On-Site Course Descriptions

CGMP Training from Line to Leadership

GMP Essentials for Drug Manufacturers

This course is appropriate for new employees or to meet the needs of current staff and refresher training. This highly interactive course gets everyone involved talking about current CGMP practices and the consequences of non-compliance. Many CGMP principles are experienced hands-on in this session. Usually customized to meet the needs of the organization, this session can last from one to three days. Call to discuss your specific needs and our recommendations.

GMP Olympics Annual Update

So your team thinks they "know it all" about CGMPs? This class puts them to the test. In one day, this class experiences four highly interactive activities; "Heard On the Street," "CGMP Speed Dash," "CGMP Challenge," and "Inspection Detection," testing their knowledge of the regulations. Everyone learns something new in this class! Call to see how this class addresses your site's specific training needs.

Executive Session Annual Update: GMPs

It is so hard to get busy executives into GMP training, even with the FDA citing companies for their executive team's lack of CGMP training. This course is designed to meet their busy schedule. From 1 to 4 hours, this class reviews current citation trends and compliance issues important to the busy executive. This course is completely customized for your company. Call us to discuss your executive training needs.

Qualstar: A Pharmaceutical Simulation

Problems with documentation, following procedures, change control or deviations? Employees work in small teams in this unforgettable 3-4-hour industry simulation. The importance of documentation, procedures, change controls and deviations are stressed through competition, citations, fines, injunctions, and in some cases, even jail terms. A very short lecture component is customized to address your site's specific compliance needs.

ICH Q7 - CGMPs for API Manufacturers

Translating CGMP for API manufacturers is made easy in this very hands-on course. With our highly interactive teaching style, everyone is engaged in discussions and learns about API CGMPs and the consequences of non-compliance.

Good Distribution Practices - World Health Organization

If your distribution team is tired of hearing about manufacturing CGMPs, then take a close look at our WHO Good Distribution Practices course. Learn how this guidance provides great insight into distribution practices and compliance with the Food, Drug and Cosmetic Act.

CGMPs for Foods: 21 CFR 110

This highly interactive course helps your team learn about the details of good food manufacturing practices including HACCP requirements. Keeping this course highly interactive, the instructor takes the class on a plant tour to phyisically identify areas of compliance and non-compliance. Other class activities keep students highly engaged.

CGMPs for Dietary Supplements: 21 CFR 111

Learn how the concepts of CGMPs have been translated into dietary supplement regulations. Using class activities and a plant tour to identify areas of compliance and non-compliance, participants remain engaged as the instructor provides insightful interpretation of these requirements.

Deviation and Continuous Improvement Tools

Root Cause Analysis for Better Deviation Investigations

One of the top reasons for a company to receive a 483 is a deficiency in the deviation investigation process. In this hands-on workshop, employees learn the most effective tools to determine the real root cause of the problem. Attendees use actual plant deviations to practice the use of the tools. Allan has taught this course all over the world with exceptional results.

Writing Better Investigation Reports

Write better deviation investigation reports in less time. A poorly written investigation report is one top reason for a company to receive a 483 citation. This course includes a review and consultation of your investigation report writing procedure to assure all critical issues are addressed. Course participants practice report writing and receive individual and group

More details of our courses can be found at
http://www.skillsplusinc.com/serv01.htm

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On-Site Course Descriptions

Deviation and Continuous Improvement Tools - Continued

Writing More Effective Procedures
Tired of hearing that all of your problems are due to poor procedures? In this highly hands-on workshop, learn to use the tools to assure that all procedures contain the verbiage needed to enable employees to do their job correctly.

Managing Meetings: Responding to “Swift and Aggressive”
In the current regulatory environment of “swift and aggressive” enforcement, organizations must respond quickly with thoughtful compliance plans. In this class, learn to efficiently manage meetings using many proven tools such as: matrix decision making, risk assessment, consensus building, root cause analysis and many others.

Critical Thinking Skills
If proposals, regulatory responses and recommendations never seem to be thoroughly thought through, or there are always surprises, then consider this class. In this one-day session, students explore 35 critical thinking dimensions with the goal of anticipating questions, objections and roadblocks to proposal or recommendation acceptance.

Creating Responsibility and Accountability
Learn to hold employees to higher standards of compliance through focused, controlled, one-on-one coaching sessions that drive toward greater responsibility and accountability in support of CGMPs.

Risk Assessment: Failure Mode Effects Analysis (FMEA)
Apply the principles of FMEA to deviations, CAPAs, validation or change control evaluations. This hands-on class teaches students how to efficiently use this tool.

