

Presentation Descriptions and Learning Objectives for EduCon 2023 Virtual

ACPE #0129-9999-23-015-L04-P/T **0.1 CEU**

ACPE #0129-9999-23-015-H04-P/T **0.1 CEU**

Knowledge-based activity

The Compounders' Code of Ethics & Your Commitment to Quality

A.J. Day, PharmD

What steps are you taking to ensure your patients have positive outcomes today and tomorrow? How does that impact your reputation, and the reputation of our industry? Join us for a discussion on The Compounder's Code of Ethics and quality systems you are building to ensure a bright future.

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

1. list examples of ethical challenges that compounding pharmacists may encounter;
2. discuss the purpose of APC's *The Pharmacy Compounding Professional's "Code of Ethics"*;
3. recognize that pharmacists can be held accountable for ethics issues by most Boards of Pharmacy; and
4. describe examples of ethical enhancements in your pharmacy's daily operations.

ACPE #0129-9999-23-016-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-016-H07-P/T **0.1 CEU**

Knowledge-based activity

Ask the Testing Lab: Common Questions from Compounders

Wayne DeHaven, Ph.D.

The new versions of USP <795> and <797> will become official on November 1st 2023. Compounding pharmacies and laboratories alike are busy preparing for the many updates to the chapters. Details are now included in the chapters which explain the basics required for establishing and extending the Beyond Use Dates (BUDs) of Compounded Sterile and Non-Sterile Products (CSPs and CNSPs). The extension of BUDs requires published literature and laboratory testing to ensure the safety and efficacy of the products through the BUD. The most common questions Pharmetric Lab receives are associated with these tests in support of the extension of BUDs. The presentation will provide details of several microbiological, biological, and analytical tests utilized in extending BUDs within the framework of the new <795> and <797>. Case studies will be provided to highlight the outcomes which can occur when the CSP/CNSP does not meet the expected outcomes.

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

1. identify the testing requirements outlined in the new version of USP <795> and <797> for establishing and extending BUDs, and for batch release;
2. describe some of the microbiological, biological, and analytical tests utilized in the extension of BUDs for CSP/CNSPs;
3. describe a stability study design where all design factors are tested at all time-points, and recognize where a reduced study design may be implemented; and
4. recognize the importance of testing the CSP/CNSPs to ensure the safety and efficacy of the products through the BUD.

ACPE #0129-9999-23-017-L04-P/T **0.1 CEU**

ACPE #0129-9999-23-017-H04-P/T **0.1 CEU**

Knowledge-based activity

How to Conduct a Gap Analysis

Melissa Stefko

This talk will map out an effective gap analysis audit plan from audit strategy development through execution and remediation with input from SMEs.

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

1. describe the worst-case scenario between state and federal regulations;
2. identify ways to enlist SMEs from different departments for execution;
3. recognize the importance of developing an internal audit strategy and timeline; and
4. explain how to gain buy-in from different department leads for follow-up and corrective actions.

ACPE #0129-9999-23-018-L05-P/T **0.1 CEU**

ACPE #0129-9999-23-018-H05-P/T **0.1 CEU**

Knowledge-based activity

Common Mistakes, Uncommon Consequences (and How to Avoid 'Em)

L. Rad Dillon, R.Ph.

A long-time accreditation surveyor has observed over the years many "sins of omission" and "of commission" - that is, practices that are either being done incorrectly, or not performed at all. He has also gathered input from a number of peers and colleagues. This presentation will provide all compounders with some valuable ways to improve the efficiency, safety, and effectiveness of their practice.

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

1. recognize the importance of fully understanding equipment instructions;
2. recall when to perform certain key pharmaceutical calculations;
3. recognize the value of collecting and using defect data;
4. apply basic statistical concepts to quality improvement projects; and
5. identify opportunities for fail-safing critical processes.

ACPE #0129-9999-23-019-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-019-H07-P/T **0.1 CEU**

Application-based activity

Cleaning and Organizing is a Practice, Not a Project: Tools to Avoid Insanitary Conditions in Your Pharmacy

Matt Martin, PharmD, BCSCP

Much of FDA's inspection activity in compounding facilities has been focused on what they consider insanitary conditions. In this presentation we will review inspection findings and talk about strategies to avoid these from existing in your practice.

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

1. define the role of guidance documents and how they can be tools for your practice;
2. differentiate between USP 800's approach to hazardous drugs and FDA's approach to insanitary conditions;
3. analyze observations from FDA 483s at compounding facilities to determine ways to avoid or remediate similar situations; and
4. describe products and practices to consider implementing based on the Insanitary Conditions guidance.

ACPE #0129-9999-23-020-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-020-H07-P/T **0.1 CEU**

Knowledge-based activity

Best Practices for Assigning BUDs Under the New USP Chapters

Melissa Stefko

This talk will dissect the new language in the USP 795 and 797 and how it is applied to setting beyond use dates. We will also discuss how to prepare your operations for the changes and how existing stability studies are affected.

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

1. summarize the new USP 795 and 797 versions that become effective November 2023;
2. recognize how the new guidances redefine the industry as a whole;
3. outline how to prepare operations for the changes; and
4. review stability studies required for Category 3 CSP.

ACPE #0129-9999-23-021-L01-P/T **0.1 CEU**

ACPE #0129-9999-23-021-H01-P/T **0.1 CEU**

Knowledge-based activity

Healthier Patients = Healthier Practice

T.W. Taylor, R.Ph.

Are you helping your patients be their healthiest? Meeting the client where they are can increase their health in measurable ways. This session will look at ways to show your patients "How the time, money and effort spent are making you are healthier!"

