

Preparing For & Managing Regulatory Assessments Workshop

- 7:45 a.m. Registration, Check In, Light Breakfast, Welcome
- 8:15 a.m. Workshop Starts – Introduction
- 8:30 a.m. Opening Remarks and Learning Objectives
- 8:45 a.m. Preparing for the Onsite Assessment
- Selecting Assessor and Scheduling the Assessment - Know Your Laboratory's Procurement Process Requirements and Start Early (Timing 6 Months Prior to Biennial Due Date)
 - Pre Assessment – Gap Analysis
 - Training – Start Early
 - Communication
 - Preparing and Sending the Assessor Pre-Assessment Material
 - Preparing for the Opening Meeting, Room Size, Materials Needed, Lab Tour, Safety Presentation
- 10:00 a.m. Break (15 minutes)
- 10:15 a.m. Finish Up the Preparation Discussion
- The Assessment Itself
- Setting the Stage for the Opening Meeting
 - Escorts – Taking Notes and Providing Feedback to Management
 - Having Onsite Materials Ready
 - Electronic vs. Paper Documents and Records and Everything In-between
 - How to Ask and Answer Questions
 - Closing Meeting and Debriefing
- 12:00 p.m. Lunch and Sponsor Remarks from Clinisys
- 1:00 p.m. FLDOH Perspective on Preparing for Assessments with Dr. Carl Kircher
- 1:30 p.m. Group Exercise – Assessment Preparation Checklist
- 2:30 p.m. Common Assessment Deficiencies and Pitfalls
- 3:30 p.m. Break (15 minutes)
- 3:45 p.m. Participant Questions and Problems for Discussion (Q & A Session)
- 4:45 p.m. Understanding the Assessment Report and Deficiencies
- Systems vs. Symptoms
 - Corrective Action Response
- 5:00 p.m. Adjourn