

*Webinar on*

# **Proper Management Of Regulatory Agency Inspections**

# • Learning Objectives

*Upon completion of this session, attendees will learn the proper way to set up for a Regulatory Inspection, ensuring the inspection flows smoothly throughout the duration, and the proper way to speak to inspectors while they are performing the audit.*

- Pre-planning and preparation activities*
- What to do when the investigator arrives*
- What documents to have ready and on hand*
- Assignments and responsibilities for the inspection*
- A review of Inspection Do's and Don'ts*
- The Opening and Close-out Sessions*

In this webinar you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated “war” rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner.

**PRESENTED BY:**

*Danielle DeLucy, MS, is the owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance.*

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

# Webinar Description

The purpose of the Regulatory inspection is an activity that should demonstrate that your company is operating according to the proper CFR requirements and maintaining a state of compliance. The key to a successful audit is being able to communicate how your quality systems assure this state of control. Many times, the arrival of a Regulatory Investigator is a daunting experience for some. This webinar, you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated “war” rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner. This preparation minimizes stress and disorder during the inspections.



# Who Should Attend ?

*Site Quality Operations Managers*

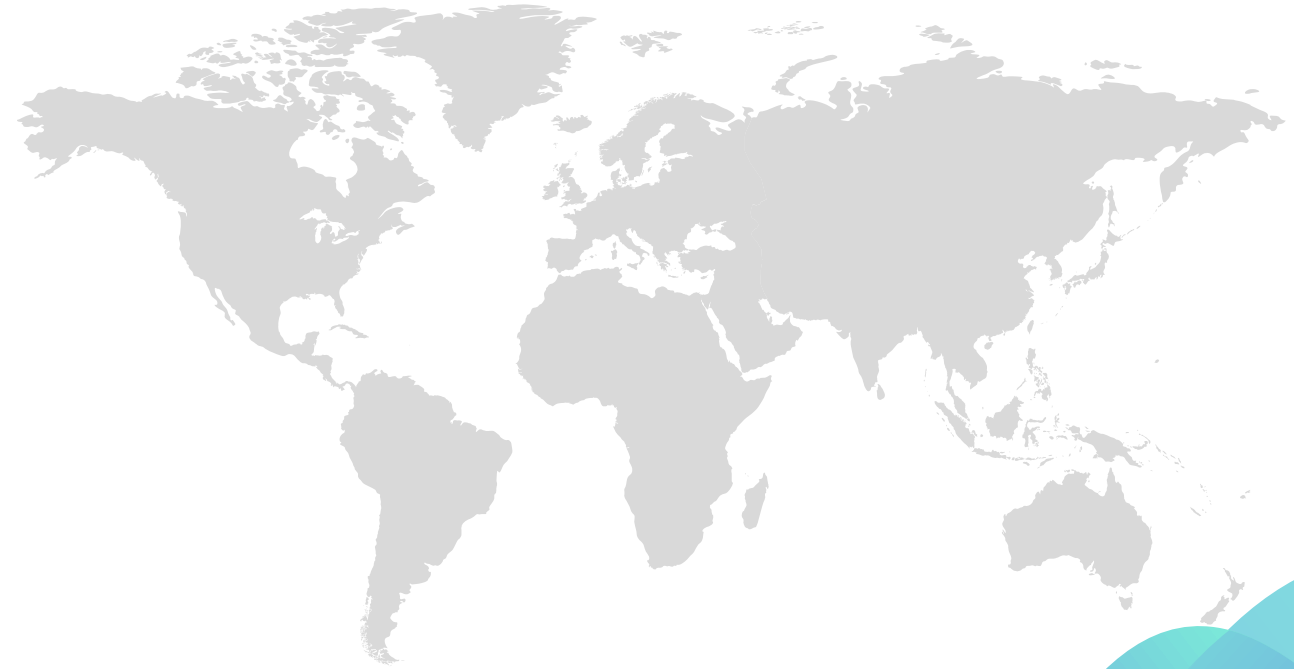
*Quality Assurance personnel*

*Plant Managers and Supervisors*

*Manufacturing Superintendents and Managers*

*Regulatory Affairs Managers*

*Individuals whose job knowledge and/or expertise may be called upon during an audit*



# Why Should Attend ?

*To learn the how to set up support groups/rooms for the inspection*

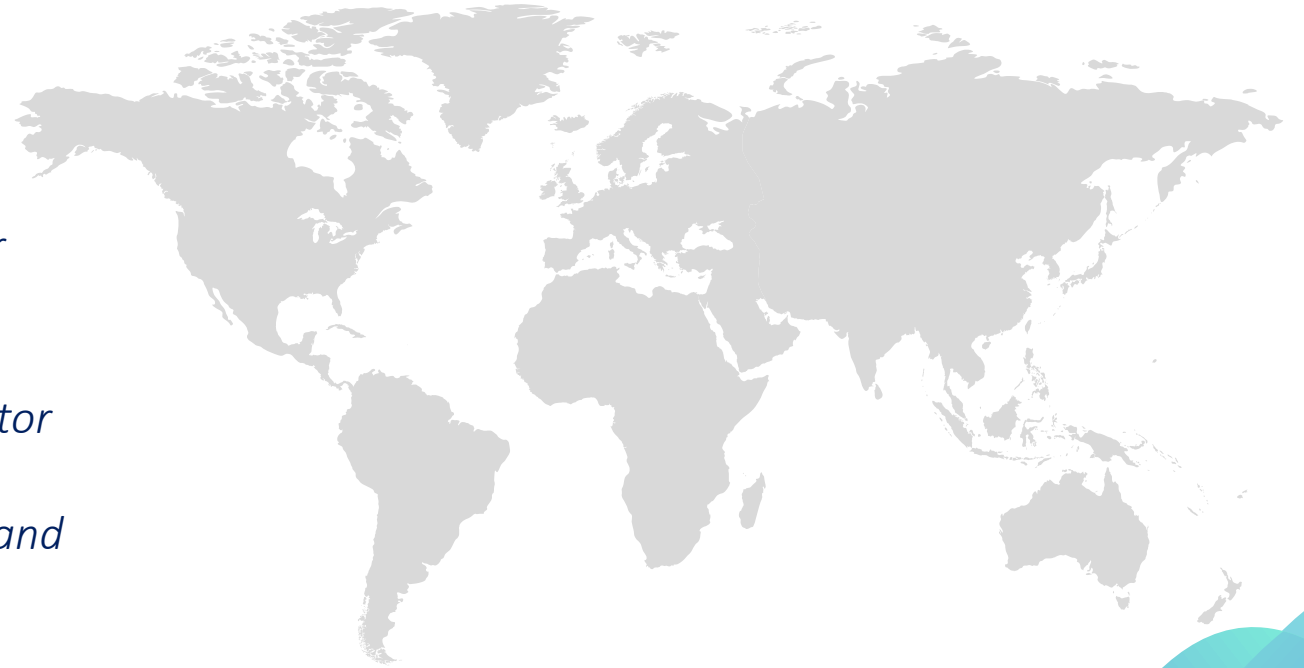
*Learn how to properly communicate with the inspector*

*To be able to organize requests from the inspectors and process them in a timely and accurate manner*

*Know what is expected of you and your company*

*Learn what not to say or do during an inspection*

*To learn how to use your internal Quality Assurance groups to help identify issues prior to an inspection*



To register please visit:

**[www.grceducators.com](http://www.grceducators.com)**  
**[support@grceducators.com](mailto:support@grceducators.com)**  
**740 870 0321**