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

1. discuss how health is a pharmacist's job, not just filling prescriptions;
2. recognize that nutrient depletions cause disease;
3. describe how nutritional repletion can reverse disease; and
4. explain how to use all the tools in their toolbox to increase patients' health.

ACPE #0129-9999-23-022-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-022-H07-P/T **0.1 CEU**

Application-based activity

Compounding for Thyroid the Right Way!

Michelle Moser, R.Ph., FACA, FAVCP, FAPC

Compounding Levothyroxine, Liothyronine & Thyroid USP is more than packing capsules. Ensuring accuracy, dosage & potency is key to providing a safe & beneficial compounded hormone product. We will talk about reading the CofA, making a triturate, the math involved, as well as should you make a long-acting or immediate release product and why!

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

1. interpret a Certificate of Analysis for use in compounding;
2. calculate a Triturate to be used in compounding;
3. apply a formula to ensure proper dosing of a T3, T4 or Thyroid capsule; and
4. list steps necessary to build an SOP for compounding T3, T4 & Thyroid capsules.

ACPE #0129-9999-23-023-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-023-H07-P/T **0.1 CEU**

Knowledge-based activity

Latest/Greatest Trends in Dermatological Compounding

Raja Sivamani, MD, MS

This presentation will review the basics of compounding within dermatology. The lecture will overview base options when considering dermatology focused compounding and will review popular ingredients that are utilized in the areas of hair loss and acne. As there are more antioxidants available on the market, the use of antioxidants will be reviewed as well.

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

1. recall novel base options for compounded dermatology products;
2. recognize popular ingredients used for compounding for hair loss, acne; and
3. discuss the use of antioxidants and non-antioxidant ingredients for photoaging.

ACPE #0129-9999-23-024-L01-P/T **0.1 CEU**

ACPE #0129-9999-23-024-H01-P/T **0.1 CEU**

Knowledge-based activity

Latest/Greatest Trends in Women's Health Compounding

Pamela Smith, MD, MPH, MS

The science behind women's hormones, their function and replacement, has been extensively studied over the years. This seminar will be conducted by Dr. Pamela W. Smith, M.D., MPH, MS who is an internationally known physician, author, and educator. It will examine the biochemistry and physiology of women's hormones, factors that influence each step, along with reasons to consider hormone replacement therapy as the standard of care for all women.

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

1. recognize the symptoms of peri-menopause and menopause;
2. review the biochemistry and physiology of female hormones;
3. recognize how the body breaks down estrogen;
4. list the functions of estrogen in the body;
5. list the functions of progesterone in a women's body;
6. recognize the functions of testosterone in a women's body;
7. identify the functions of DHEA and cortisol in the body;
8. recognize the symptoms of DHEA dysfunction;
9. review the symptoms of hypercortisolism and hypocortisolism;
10. explain the science behind bio-identical hormone replacement;
11. summarize methods of hormone testing;
12. recognize the functions of pregnenolone in the body;
13. review the medical literature concerning natural versus synthetic hormone replacement; and
14. recall the level of each sex hormone that a woman makes in the body during different phases of her menstrual cycle.

ACPE #0129-9999-23-025-L07-P/T **0.1 CEU**

ACPE #0129-9999-23-025-H07-P/T **0.1 CEU**

Application-based activity

Latest/Greatest Trends in Geriatric & Hospice Compounding

Mindy Cormier, R.Ph., PharmD

As the global patient demographic changes with the rapid increase in geriatric patients, so does the need to change and adjust healthcare treatments and goals in order to optimally manage associated diseases and to improve quality of life. This activity will discuss the growing market for compounding sterile and non-sterile preparations for the geriatric and hospice population, as well as to discuss compounded treatments covering a variety of disease states specific to this growing demand in healthcare.

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

1. recognize the growth in the geriatric and hospice population and the need to readjust healthcare treatments and goals for the management of associated diseases and improvement in quality of life;
2. identify the gaps in overall care of the geriatric and hospice population and the need for improved treatment options through compounding;
3. evaluate current options for compounded treatments for the geriatric and hospice population including mucoadhesive treatments for nose/throat conditions, wound care, as well as sterile and non-sterile preparations for oncology and adjunctive treatments; and
4. apply skills and knowledge through different case scenarios and critically evaluate formulation treatment options for diverse patients.

ACPE #0129-9999-23-026-L03-P/T **0.1 CEU**

ACPE #0129-9999-23-026-H03-P/T **0.1 CEU**

Knowledge-based activity

And Now a Word from Legal Counsel...

Martha M Rumore, PharmD, JD, LLM, FAPhA

Beta lactams? Semaglutide compounding? Insanitary conditions? Animal compounding? This session will address law and regulations pertaining to compounders, including the current state of the Federal Food, Drug and Cosmetic Act Section 503A on compounding shortage medications and substances such as peptides, DTE and bHRT therapies. Implementation of revised USP guidelines for sterile and non-sterile drug products, as well as the future of interstate distribution of compounded drug products, will be discussed.

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

1. describe the current state of Federal Food, Drug and Cosmetic Act Section 503A compounding in a (post) COVID-19 environment, addressing compounding shortage medications and inspections;
2. review the current state of Section 503A compounding using certain substances such as peptides, DTE, semaglutide, and bHRT therapies;
3. explain the recent implementation of revised USP guidelines for compounded sterile and non-sterile drug products (USP<795> and <797>); and
4. discuss the future of FDA's limitation on compounding and interstate distribution of compounded drug products after the U.S. District Court's decision in *Wellness Pharmacy, et. al v. FDA*.