, Subparts A through E
- What is a Current Good Tissue Practices (cGTP) Quality Program?
- Subpart D, the twenty-one (21) elements of the cGTPs
- Comparison with the cGMPs (pharma) and the QSRs (medical devices)
- Elements of a cGTP Quality Program

Session 2:

- Corrective and Preventive Action
- Root Cause Analysis

Session 3:

- Personnel and Training
- Records Management
- Facilities Controls
- Equipment Controls

Session 4:

- Supplies and Reagents – Receipt, Verification and Storage
- Labeling Controls
- Storage Controls

Session 5:

- HCT/P Tracking
- Complaint File
- Biovigilance Reporting

Course Description

Participants in this Course will receive a comprehensive Training Binder which includes the 21 CFR 1271 regulations, along with all relevant FDA Guidance Documents. Detailed instruction includes:

- 21 CFR 1271 Subpart C—Eligibility Determination of Donors of Human Cellular and Tissue-Based Products
- 21 CFR 1271 Subparts D, E, & F—Current Good Tissue Practice Regulations:
  - 1271.150—Regulations Overview & Core cGTP requirements
  - 1271.155—Exceptions & Alternatives
  - 1271.160—Establishment & Maintenance of a Quality Program
  - 1271.170—Personnel
  - 1271.180—Procedures
  - 1271.190—Facilities Controls
  - 1271.195—Environmental Control & Monitoring
  - 1271.200—Equipment Controls
  - 1271.210—Supplies & Reagents
  - 1271.215—Recovery
  - 1271.220—Processing & Process Controls
  - 1271.225—Process Changes
  - 1271.230—Process Validation
  - 1271.250—Labeling Controls
  - 1271.260—Storage Controls
  - 1271.265—Receipt, Pre-distribution Shipment, & Distribution of an HCT/P
  - 1271.270—Records Management
  - 1271.290—Tracking
  - 1271.320—Complaint File
  - 1271.350—Reporting
  - 1271.370—Labeling (Marketing/Claims)

Who Should Attend?

This course is intended to provide both didactic and interactive training for the implementation of the requirements of the Current Good Tissue Practice regulations, intended for:

Gain a detailed understanding of the requirements of the cGTPs and be able to establish and execute a realistic plan for achieving and maintaining compliance with these comprehensive regulations.

- Quality Assurance personnel responsible for the establishment and maintenance of the cGTP Quality Program, and for auditing.
- Managers and personnel responsible for obtaining informed consent and for conducting risk assessment screening of potential donors.
- Managers and personnel responsible for the aseptic recovery of donor tissues from appropriately consented donors.
- Personnel responsible for writing and managing controlled documents within the Quality Management System.
- Personnel responsible for records management and retention.

To schedule one of our courses at your facility...or to attend on off-site course, e-mail or phone our Training Coordinator:
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