What Makes World Class Audit Programs Different?

Imagine sitting in a class of 20 audit program managers. There is a vice-president of regulatory affairs on your left and global quality manager on your right. You will get more from the person sitting next to you than you have ever received in any other course before.

This course is not for new auditors, and you won't learn ISO 13485, ISO 14971, or even ISO 9001. You will receive the latest version of ISO 19011, "Guidelines for auditing management systems", but you will not review that Standard clause by clause. Instead, sixty percent of the material presented will be learned in group activities with role playing and realistic examples. There will be **NO** PowerPoint® slides, and the instructors will never speak for more than 30 minutes.

This is an advanced course for audit program managers who recruit, hire, and train auditors. The instructors have experience performing hundreds of audits and managing audit programs. The material in this course covers management of internal audits (1st party), supplier audits (2nd party), and remote auditing strategies.

Class size is limited to 20 students to ensure that everyone is able to participate fully in the discussions and ask any questions they need to resolve. We will also have generous breaks to allow for short conference calls, answering emails, and networking.

This course is for big and small companies, because diversity is critical to the learning process. A global perspective is also essential to ensuring that your audit program is adequate to meet the requirements of any regulatory body. Therefore, this course includes instructors from opposite sides of the planet.

Brigid Glass is a Quality Management Systems consultant who resides in New Zealand. She is a lively and passionate trainer who specializes in coaching smaller medical device companies to build Quality Management Systems (QMS) for compliance with ISO 13485, ISO 14971, the 21 CFR 820 (FDA QSR), and other international regulatory requirements. Her approach gives them a sense of ownership in their documentation, a QMS that supports their business objectives and the skills required to maintain effectiveness. She has 18 years of medical device experience. This experience includes senior positions in Quality and Regulatory Affairs. To learn more about her, please connect with Brigid on LinkedIn: http://www.linkedin.com/in/brigidglass.

Rob Packard was a BSI Lead Auditor, instructor for BSI, and Director of Quality for several companies. Now he is a full-time regulatory consultant specializing in regulatory submissions for the USA, Canada and Europe. In addition to consulting and teaching courses, Rob teaches webinars, manages two LinkedIn Groups specific to QA/RA, writes articles for BoneZone, and posts new blogs on related topics every week. He is founder of the Medical Device Academy and resides in the Green Mountains of Vermont. To learn more about him, please connect with Rob on LinkedIn: http://www.linkedin.com/in/deviceqms.

This 2-day course will be taught in three different cities back-to-back:

April 11/12 – San Diego, CA April 15/16 – Orlando, FL April 17/18 – Las Vegas, NV

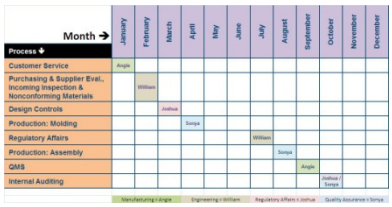
Early-bird pricing is $1,600—until February 18th. The price increases to $1,900 on February 19th. Hotel accommodations for two nights are included in the pricing (Homewood Suites in San Diego, and Embassy Suites in the other two cities—each is located near the respective airport). If you live locally and do not need a hotel room, when you register please select "Registration no hotel (San Diego)", "Registration no hotel (Las Vegas)", or "Registration no hotel (Orlando)" at the bottom of the registration page. The registration fee will be automatically reduced by the actual cost of the hotel for two nights plus tax. If you want to be invoiced, or to pay by check, please email Rob directly at: rob@13485cert.com.

Day 1		Day 2	
10:00a-10:15a	Introductions	8:15a-9:30a	Coaching New Auditors
10:15a-11:30a	Audit Programme Planning	9:30a-10:00a	Break
11:30a-1:00p	Break with Lunch Provided	10:00a-11:15a	Remote Auditing
1:00p-2:15p	Turtle Diagrams	11:15a-12:45p	Break with Lunch Provided
2:15p-2:45p	Break	12:45p-2:00p	Risk-Based Auditing
2:45p-4:00p	Interviewing Skills	2:00p-?	Catch an early flight home!
4:00p-?	Networking / Social Hour		

To Register ➔ http://www.medicaldeviceacademy.com/registration/

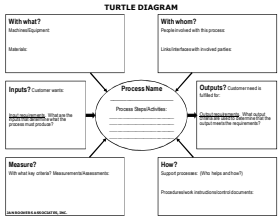
Six Training Modules to Make Your Audit Program Better

Audit Programme Planning



It's that time of year when you have to pull together the annual audit schedule again. Are you 100% satisfied with your audit programme or would you like to improve it? In the first module we will review the overall process of planning audit programmes and discuss approaches to get more from your auditors and the audit programme. This strategic approach to planning will change your approach forever.

Process Approach & Turtle Diagrams



Checklists are great for making sure that all aspects of the regulations are covered, but is there a way to get more out of your audits? Imagine how nice it would feel to eliminate that "Control of Records" audit, and several other audits from your schedule that consist primarily of reviewing mountains of paperwork. After completing this second module you will understand why separate audits of support processes are largely unnecessary, you will be able to complete turtle diagrams for any process in minutes, and you will learn how to strategically select auditors according to the process flow.

Interviewing Skills

You have to prepare an auditor to visit a supplier who is less than co-operative. Or maybe you heard that one of your audit team irritated your boss during the previous audit. Maybe you aren't getting to the bottom of the critical quality issues quickly enough. Wouldn't it be great to sharpen the tools in your toolbox so that you get the results you need from your audit programme? This module includes role playing to help you master techniques that will allow you and your audit team to achieve your strategic goals. When auditors learn these skills, the perception of auditing by other managers and your suppliers will be transformed from a dreaded activity to a welcome opportunity.

Coaching New Auditors

You may not have been counting, but some variation of the word "learn" has been used seven times already. However, we have not talked about you training or teaching other auditors. An important part of this course is learning how to train auditors to use the techniques we are teaching you. The fourth module is 100% devoted to "training the trainer." You are going to have fun role-playing as the "newbie", and one of your peers will be learning how to identify ***The Teachable Moment***. That's when you ask "Why?"

Remote Auditing

Does your audit programme include distant suppliers or multiple manufacturing locations? Do you have the resources to visit and audit them all? Have you attempted remote auditing? We will discuss when remote auditing is appropriate, and you will learn techniques for planning and conducting an audit of a remote organization while sitting at your desk or in the conference room down the hall. In this module, you will plan and role-play a remote audit.

Risk-Based Auditing

Imagine you have 300 suppliers and you have to develop a schedule for evaluating 100% of those suppliers. Which suppliers will you visit on-site? Which suppliers will you audit remotely? Which suppliers will only require monitoring of % on-time and % nonconforming lots? You don't have unlimited resources. Therefore, you need to implement a risk-based approach to auditing. In this final module, you will learn how to use trend analysis, SPC, validation data, risk control plans, and previous audit findings to make the most of precious resources—your auditors.

http://bit.ly/SNICKER

To Register ➔ http://www.medicaldeviceacademy.com/registration/