**NEW** 21 CFR 211: Pure, Safe and Effective - This 25-minute program reviews the details in 21 CFR 211 necessary to assure everyone appreciates the importance of CGMP compliance. If you need a quick overview for new employees or an annual refresher, then this is the solution.

**NEW** Overcoming the Documentation Nightmare - This program provides an interesting review of proper documentation practices for both paper-based and electronic record environments. Allen brings his dynamic presentation style to this program that clients have come to expect. Actual plant video footage engages the learner.

21 CFR 211 Review - This 20-minute program summarizes the eleven subparts of 21 CFR 211. Through the use of interesting graphics and actual in-plant video, each subpart is explained in easy to understand language. This course also serves as a strong overview for contractor CGMP training.

21 CFR 820 Review - This 60-minute program summarizes the subparts of 21 CFR 820. Through the eyes of an actual medical device manufacturing facility, each subpart of the regulation is explained in easy to understand language. This class can also serve as a strong overview for contractor QSR training.

Building and Facilities - In support of CGMP compliance, the conditions under which a product is made are closely scrutinized during audits and inspections. This 78-minute program examines the elements from building design, layout and dedicated space, to material and product flow, work space responsibilities, repair, maintenance and other controls needed to assure a compliant facility. This program is a thorough review of 21 CFR 211 Subpart C.

Contamination Control - This 25-minute program addresses the sources of contamination and methods of preventing contamination of products. This is a great session for new employees, or as part of a contamination control breach preventive action.

Equipment and CGMPs - This 50-minute program explores the requirements of 21 CFR 211 Subpart D, specifically the design and construction requirements for equipment, including lubrication and coolants. The class addresses cleaning and maintenance requirements including automatic and electronic equipment, and also covers the requirements for equipment identification, personnel training and required documentation.

Materials and CGMPs - This 40-minute program traces the CGMP requirements from supplier qualification through manufacturing and packaging. This is a solid review of 21 CFR 211 Subpart E.

Organization and Personnel - This 20-minute program summarizes the essential elements of 21 CFR 211 Subpart B. This is a great subpart orientation for new employees who need to understand their overall role and job responsibility.

Production and Process Controls - This 20-minute training program is an in-depth review of the requirements of 21 CFR 211 Subpart F. This program uses a variety of video segments from actual plant operations as the essential elements of this subpart are reviewed.
Root Cause Analysis for Better Deviation Investigations - One of the top reasons companies receive 483 observations is related to the deviation investigation process. In this program, employees learn about the tools to effectively determine the real root cause of the problem. If your deviation investigation reports frequently conclude with, “operator error...” or that there was “no assignable root cause...”, then you need to take this course!

Surviving an FDA Inspection - This 88-minute program addresses the preparation and execution of the company’s plan to successfully manage a regulatory inspection. Employee responsibilities, forming the company’s inspection team, interacting with the FDA and management’s response during the inspection are highlighted. Content is demonstrated through scenes between the inspector and company officials, and is suitable for all levels of the organization.

About Our E-learning Programs
All of our e-learning courses are fully live action narrated. Most have Allan as the on-screen narrator bringing his energy and enthusiasm to each course.

Movie Version
Designed to be used in a classroom setting, the presentation is a continuous play without interruption. This is a great way to present content without the use of your on-site instructor. In this version, the CD includes reproducible student handouts and a final exam with answer key.

Interactive E-Learning Version
Designed for self-study or classroom use, these courses present challenging questions to the student following short segments of presentation. The course concludes with a cumulative final exam, with the passing grade for the interactive questions and the final exam set by you. This version includes reproducible student handouts and a quiz with answer key. We can also host the content for you on-line.

Learning Management System Plug-in Version
Published in AICC or SCORM, these courses work with just about all learning management systems. This version is the same as the interactive E-learning courses with added features that work within most LMS environments. You set the passing grade for the interactive questions and final exam. You decide if you want the final exam within the presentation or within the LMS Quiz Module. A word file is provided to easily add the final exam to the LMS Quiz Module. We can also host this on-line for you and establish your designate as the “teacher” for course gradebook access.

Benefits
1. Development completed for you.
2. Detailed content in succinct presentations.
3. Immediate CAPA responses.
4. Cost effective regardless of company/site sizes.
5. Supports sustainable CGMP documentation compliance.

Features
1. Unlimited use at your company site.
2. Global licensing options available.
3. No license renewal after original purchase.
4. Scenes from actual production facilities.
5. Practice quizzes throughout each course.

Format Options
1. E-Learning continuous run movie.
2. Interactive E-Learning accessed from a CD or intranet.
3. Learning Management System (LMS) plug-in.

Follow this QR Code to our E-learning website

Email: allan.dewes@skillsplusinc.com | Website: http://www.skillsplusinc.com