

GMP Training Workshop

May 12-13, 2010 Hilton Woodbridge-Iselin, NJ

One comprehensive workshop—two days



Introduction to Drug Good Manufacturing Practice (GMP): Meeting FDA Requirements

Presented by

enKap
ENGAGED KNOWLEDGE APPLICATION

Publisher of



Why Attend this Seminar?



A Complete Review of Every
Part 211 Regulation Subpart

- Personnel
- Buildings and Facilities
- Equipment
- Control of Components
- Production and Process Control
- Packaging and Labeling Control
- Holding and Distribution
- Laboratory Controls
- Records and Reports
- Returned and Salvaged Drug Products

[Click here](#) to access additional information on Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (21CFR).

**This Training Workshop Features Multiple
“Hands On” Application Exercises**

7:30 a.m.

Registration/Continental Breakfast

8:30 a.m.—10:00 a.m.

GMP Regulations: An Introduction

- Origin of The Food, Drug, and Cosmetic Act (FD&C Act)
- Relationship to the Code of Federal Regulations Title 21 (CFR21) and Good Manufacturing Practice Regulations (GMPs) Parts 210 and 211.
- Structure of 21 CFR Parts 210 and 211

Part 210: Importance

The significance of Part 210 of the GMP regulations is sometimes not fully appreciated. The focus is often on Part 211, which contains specific regulations that state requirements for compliance with GMP.

Part 210 is important because it specifically makes the connection of the GMP regulations to the Food, Drug, and Cosmetic Act (FD&C Act) and consequences of non-compliance.

- Application and status of GMP
- Consequences of non-compliance with GMP
- GMP regulations are not in conflict
- Definitions of terms per 210.3 regulation

10:00 a.m.—10:15 a.m.

Morning Break

10:15 a.m.—12:00 noon

Part 211: Subpart B—Personnel

It can be said that people are the most important factor in GMP compliance. They write procedures, handle and test components, container closures, in-process materials, packaging materials, labeling and finished product. They also manufacture product and

complete required documentation and records.

- Responsibilities of the Quality Unit (211.22)
- Qualifications of Individuals
- Training requirements
- Contamination control

APPLICATION EXERCISE

Learners will outline a training program that FDA determines to be acceptable.

Part 211: Subpart C—Buildings and Facilities

There is an expectation that buildings and facilities in which human and veterinary drugs are manufactured are well-designed, spacious and well-maintained. This includes those systems, such as air handling, water and contamination control is consistent with that of a facility for drug manufacture.

- Building design and construction
- Utility systems
- Sanitation and contamination control
- Maintenance

APPLICATION EXERCISE

Learners will develop a cleaning procedure for a facility.

12:00 p.m.—1:00 p.m.

Lunch

1:00 p.m.—2:30 p.m.

Part 211: Subpart D—Equipment

There are some that say that a manufacturing process can be defined as the interaction of people, materials, and equipment to produce a product. GMP regulations recognize the role and importance of equipment in the manufacturing of a drug product.

- Equipment design and construction
- Equipment cleaning and maintenance
- Calibration and validation

APPLICATION EXERCISE

Learners will develop a cleaning and maintenance procedure for a major piece of manufacturing equipment.

2:45 p.m.—3:00 p.m.

Break

3:00 p.m.—4:00 p.m.

Part 211: Subpart E—Control of Components and Drug Product Containers and Closures

This Subpart specifies the requirement for written procedures that detail the practices for receipt, storage, handling, sampling, testing and approval or rejection of components and drug product containers and closures.

- Receipt and control of materials
- Testing and approval of materials
- Use of approved materials
- Requirements for containers and closures

4:00 p.m.—4:15 p.m.

Question & Answer Session

Attendees will have the opportunity to ask the instructor questions. This time can be used to expand on any topic discussed earlier in the day which may be of particular interest to attendees.

Training concludes for the day

Day Two

7:30 a.m.

Continental Breakfast

8:30 a.m.—10:00 a.m.

Part 211: Subpart F—Production and Process Control

Production and process controls are necessary to assure that a drug product meets the standard of identity, quality, purity, strength and effectiveness required by FDA.