Overcoming Human Errors
If more than 25% of deviation root causes are attributed to human error, then you need this class. Human error is not a root cause, it is a symptom of errors. Students learn to better undertstand the factors which contribute to “human error” and how to overcome them.

Inspections and Auditing

FDA Inspection Training
If you are expecting a regulatory inspection anytime soon, consider a review of how to best prepare for and participate in a regulatory inspection. Focusing on the FDA, this class uses lecture, activities, demonstrations, and role plays to assure you have a successful strategy for handling an inspecton, and that employees respond accurately and correctly during FDA interviews.

Auditing for Compliance
If you need to train new auditors to audit suppliers, contract manufacturing or packaging partners, or to conduct internal audits, this class puts them on the right track. From planning the audit through to its implementation, this class teaches the tools they’ll need.

Auditing Batch Records
Learn a proven method to review batch records and identify documentation and process deviations in this very hands-on program. This program is also a valuable review for those who need a more in-depth understanding of the impact of good documentation practices.

Supplier Selection and Oversight
Learn to take a risk-based approach to supplier selection and oversight. In this course, your team creates a working model to evaluate suppliers and provide the appropriate level of oversight necessary to assure uninterrupted plant operatons.

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On-Site Course Descriptions

Trainer Skills

Train-the-Trainer Workshop

In this workshop, employees are challenged to demonstrate their knowledge of CGMPs and their ability to present and facilitate instruction in the content area. Students learn effective strategies for responding to questions, managing the classroom environment, facilitating discussions, designing and conducting activities, and managing disruptive employees.

Training Skills for SOP Trainers

This very focused workshop teaches trainers responsible for training others on specific procedures. Employees learn to identify learning goals, organize content for presentation, present content, coach employees to achieve high standards of performance, and much more!

Training Skills for OJT Trainers

This highly interactive class provides instruction and support in training competency skills for the employee assigned the role of technical or SOP trainer. Turn job skills training into a performance improvement process and not just an exercise to complete. In this course, trainers learn the essential elements of motivation and coaching and concludes with coaching on the line.

About our Founder:

Allan Dewes, President of SkillsPlus International Inc., possesses more than 30 years of experience in identifying training needs, and developing and delivering practical, cost-effective training solutions for CGMP compliance. Allan has trained thousands of employees from all levels of the organization, from line personnel to executive staff, and in a variety of international cultures. As a compliance consultant making recommendations, Allan applies current knowledge of the regulatory expectations along with current industry best practices balanced with client capabilities. As a conference presenter and course facilitator, Allan Dewes, is an internationally recognized training and development consultant, solving real business/compliance problems with practical, cost-effective solutions. He delivers exciting, creative, and participative training and workshop sessions through public seminars, on-site courses and national conventions. Allan is also the author and publisher of various E-learning materials: the GMP Training Instructor Guide for Pharmaceuticals, GMP Training Instructor Guide for Medical Devices, and interactive training tools such as the GMP Challenge and Inspection Detection, and the GMP Trainer's Survival Kit.

Associates:

Paula Marks is the CEO and founder of Great Marks Professional Services, LLC. A Quality Assurance professional, Ms. Marks has practical and management experiences in various pharmaceutical, biotechnology, cell-therapy, research and development, and medical device/IVD companies. Paula is a certified training professional with 18 years of experience as a Trainer and Facilitator, and is certified to lead and coach executive professionals in leadership development. Ms. Marks is a sought after Quality SME and Trainer who is consistently hired to assume key roles related to cGMPs, QSRs, remediation, quality, and compliance deficiencies. She brings a respected ability to interpret FDA Consent Decrees and Warning Letter observations within challenging and difficult manufacturing environments. Her experience on diverse domestic and international teams yields successful outcomes of: removal of Consent Decree statuses, and compliant closure of Warning Letter observations. Paula's technical expertise includes the: interpretation, administration and set-up of manufacturing operations, quality assurance, quality/compliance systems (specifically, electronic document management systems), deviation and CAPA investigatory activities, aseptic processing, contamination control, regulatory affairs, new product design, and product release testing systems for compliance to regulatory bodies (both domestic and international). Ms. Marks is a member of the: ISPI (International Society for Performance Improvement), ASQ (American Society for Quality) and the Association for Talent Development (ATD, formerly ASTD). Paula has a B.A. degree in Liberal Arts from the Antioch University, and an M.S. degree in Education from Capella University. She is currently working on her Ph.D. dissertation in Education.

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