

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 Quality Consultants, LLC

*“Building a culture of compliance...
...advancing to a culture of performance!”*

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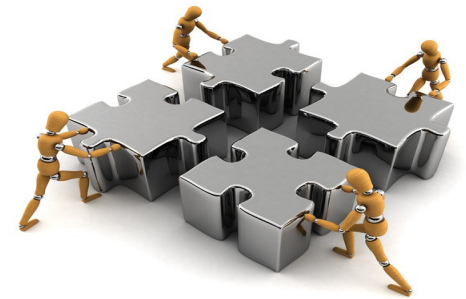
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Current Good Tissue Practice Training Series

Creating a Culture of Quality



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

Learn :

- ◆ How to Identify the Current Culture of Your Organization
- ◆ Essential Elements of Cultivating a Quality Culture
- ◆ The JC&A “Complete Quality Process” (CQP)
- ◆ Communication Fundamentals
- ◆ Measurement
- ◆ Rules for Recognition

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“To facilitate an evolving culture of quality improvement, leaders must understand the nature of organizations. Organizations are patterns of communicative interaction between interdependent individuals. A Quality Culture does not just happen because Management declares commitment to quality and compliance.”

WHY THIS COURSE?



Culture is the shared beliefs, values, attitudes, institutions, and behavior patterns that characterize the members of a community or organization.

In a healthy business culture, what's good for the company and for customers comes together and becomes the driving force behind what everyone does. It is a culture that naturally emphasizes continuous improvement of processes, one that results in a healthy workplace, satisfied customers, and a growing, successful company.

Developing a positive quality culture is an indispensable ingredient in achieving an organization's mission and objectives. Management must have a handle on the current culture, in order to encourage employees to embrace the company's quality strategy and make it successful.

Larger organizations often perform assessments of the current quality culture, which has proven highly beneficial. However, smaller organizations typically do not have the resources, time or expertise to perform this type of appraisal. Our experience with small organizations in the human tissue and medical device industries has led us to develop tools in assessing the quality culture and identifying opportunities to assist management in the development of a constructive quality culture.

COURSE OBJECTIVES

- ⇒ What is “quality?”
- ⇒ What is meant by a “Culture of Quality?”
- ⇒ The Basis of Quality
- ⇒ Difference between “Quality Assurance” and “Quality Control”
- ⇒ Quality System Architecture
- ⇒ How to identify your organization's culture
- ⇒ The responsibility of Top Management
- ⇒ The Complete Quality Process
- ⇒ The Role of Communication

Learn what JIM HAS IDENTIFIED AND DEFINES AS THE SEVEN (7) COMPONENTS OF THE “COMPLETE QUALITY PROCESS” (CQP)

1. Top Management Commitment
2. Organizational Leadership
3. Structured 100% Employee Involvement
4. Communications
5. Training
6. Measurement
7. Recognition, Gratitude and Celebration

LEARN MANAGEMENT BEHAVIORS THAT FOSTER A QUALITY CULTURE

- ◆ Creating and maintaining an awareness of quality
- ◆ How “leadership” creates an environment in which others can self-actualize in the process of doing their jobs.
- ◆ Encouraging self-development and empowerment.
- ◆ How Management ensures that the organization provides opportunities for employee participation to inspire action.
- ◆ The value of recognition and rewards.

10 PROCESS IMPLEMENTATION LESSONS

1. You won't get there without an end in mind
2. Improvement competence must be grown organically
3. Sustained improvement must be self-sustaining
4. Local optima do not equal system improvement
5. Activity does not translate into results
6. It will get worse before it gets better
7. Not everything is a nail
8. How long depends on how much
9. Without clear accountabilities, no one is accountable
10. Crossing the goal line does not always score

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DEADLY SINS OF QUALITY MANAGEMENT

- ◆ Placing *budgetary* considerations ahead of *quality*
- ◆ Placing *schedule* considerations ahead of *quality*
- ◆ Placing *political* considerations ahead of *quality*
- ◆ Arrogance
- ◆ Lacking fundamental knowledge, research or education
- ◆ Pervasively believing in entitlement
- ◆ Practicing autocratic behaviors, resulting in “endullment”

**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**