

## The Compound Conference

October 9, 2016

Learning Objectives

### What's Going on with FDA—Guidance Documents and Inspections

*John Voliva, R.Ph., Executive Vice President*

*International Academy of Compounding Pharmacists*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. describe the difference between a draft and final FDA Guidance;
2. identify the major deficiencies described in FDA records of inspection (483s); and
3. explain how FDA utilizes Guidances in their regulatory scheme.

UAN: 0129-0000-16-104-L04-P 0.1 CEU

UAN: 0129-0000-16-104-L04-T 0.1 CEU

*This is a knowledge-based activity.*

### Sterility Testing of Laboratory Equipment—What Every Compounder Must Know

*Kelsey Feathers, CNBT Certified, President*

*Josh Hatfield, CNBT / NSF Certified, QA Supervisor*

*Laboratory Certification Services, Inc.*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. identify key points for USP <800>;
2. define Primary Engineering Control (PEC) and list acceptable methods for creating and controlling a defined, sterile environment for pharmaceutical compounding; and
3. discuss important considerations for new or remodeled cleanrooms.

UAN: 0129-0000-16-105-L04-P 0.1 CEU

UAN: 0129-0000-16-105-L04-T 0.1 CEU

*This is a knowledge-based activity.*

### Implementing USP <800>: Critical Information for Compliance

*Ken Speidel, R.Ph., BS Pharm, PharmD, FACA, FIACP*

*Vice President, Compounding Compliance, Gates Healthcare Associates*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. review why standards are necessary to reduce the risks of exposure to hazardous drugs;
2. recall USP <800> compliance requirements for hazardous drug compounding;
3. identify appropriate containment-primary engineering controls used for chemical weighing and non-sterile and aseptic processing;
4. discuss required and advised standard operating procedures and processes;
5. describe workflow changes that may be required when working with hazardous drugs; and
6. define air quality control and monitoring parameters for sterile hazardous drug compounding.

UAN: 0129-0000-16-106-L04-P 0.15 CEU

UAN: 0129-0000-16-106-L04-T 0.15 CEU

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### **Innovative Compounding for Personalized Health**

*Jim LaValle, R.Ph., C.C.N.*

*Founder, Metabolic Code Enterprises, Inc.*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. discuss the application of compounding to develop products to assist in weight loss and cognitive function;
2. describe compounding formulations of value in nutrition and vitamin supplementation;
3. define “quantified health” and how pharmacists can help patients achieve health goals; and
4. discuss novel approaches to provide mineral and nutrient delivery.

UAN: 0129-0000-16-107-L04-P                      0.15 CEU

UAN: 0129-0000-16-107-L04-T                      0.15 CEU

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### **Is Pharmacy Going to the Dogs? Innovative Veterinary Dosage Forms**

*Tom Wynn, R.Ph., Compounding Consultant*

*Fagron Academy*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. recognize the growth potential in the veterinary compound market;
2. identify obstacles in compounding veterinary dosage forms; and
3. discuss innovative oral and topical options for veterinary use.

UAN: 0129-0000-16-108-L04-P                      0.1 CEU

UAN: 0129-0000-16-108-L04-T                      0.1 CEU

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### **FDA Inspection... What You Can Expect ... Because They Will Come**

*Matthew J. Buderer, R.Ph., FIACP and Dannielle Dombrowski, CPhT, Quality*

*Assurance/Quality Control Compliance Manager, Buderer Drug Co.*

At the completion of this activity, the pharmacist/technician participant will be able to:

1. explain how thorough and complex and FDA inspection can be;
2. discuss challenges in decision making on how to comply with FDA when it conflicts with USP and state law; and
3. describe how to respond to a Form 483 Inspectional Observations.

UAN: 0129-0000-16-109-L04-P                      0.1 CEU

UAN: 0129-0000-16-109-L04-T                      0.1 CEU

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