

Webinar on

Through The Eyes Of An Auditor

Learning Objectives

- What the auditor is looking for and why*
- The first five minutes, Entering and touring a cleanroom*
- Touring the plant and manufacturing area*
- Entering and touring the warehouse*
- Entering and touring lab areas, Reviewing the quality system*
- Reviewing documents, Summary*



This webinar provides insight into the kinds of clues an auditor might use in determining what areas to focus on.

PRESENTED BY:

José Mora is a Principal Consultant specializing in Manufacturing Engineering and Quality Systems. For over 30 years he has worked in the medical device and life sciences industry specializing in manufacturing, process development, tooling, and quality systems. Prior to working full time as a consulting partner for Atzari Consulting, José served as Director of Manufacturing Engineering at Boston Scientific and as Quality Systems Manager at Stryker Orthopedics, where he introduced process performance, problem-solving, and quality system methodologies.



Don-Demand Webinar

Duration : 90 Minutes

Price: \$200

Webinar Description

Internal and external audits are an integral part of running a medical device or biotechnology manufacturing operation. To be sure, auditors must follow standards such as ISO 13485, ISO 14971, or regulations such as 21 CFR Part 820. Additionally, an auditor has personal experiences of what a state of control looks like and has visited sufficient places to know what to look for.

Anyone in a medical device setting must be prepared for an audit at any and all times. This webinar provides insight into the kinds of clues an auditor might use in determining what areas to focus on. It isn't intended to cover all regulations and standards. What it does cover is the general mental checklist that will influence how well an audit goes, as well as the culture and environment a company's management must encourage so that impression is a good to excellent one.

An external auditor is coming to your plant. Their first impression may have a major impact on your plant's future as well as your own career. How will your plant look to that auditor?



Before they even set foot in the door - what your grounds and outside facility says about your operation

Approaching the production area – tell-tale signs that will influence the auditor's perception

Your cleanroom gowning area - how the audit could be almost over before it has even started

It's only a utility room - why would they want to look in there?

Your janitor's closet - it might as well be your front porch

Do you follow your own rules? The auditor is noticing this very carefully - and taking notes

Can you "put your hands on it." Documents, procedures, manuals, and reports - why five minutes may be too long to change the first impression.

Process and environmental control - quick impressions



Who Should Attend ?

