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*

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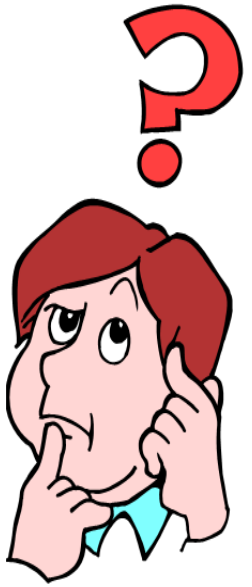
Current Good Tissue Practice Training Series

Setting Up an Effective Corrective and Preventative Action System



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The end result objective of CA/PA is, quite simply, a solution to the issue from which the Corrective Action Request (CAR) was generated. If it is not driving toward a solution, a CAR is a waste of time and resources. For organizations in regulatory environments, the CAPA System is an over-arching umbrella—all control points flow through to the CAPA system.

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"CA/PA is the *HEART* of any Effective Quality Management System"

CA/PA

Learning Objectives

⇒ The essential components of an effective CA/PA system

⇒ Corrective action, remedial action, and preventive action—learn the difference

⇒ Understanding the internal & external sources that must feed into the CA/PA system

⇒ Flow-charting the CA/PA system

⇒ Writing a CA/PA procedure / CA/PA forms

⇒ CA/PA System software

⇒ PICCC Tactic [**P**roblem...**I**nvestigate...**C**omparison...**C**lues...**C**ause]

⇒ CA/PA documentation and verification

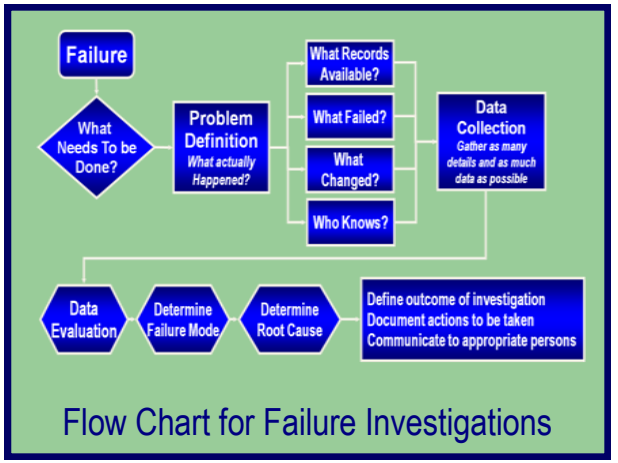
⇒ Trending and Management Review

Key Elements of a Sound CA/PA Program

- Documented procedure
- Method for documenting *(Form or software)*
- Inputs *(data sources)*
- Method for analyzing inputs
- Method for prioritizing
- Containment
- Investigation *(determine root cause)*
- Disseminate Information
- Identify solutions *(corrective or preventive)*
- Verification or validation
- Impact assessment *(risk analysis)*, where appropriate
- Corrective Action Plan
- Implement and Monitor
- Effectiveness verification
- Management Review

Who Should Attend?

- Those with management responsibility to ensure that all nonconformance issues (in cGTPs, these are defined as **deviated product**) are documented and evaluated.
- Anyone who is appointed a Management Representative of the Quality System.



Flow Chart for Failure Investigations

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