- Written procedures and deviations
- Equipment identification
- Sampling and testing
- Microbiological contamination
- Reprocessing

APPLICATION EXERCISE

A tablet blend has to be reprocessed. Learners will devise a solution.

10:00 a.m.—10:30 a.m.

Break

10:30 a.m.—12:00 p.m.

Part 211: Subpart G—Packaging and Labeling Control

Packaging and labeling operations are of heightened concern for FDA, due to the number of recalls that result from mislabeling, mixed product, missing lot numbers, incorrect lot numbers and expiration dates. Packaging and labeling are the final major manufacturing operations.

- Materials examination and usage
- Labeling issuance

- Packaging and labeling operations
- Tamper-resistant packaging
- Drug product inspection
- Expiration dating

APPLICATION EXERCISE

Several label inventories are incorrect.

12:00 p.m.—1:00 p.m.

Lunch

1:00 p.m.—2:30 p.m.

Part 211: Subpart H—Holding and Distribution

This regulation requires that there be procedures and systems in place that provide for the holding of drug products prior to release by the Quality Unit, proper storage under temperature and humidity conditions consistent with product labeling, oldest inventory is distributed first, and product can be easily traced in event of a recall.

- Warehousing and distribution practices
- Storage and shipment of drug products
- Product recalls

Part 211: Subpart K—Returned and Salvaged Drug Products

Returned drug products and salvaged drug products must be managed according to GMP regulations. The 211.204 and 211.208 regulations in Subpart K contain the GMP requirements for handling returned and salvaged drug products.

- Product returns
- Process for handling returned products
- Salvaged products
- Process for handling returned products

APPLICATION EXERCISE

Develop a plan for salvaging a rare and expensive antibiotic from a facility that has been flooded.

2:30 p.m.—2:45 p.m.

Break

2:45 p.m.—3:45 p.m.

Part 211: Subpart I—Laboratory Controls

Subpart I specifies the practices necessary to assure compliance with GMP regulations involving the requirements for sound laboratory practices, including: change control, deviations, specifications, sampling plans, standards, test procedures and other laboratory controls.

- Testing and release for distribution
- Stability testing
- Reserve samples
- Special test requirements

Part 211: Subpart J—Records and Reports

Records and reports required under Subpart J provide documentation of practices and activities involved in assuring the drug product produced at the manufacturing facility meets standards of safety, purity, strength and quality it claims to possess.

- Equipment cleaning, maintenance and use logs
- Component, labeling, container/closure records
- Master records
- 211.192 requirements
- Laboratory records
- Distribution records
- Complaints

Training Concludes

What Attendees Will Learn In This Workshop

This Training Workshop intends to provide learners with a functional understanding of the GMP regulations' purpose, content, requirements and application through a combination of lecture, examples, facilitated discussion and activities that will address these key topics as they relate to GMP regulations.

Following the completion of this training, attendees should be able to explain/identify the following:

- Relationship of the FD&C Act to GMP regulations
- Terms listed in Part 210
- Subparts of Part 211 and their content
- Practices that comply with Part 211 regulations
- Interaction of GMP regulations and how they compliment each other
- Practices at their firms for meeting GMP requirements

Who Should Attend

- Quality Assurance
- Packaging
- Operations
- Manufacturing
- Training
- Regulatory Affairs
- Validation
- Transportation and Logistics
- Attendees should be employed by a pharmaceutical manufacturer or supplier

General Information

The training workshop fee includes continental breakfast, lunch and all conference materials.

About Your Instructor



John Stromp currently serves as a GMP Subject Matter Expert and Instructional Designer for the FDA Compliance Learning Community of enKap.

In his 25-year career, he has worked at a number of major pharmaceutical and medical device manufacturers, including:

Bausch and Lomb, Duramed Pharmaceuticals, Glaxo-SmithKline, and American Red Cross in packaging development, quality assurance and regulatory affairs.

He considers significant industry accomplishments to include: validation of parametric release for sterile product, electronic specification system and won the Vice President Award for Packaging Design.

He has conducted in-house training on subject matter related to conducting effective validations, electronic records and signatures and Good Manufacturing Practice (GMP).

