VIRTUAL EVENT

# Compounding Pharmacy Compliance

## 2021 Continuing Education Bundle

### Videos

1. **Current Trends in Addressing Beyond-Use-Dates and Stability Testing**
   This session provides an overview of 503B cGMP Guidance stability recommendations, while outlining the utility if ICH Guidances in the design of a stability program. Specifics are offered on the identification of quality target product profiles, and critical quality attributes when establishing acceptance criteria. Additional considerations when performing stability studies are also shared via case study and personal recounts.
   *Presented by: Lisa McChesney-Harris, PhD.*

2. **Serving Diverse Patients and Populations in Drug Compounding**
   In this breakout discussion our panelists discuss the specific challenges in serving diverse communities and populations, offering insights based on experiences and best practice models. In addition, our pharmacy leaders share techniques for hiring and training diverse teams, bringing needed value to their practice.
   *Presented by: Lou Kennedy, CEO, Helen McKnight PharmD, MBA, BCSCP and Robert MacArthur, PharmD, BCSCP*

3. **Evaluate and Assess Risk Mitigation in Drug Compounding**
   In this fundamental session review the areas of risk in drug compounding, outline processes for evaluation of risk in drug compounding, and review resources and develop steps to mitigate risk.
   *Presented by: Cindy Brasher, PharmD, MS*

4. **Expectations for the Future – an FDA Update**
   In this FDA led session learn about compounding initiatives that were response to COVID-19 Public Health emergency, and how that will impact policy going forward, as well as current policy oversight schemes. In addition, receive updates on the regulatory objectives of the current MOU, and better understand the NABP information sharing system, and how it will support boards of pharmacy that sign the MOU.
   *Presented by: Gail Bormel, RPh, JD, Melissa Madigan, Assoc. Executive Director, NABP*

5. **Exploring Innovations in Drug Preparations and Administration — Ready-to-Administer Products, IV Robotics and More!**
   This innovative session provides the means to evaluate current compounding innovations and opportunities focused on safety during drug preparation and administration, while recounting the risks surrounding drug preparation outside the main compounding facility. Plus, here case study highlights and benefits for implementing Ready to Administer products in your facility.
   *Presented by: Clinton Meachum*

6. **Impact of the Memorandum of Understanding on Compounding Pharmacies**
   Join this Breakout Discussion: Impact of the Memorandum Of Understanding (MOU) to hear members of FDA, State Boards, NABP, and the Alliance for Pharmacy Compounding's Public Policy Counsel as they discuss the industry impact to the MOU, highlight to New Hampshire, the first state board to sign, and the next steps for this program and the participants.
   *Presented by: Gail Bormel, RPh, JD, Jenni Wai, RPh, MBA, Alexandria Fujisaki, Gabrielle Cosel, Melissa Madigan, and R. David Pore*

7. **Lasting Impacts from the COVID-19 Pandemic**
   This panel discussion brings compounding industry together to discuss the current roles, responsibilities and regulation of drug compounders in the wake of COVID-19. Specific emphasis on the role of compounding pharmacies in response to drug and PPE supply shortages, the role of the pharmacist in immunization, and the impact to workflow, and expectations of the pharmacist in national health emergencies. Plus, discussions on the s considerations of state regulator to quickly adapt compounding needs during a public emergency, as well as necessary modifications in policy, workflow, and resource allocation in hospital pharmacies that have occurred as a result of the pandemic.
   *Presented by: Helen McKnight, PharmD, MBA, Jenni Wai, RPh, MBA, Masoud Rashidi, PharmD, and Michael Blaire, VP*

8. **Managing Organizational Change in Compounding Pharmacy**
   In this management level session you will recognize the consistent occurrence of change, both within the industry and without. Learn techniques to identify change through data collection, monitoring and trending, while maintaining control of the change and mitigating negative impacts. Discover tools to develop a timetable of change as it occurs and list sources of change.
   *Presented by: Christopher Smalley*

9. **The Mindset of Quality Operations**
   This session provide an outline for developing a mindset needed to avoid lagging behind a rapidly changing industry. Provided here are insights into the difference between affixed mindset and a growth mindset, as it relates to pharmaceutical compounding, compliance and patient safety, plus several case study scenarios for comparison.
   *Presented by: Ross Caputo, Ph.D*.

## Slide Decks

1. **Keynote Address, Expectations for the Future**
   *with Gail Bormel, RPh, JD, Director, Office of Compounding Quality and Compliance, CDER Office of Compliance*
   The FDA update includes a timeline of events beginning with the Fungal Meningitis Outbreak, and moving through key events and guidances, such as Drug Quality and Security Act, Pharmacy Compounding Advisory Committee Meetings, Compounding Quality Center of Excellence, COVID-19 Public Health Emergency Temporary Policies; Memorandum of Understanding, and the future of Compounding policy as discussed at the 2021 Pharmacy Compounding Advisory Committee Meeting.

   *with Melissa Madigan, PharmD, JD, National Association of Boards of Pharmacy, Associate Executive Director, Professional Affairs*
   The NABP update relays important information about the MOU including what boards that sign the MOU need to do, and the way NABP's information sharing network will help. new capabilities for boards of pharmacy and methods by which the system will flag compounding pharmacy data for states and FDA. Plus learn about the type of information that will be collected, and when, and how complaints will be handled under the MOU.