R&D

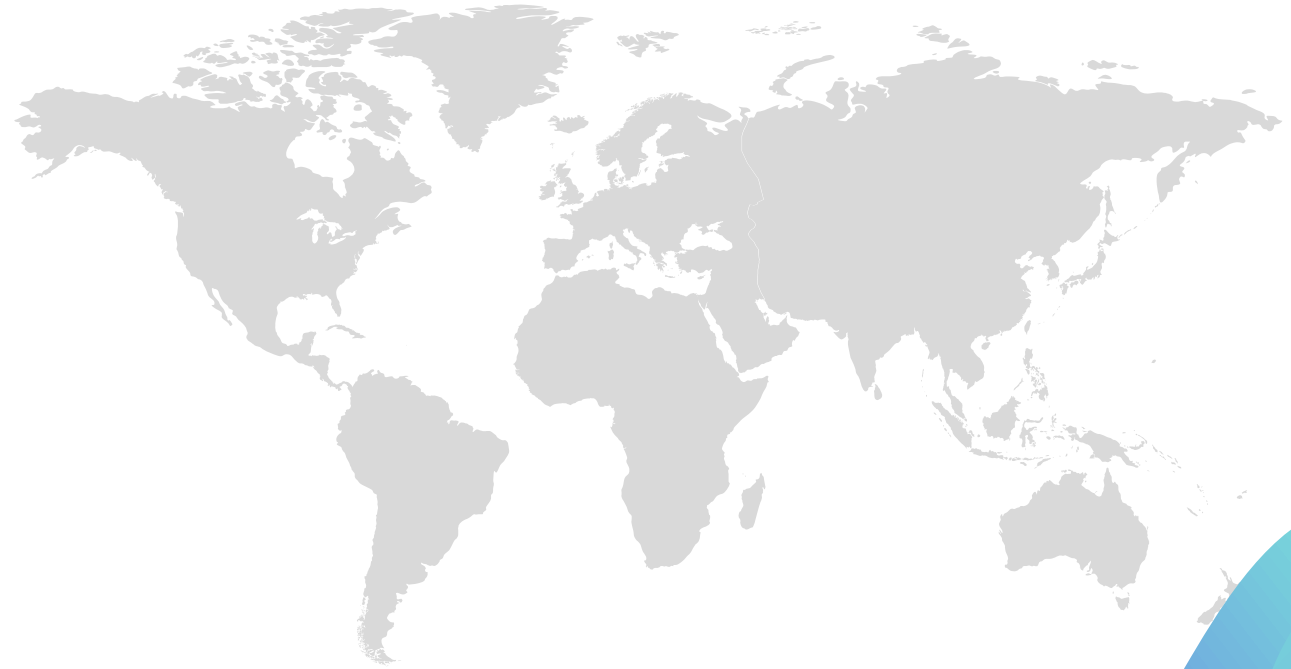
Manufacturing Engineering

Design Assurance

Quality Assurance

Operations

Document Control



Why Should Attend ?

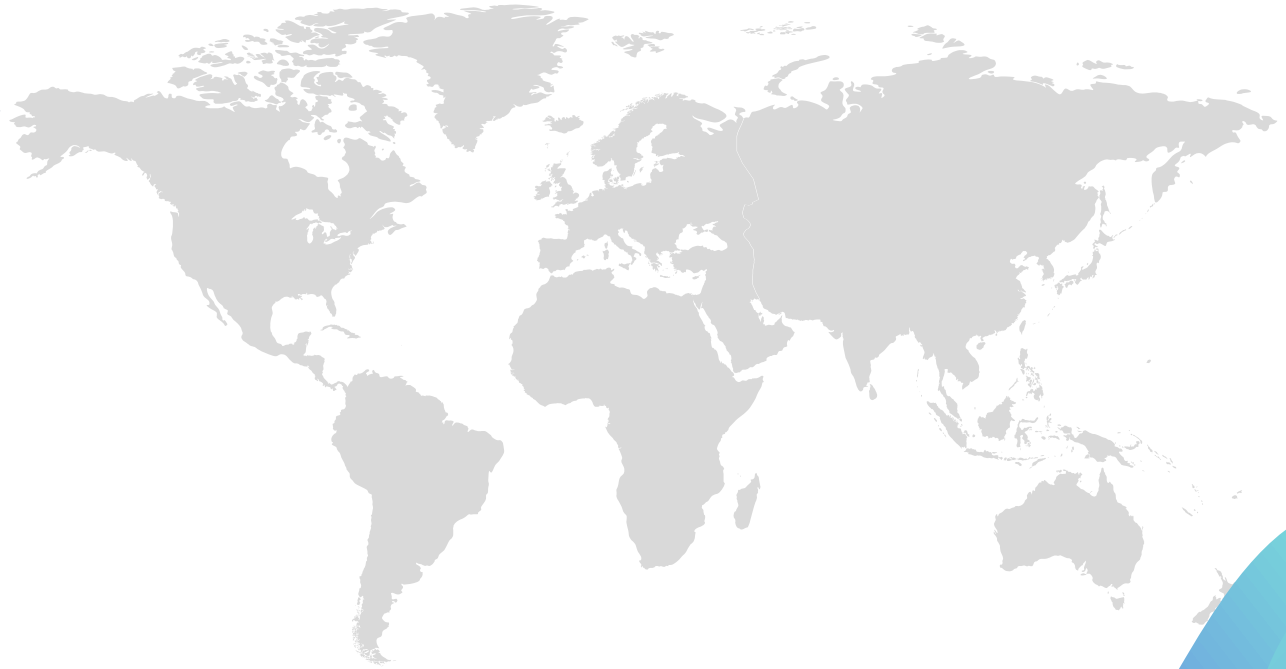
An experienced auditor does not need to dig very far - he or she already has a mental checklist. You need to know what that is

The importance of housekeeping, proper maintenance, orderliness and following safety rules

The importance of visual indicators - and following them

Utility rooms and custodial closets are often places to hide clutter. Some experienced auditors know that this tells them more about your systems than the clean and presentable areas

How using the same logic as the auditors can help you be in a state of constant readiness



To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321