In FDA inspections, he has served as primary escort, been involved in close-out meetings and answered 483 observations. John is an Instructional Designer/ Developer for computer-aided instruction, as well as a Certified Teacher in Ohio and West Virginia.

GMP Training Workshop Venue

May 12-13, 2010

Hilton Woodbridge
 120 Wood Ave. S.
 Iselin, NJ 08830
 732-494-6200

[Hilton Woodbridge](#)

**Mission Statement:**

enKap provides an exclusive learning community for professionals in FDA-regulated industry to continuously strengthen and apply their foundation of knowledge related to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Our training workshops are based on the principle of engaging learners through a variety of active learning and instructional activities.

**FDA COMPLIANCE DIGEST**

To view our November 2009 Sample Issue or November 2009 Premier Issue article excerpts click on the links below.

FDA Compliance Digest November 2009
 Sample Issue: [click here](#)

FDA Compliance Digest November 2009
 Premier Issue article excerpts: [click here](#)

Exclusive GMP, GCP and GLP Editorial Lineup:

The January 2010 Issue will include the following "How To" Meet FDA Requirements Articles, Check-lists, SOPs and PowerPoint Training Presentations:

- Complaint Handling
- CAPA
- Ensuring GCP Quality in Your Clinical Trial
- Informed Consent
- Computer Validation Requirements
- SOP on SOPs
- Part 11 Compliance Assessment Checklist
- Good Documentation Practice

Upcoming enKap Training Workshops

[CAPA Training Workshops - \(click here for brochure\)](#)**Two Workshops in One Location**

April 20-21, 2010 Boston/Waltham, MA

1. CAPA: Effective System Management - One Industry Professional Shares His Expertise
2. Supplier-Related CAPA: Conducting Effective Root Cause Investigations

[GMP Training Workshop: Master Production Batch Records Training Workshop - \(click here for brochure\)](#)**One Workshop in One Location**

April 22, 2010 Boston/Waltham, MA

Effective Generation and Control of Master Production Batch Records (MPBR)

enKap also provides webinar recordings.

See our website at:

<http://www.enkap.com/>

and click on Webinar Recordings

Registration Form

GMP Training Workshop

May 12-13, 2010
Hilton Woodbridge-Iselin, NJ

Training Workshop Fee - \$1095.00



Introduction to Drug Good Manufacturing Practice (GMP): Meeting FDA Requirements

Four easy ways to register:

1. Call: 561-795-2785
2. Online: <http://www.enkap.com>
3. Fax this completed form: 561-798-8138
4. Mail this completed form: enKap, 125 South State Road 7, Suite 104-222, Wellington, FL 33414

Contact Information

Last Name:	First Name:	M.I.:	
Job Title:			
Department:		Company:	
Mailing Address:			
City:	State/Province:	Zip/Postal Code:	Country:
Business Phone:		Fax:	

PAYMENT

Enclosed find my payment of \$ _____
All payments must be in U.S. Dollars. Federal Tax ID #26-4253129

Early Registration Discount: Register for this training workshop by April 1, 2010 and save 10%. After this date, price will be \$1095.00

Credit Card

American Express MasterCard Visa Discover PayPal

Total Amount:	Credit Card Number:		
Expiration Date:	Security Code (found on back of card):		
Name (exactly as it appears on card):			
Billing Address (if different from above):			
City:	State/Province:	Zip/Postal Code:	Country:
Billing Phone (if different from above):		Signature:	

Check

- Forward together with completed registration form payable to enKap (checks must be in U.S. dollars and drawn on a U.S. bank). No personal checks will be accepted.

Invoice

- Please mark here to request an invoice from enKap. You are not considered registered until payment is received and a confirmation has been sent from enKap.

Refunds: Refund requests must be made in writing and received by April 1, 2010. You will receive a refund, less a \$200.00 cancellation fee. After the above-mentioned date, no refunds will be approved. enKap's liability is limited to refund of the training workshop registration fee only. **Substitutions:** If you are unable to attend, substitutions can be made anytime. **Group Discounts:** Available for three or more individuals from the same facility. Call the enKap community desk toll-free at 1-877-823-4GXP for more details.