2. **Mindset of Quality in Compounding**
   *with Ross Caputo, Ph.D., President, Eagle Analytical*
   Learning objectives highlighted in this presentation include: outlining the right mindset that compounders need to adopt in order to avoid lagging behind as the industry is shifting, discussion of the difference between a fixed

mindset and a growth mindset as it relates to pharmaceutical compounding, compliance, and patient safety, and a comparison of alternative mindsets as presented through a series of scenarios.

3. **Exploring Innovations in Drug Preparations and Administration – RTA Products and IV Robotics**
   *with Clinton Meachum, CPhT, CSPT, Moses H. Cone Memorial Hospital | Cone Health*
   The slides are a companion to the video presntaion and wil cover: Identification of the risks surrounding drug preparation outside of the main compounding facilities, Review of the benefits for implementing Ready to Administer products for compounding facilities, and Evaluating current compounding innovations focused on safety during drug preparation and administration.

4. **Impacts of COVID-19 Pandemic – Current Roles, Responsibilities and Regulation of Drug Compounders**
   *with Helen McKnight, PharmD, MBA, Jenni Wai, RPh, MBA, Masoud Rashidi, PharmD, and Michael Blaire, VP*
   A companion to the video, these slides further highlight the role of compounding pharmacies and pharmacists in drug and PPE supply shortages, immunization efforts, and expectations of the pharmacist in national health emergencies. How much time and resources should you be devoting to immunization against COVID? Plus continuing ed assessment questions to help test your knowledge.

5. **Managing Organizational Change –Embracing Culture, Processes, Infrastructure and Technology**
   *with Chris Smalley, former Director of Engineering, Merck (Merck, Sharp & Dohme)*
   Companion slides to the presentation covering employee morale, supply chain, technology, and tools for monitoring change, as well as knowing what you can do to mitigate/minimize the impact of the change.

6. **Evaluate and Assess Risk Mitigation in Drug Compounding**
   *with Cindy Brasher, PharmD, MS, BCPS, Manager of Compounding, St. Jude Children's Research Hospital*
   Fundamentals on the importance of evaluating and mitigating risk in sterile compounding with compelling examples from the disaster at NECC to everyday incidents. Plus identifying who is in charge of patient safety, recognizing internal risk and employee safety, as well as gap analysis tools, environmental monitoring programs and impact evaluations.

7. **Skepticism Around Laboratory Service Providers**
   *with Prompt Praxis Laboratories*
   This solution provider delivers sound advice for vetting and contracting with a contract lab. Slides cover Systemic Design Elements, Analytical Capabilities, Standardized Laboratory Instrumentation, expectations for Resources and Outcomes, Method Validation Strategies and Rapid sterility services.

8. **Current Trends in Addressing Beyond-Use-Dates and Stability Testing**
   *with Lisa L. McChesney-Harris, PhD, CEO, CSO & Founder, Prompt Praxis Laboratories*
   These slides provide a Review of 503B cGMP Guidance Stability Recommendations, testing requirements and restrictions, identification of Quality Target Product Profile, and Critical Quality Attributes when Establishing Specifications or Acceptance Criteria, Utility of ICH Guidances when Designing a Stability Program, and Considerations when Performing Stability Studies. Plus receive a bonus Educational Aide – Synopsis and Example of QTPP's and CQA's When Designing a Stability Study.

9. **Sterile Compounding for Clinical Research for 503A and 503B Facilities**
   *with Robert B. MacArthur PharmD, MS, BCSCP, Pharmacy Director, The Rockefeller University Hospital*

Overview of Jargon, techniques in sterile compounding, plus learn to recognize the value of the clinical trial supply market, different types of products that fall under the definition of sterile phase 1 clinical trial supplies and understand the roles filled by the "triad" of Sponsor, Manufacturer and Formulator, recall issues affecting the success of early phase research projects, review of FDA guidance documents, FDA regulations, USP resources and Investigational New Drug Application Chemistry Manufacturing and Controls sections that apply to sterile compounding for clinical research.

10. **Best Practices for Aseptic Techniques**
    *with Dennis Champagne, Leiters. COMPOUNDING HEALTH™*
    These slides provide a comprehensive overview of Aseptic technique, product segregation, sources of contamination and common practice, guidelines on cleanroom behavior, set-up and maintenance of cleanroom work area, cleaning programs and material transfer protocols. Plus, Environmental Monitoring steps, including sampling condition, sample locations, Aseptic sampling, data trending and analysis and trend reports.

## Toolkit

1. **Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products** *(Guidance, FDA/HHS)*
2. **Botanical Drug Development** *(Guidance, FDA/HHS)*
3. **Contract Manufacturing Arrangements for Drugs: Quality Agreements** *(Guidance, FDA/HHS)*
4. **Current Good Manufacturing Practice for Phase 1 Investigational Drugs** *(Guidance, FDA/HHS)*
5. **Drug Compounding Resolutions and Guidance During COVID-19** *(Guidance, State of Ohio Board of Pharmacy)*
6. **FDA Temporary Policy for Outsourcing Facilities** *(Guidance, State of Ohio Board of Pharmacy)*
7. **Guidance to Industry and Reviewers - Exploratory IND Studies** ***(Guidance, FDA/HHS)***
8. **IND Meetings for Human Drugs and Biologics Chemistry Manufacturing and Controls Information** *(Guidance, FDA/HHS)*
9. **INDs for Phase 2 and Phase 3 Studies Chemistry Manufacturing and Controls Information** *(Guidance, FDA/HHS)*
10. **NCI Drug Accountability Record Template** *(Fillable Form)*
11. **PDA-FDA Joint Regulatory Conference 2017 – Change** *(Meeting Transcript)*
12. **Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks** *(Guidance)*