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.

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."*

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Current Good Tissue Practice Training Series

Good Documentation Practices

Plan an On-Site Course at your facility today!

THE DO'S & DON'T'S OF GOOD DOCUMENTATION WHEN WRITING IN CGTP DOCUMENTS

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THE GOLDEN RULE OF GOOD DOCUMENTATION: Documentation must be done concurrently with the performance of each step; must be accurate, indelible, and legible, identifying the person performing the work, and the date of the entry.

WHY ATTEND THIS COURSE?

This course will help provide you with some of the minimum standards, reasoning and rules that you will be required to provide when completing **c**urrent **G**ood **Tissue** Practices (cGTP) documentation.

In a facility that maintains compliance with Current Good Tissue Practices (cGTP) or any other regulated environment, numerous types of documentation exist and serve a variety of functions. Examples of the functions of documentation include:

- Providing a record of what was done
- Instructing an individual on how to perform tasks
- Defining specifications
- Ensuring traceability
- Providing evidence that a product was made according to regulatory or in house requirements.

We will cover the standards that will guide you as you perform some of the following critical steps in your documentation:

⇒ **CORRECTIONS:**
⇒ **DEVIATIONS:**
⇒ **VOIDING RECORDS:**
⇒ **RE-CREATING AND RE-WRITING RECORDS**
⇒ **ROUNDING OFF RULES:**

When you place your signature or initial on a cGTP document, you have validated that you have just completed that activity in the view of the FDA. cGTP documents and records include, but are not limited to:

If you've tried "Googling" the FDA requirements for ***Good Documentation Practices*** *(GDP),* you'll find that **they don't exist** because it's an **expected practice** and not a Code of Federal Regulations (CFR) requirement.

- Standard Operating Procedures (SOPs)
- Informed Consent
- Donor Screening (Medical, Social, Sexual History)
- Donor Testing
- Recovery Operations
- Receipt and Storage of HCT/Ps
- Processing and Processing Controls (Batch Records)
- Facility Cleaning and Maintenance
- Equipment Cleaning and Maintenance
- Environmental Monitoring
- Receipt and Inspection of Supplies and Reagents
- Product Testing
- Product and Sample Labeling
- Analytical Methods
- Validation Documents: Examples: Sterilization Process Validation
- Complaint File
- Corrective Actions

WHO SHOULD ATTEND THIS COURSE

The rules set forth in documentation apply to all personnel in a regulated organization. Individuals involved with obtaining informed consent, donor screening, recovery operations, receipt, processing, testing, support, packaging, labeling, and distribution of FDA regulated materials will be expected to know and abide by the common rules of documentation.

Caution!

It's the Law!

It's Good Business Practice!

It's Best Industry Practice!

Willful **noncompliance with the documentation practices outlined in the GDP SOP should result in dismissal and possible criminal prosecution.**

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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