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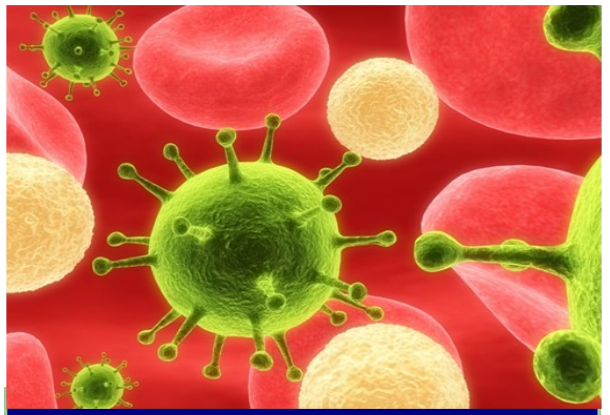
Current Good Tissue Practice Training Series

Clean Room and Aseptic Processing Training



Attend one of our Courses—or schedule an On-Site Course at

We will Cover:

- Basic Microbiology and Aseptic Technique
- Aseptic Gowning and Clean room Behavior
- General Facility Requirements
- Environmental Monitoring

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"...manufacturers should have a keen awareness of the public health implications of distributing a non-sterile product. Poor cGMP conditions at a manufacturing facility can ultimately pose a life-threatening health risk to a patient."

FDA

What Will We Discuss?

Part 1—Microbiology

- Understand why aseptic processing is necessary
- Discover what leads to non-sterile conditions
- Learn how contamination may occur
- Gain knowledge of the methods that can be used to reduce the chances of contamination
- Learn how an aseptic process can be achieved

Part 2—Aseptic Gowning and Clean Room Behaviors

- Review general gowning and behavior requirements for aseptic areas
- Discuss pre-gowning requirements to ensure proper aseptic technique can be achieved
- Detail the required gowning materials
- Outline pre-gowning activities that are performed just prior to gowning
- Describe a standard procedure for aseptic gowning
- Review required post-aseptic activities
- Discuss common audit observations related to aseptic gowning

Part 3—Facility Requirements and Environmental Monitoring

⇒ Acceptable/desired site suitability parameters to control contamination & cross-contamination

⇒ Proper procedures for routine, scheduled, documented sanitization of an aseptic processing area

⇒ Environmental Monitoring including:
- Air Particulates
- Work Surfaces
- Water Quality
- Other Monitoring including: pressure, temperature, humidity, sterilization

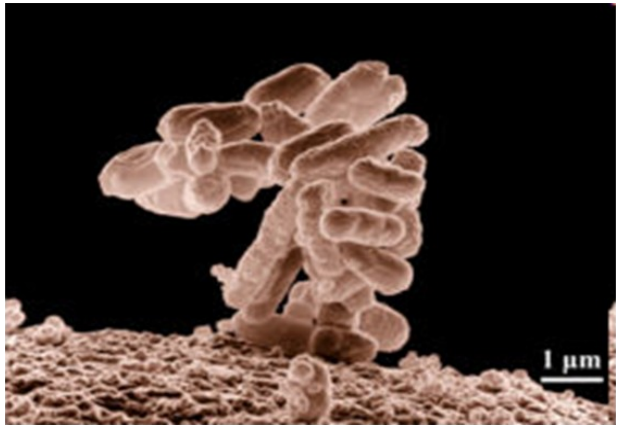
Objectives of this Course

⇒ Attendees of this course will help their organization to avoid FDA observations during an audit.

⇒ The ultimate goal is to protect the end user of the manufactured product (the patient).

Who Should Attend?

This very practical training course is a must for all personnel with assigned responsibilities for working in cleanrooms and other controlled environments (i.e., tissue recovery suites)



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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Phone: (336) 601-0957