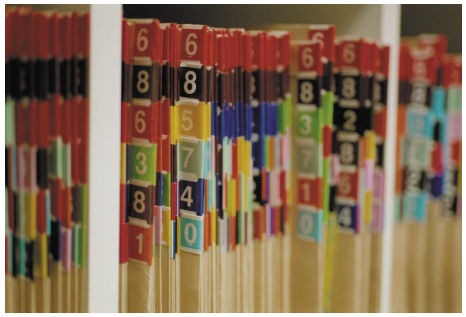
About the Instructor:

Jim Colyn is the President and Principle Consultant of Jim Colyn & Associates Quality Consultants. He is a Lead Assessor of Quality Systems (RAB) with 17 years of experience in 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 well as 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.

Most recently, 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), and Medical Device Regulations (21 CFR 820) which resulted in an enviable compliance history.

Over the years, Jim has established strong working relationships with personnel within the Food and Drug Administration.



Participants in Our Courses Designed for Regulated Industries say…

- *"I never understood the difference between policies, SOPs, and specifications. This course has prepared me to be more effective in my job."*
- *"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

SOP Writing & Document Management

for Compliance within Regulated Industry

Plan an On-Site Course at your facility today!

A practical 3-day course to help you...

- Understand the role of SOPs in documenting cGTP , QSR, and cGMP operations
- Understand the difference between SOPs, Policies, Work Instructions, and Specifications
- Understand regulatory agency and industry expectations
- Identify responsibilities for document preparation, review, and approval
- Use appropriate formatting and technical writing techniques
- Analyze the adequacy of existing SOP systems
- Document and Data control systems
- Good Documentation Practices

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Writing SOPs, Policies, and Specifications in Compliance with Current Good Tissue Practices, Quality System Regulations, and Current Good Manufacturing Practice Regulations

Know How to Implement and Use a Successful Document Development and Control Program

Learn Effective Principles in Writing SOPs, Policies and Specifications

Lear Good Documentation Practices

Policies, SOPs, and Specifications are the primary means used within the human tissue, medical device, pharmaceutical, and other FDA-regulated industries to describe **what** and **how** operations are performed. They are a basic requirement of Current Good Tissue Practice (cGTP), Quality System Regulations (QSR), Current Good Manufacturing Practice (cGMP) regulations globally, as well as ISO 9001 and ISO 13485 Quality Management Systems, and are regarded by regulatory agencies as a rigid, legal written commitment. Thus SOPs are among the main documents scrutinized by the agencies during their inspections.

This practical course defines the different types of documents required in regulated industries (i.e., SOPs, Policies, Forms, and Specifications), and covers the various elements you must consider to ensure that your organization's individual documents and the SOP program for cGTP, QSR, and cGMP operations are effective and efficient.

Key Learning Objectives

Learn about the course schedule, or schedule this results-oriented course on-site this and learn about:

- The difference between policies, SOPs, and Specifications
- The role of SOPs in regulated documentation systems
- Regulatory agency and industry expectations
- Determining the role of the different types of documents, and what documents need to be written
- Analyzing existing SOPs to determine gaps and overlap in regulatory coverage
- Needs for different types of documents
- Typical formats used in Quality documents
- Determining who should prepare, approve and authorize SOPs
- Understanding and describing operational flow
- Assessing what level of detail to address
- Writing accurately, clearly, unambiguously and succinctly
- Printing techniques that help make SOPs easy to read and understand
- Managing effectively and efficiently the document and data control system
- Defining responsibilities, handling tracking and revisions, compiling the SOP on SOPs, and understanding SOP costs
- Archiving documents to retain a historical perspective

To schedule a course at your site, call (931) 707-0741 or E-mail: Jim@JColynConsulting.com

Who Will Benefit

This course will benefit all who are involved in the preparation, implementation or management of individual SOPs or of the SOP system for GMP operations. Typically it will assist personnel from all phases of production and quality operations and relevant personnel from R&D. These areas of responsibility include

- Quality Assurance/Quality Control
- Senior Management
- Regulatory affairs
- Tissue Recovery personnel
- Purchasing
- Production (including manufacturing, labeling, and packaging)
- Warehousing/distribution
- Maintenance/engineering
- Technical Services
- Clinical supply management
- Any one in your organization with assigned responsibility for writing policies, SOPs, and/or Specifications.

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