



Concurrent Sessions



<p>Concurrent Sessions A Thursday 10:00 -10:45 a.m.</p> <p>1A Engineering Audits <i>John Trahan</i> <i>Intermediate</i></p> <p>This case study of a work in progress touches on traditional and evolving approaches to engineering quality and explores the influences of technology, lean principles and customer expectations.</p>	<p>5A ISO 13485: 2003 – Opportunities for Improvement <i>Paul Brooks</i> <i>Intermediate</i></p> <p>This session will review experience gained from auditing medical device manufacturers for regulatory compliance against the latest version of ISO 13485.</p>	<p>4B The Makings of a Smart Team <i>Denise Wynne</i> <i>Getting Started</i></p> <p>An innovative approach to teambuilding, coaching, mentoring, and growing internal teams to ensure success as well as consistent use of processes, audits and tailoring.</p>
<p>2A Internal Audits and Corporate Risks <i>Andy Hofmann</i> <i>Getting Started</i></p> <p>It is time to take the integrated audit to the next level: Risk Management. We will explore how an integrated audit might be employed to assess applicable risk controls.</p>	<p>Concurrent Sessions B Thursday 11:00-11:45 a.m.</p> <p>1B Supplier Chain Auditing <i>Lawrence G Mossman</i> <i>Getting Started</i></p> <p>Implementation of a strategic auditing process to address Supplier Chain issues and needs.</p>	<p>5B ASQ's Biomedical Auditor Certification – an Overview <i>Dan Whelan</i> <i>Getting Started</i></p> <p>The biomedical quality auditor works with medical devices, including in vitro diagnostics and biologics that are regulated as medical devices. This auditor conducts systematic and independent examinations of quality activities and related results encompassing many types of biomedical related entities.</p>
<p>3A Quality Model Convergence... Integrating Baldrige, Lean, Six Sigma, Balanced Scorecard, and ISO Part 1 <i>Margaret Dospiljulian</i> <i>Advanced</i></p> <p>Share tools and techniques in an interactive session that will successfully guide your organization through the performance excellence world.</p>	<p>2B Linking Audit Management & Downstream Value Chain <i>Charity Callahan</i> <i>Getting Started</i></p> <p>This presentation is about how linking Risk Management with Audit Management Business Processes with downstream value systems (and technology) can create a holistic approach to Auditing as a whole as</p>	<p>Concurrent Sessions C Thursday 1:45-2:30 p.m.</p> <p>1C Auditing Six sigma efforts <i>Doug Berg</i> <i>Intermediate</i></p> <p>Auditing Six Sigma programs and projects would focus on adherence to the general process with an aim of identifying</p>

	well as ensure quality by design practices in any new product/service development through commercialization even post launch activities.	opportunities for improvement. It would also provide an objective assessment of the process from project selection and objectives through long term results and measurable benefits.
<p>4A Tails in the Boardroom: Canine Lessons for Business Teams <i>Shannon MacFarlane</i> <i>Getting Started</i></p> <p>This study is an examination of how common canine behaviors within packs, (e.g., conflict management leadership, and communication) is equally effective when employed by members of business teams.</p>	<p>3B Quality Model Convergence... Integating Baldrige, Lean, Six Sigma, Balanced Scorecard, and ISO Part 2 <i>Margaret Dospiljulian</i> <i>Advanced</i></p> <p>Share tools and techniques in an interactive session that will successfully guide your organization through the performance excellence world.</p>	<p>2C Quality Audit Tracking Systems: The Key to Efficiency, Effectiveness and Value <i>Ed Lyons</i> <i>Getting Started</i></p> <p>This session will teach participants how to approach issues surrounding quality audit software design. Participants will learn the right design questions to ask, how to evaluate vendor packages, estimating costs, and some of the pitfalls to avoid.</p>



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<p>3C Auditing for Effectiveness <i>Stan O'Donnell</i> <i>Intermediate</i></p> <p>In the world of auditing many auditors today make the critical mistake of not reading the standards at regular intervals. Standards should be treated in the same manner as a contract document i.e., if it is required by the standard, it will be there in black and white.</p>	<p>2D Lean Living <i>Mike Micklewright</i> <i>Intermediate</i></p> <p>Lean and Single Piece Flow are not natural. Batching is. I am a Batcher. In fact, I am a Son of a Batcher! This presentation will explain why Batchin' is something so wrong, that seems so right.</p>	<p>Concurrent Sessions E Thursday 4:15-5:00 p.m.</p>
<p>4C Internal Auditing: The New Collateral Duty <i>Becky Heatherington</i></p>	<p>3D Is Your Quality System On Budget and On Track <i>Fernando Casanova</i></p>	<p>1E What to look for when auditing Corrective Action <i>Duke Okes</i> <i>Intermediate</i></p> <p>This presentation will review the similarities and differences between Corrective Action and Root Cause Analysis processes, showing that while they are interrelated, their differences are one of the reasons corrective actions are often not very effective.</p>

<p><i>Getting Started</i></p> <p>Downsizing, multitasking... buzzwords in today's business world. But are the very realities that these words are derived from, pushing some aspects of the company to smaller and smaller groups, ultimately "downsizing" them right out of business? How do we make it all work, on a limited budget?</p>	<p><i>Getting Started</i></p> <p>What do you do when you have built a solid quality foundation in a company and now you are faced with proving it to the world? You perform internal audits to ensure compliance and collect data to improve on processes. But what happens if the cost for dedicated internal auditors becomes prohibitive? You deputize!</p>	<p><i>Robert Tipton</i> <i>Advanced</i></p> <p>The presentation will show several formulas for calculating traditional performance metrics. A detailed comparison between the various types of performance metrics will be illustrated. Included in the presentation is the relationship of CPK Values to Z-Table Percent Failures.</p>
<p>5C Understanding Statistical Sampling Plans in Auditing <i>Steven Walfish</i> <i>Getting Started</i></p> <p>This presentation will provide valuable assistance to all regulated companies that need to validate their systems, including companies in the Medical Device, Diagnostic, Pharmaceutical, and Biologics fields.</p>	<p>4D Integrating Compliance System <i>Sandra Villa</i> <i>Intermediate</i></p> <p>In today's economy the workforce is shrinking, but requirements are growing. How do organizations balance the demands of managing their compliance program with fewer employees?</p>	<p>3E "Do Right Things, Right, The First Time And Every Time" Through An Integrated Management System <i>Jim Heaviland</i> <i>Intermediate</i></p> <p>The speaker will discuss the use of a Management System as a model of how to use quality assurance processes to drive compliance and improvement, ensure added value and bottom line improvement.</p>
<p style="text-align: center;">Concurrent Sessions D Thursday 2:45-3:30 p.m.</p> <p>1D Enhance Your Audit Efficiency Utilizing Flowcharts <i>Roger Kell</i> <i>Getting Started</i></p> <p>For this presentation, a flowchart depicting the auditing process will be examined and then modified to make the auditing process more efficient.</p>	<p>5D Clinical Site Monitoring Resource Conservation Through Implementation of Clinical Research Site "Internal Quality Management Plans" <i>Mary Low & Bill Schaal</i> <i>Intermediate</i></p> <p>Our presentation will describe the evolution of an effort to include the sixteen basic principles, a template, a QM plan, and various training methods to facilitate a QM plan implementation by clinical research site staff.</p>	<p>4E Herding Cats: Standardizing Auditors <i>Colleen McGuigan</i> <i>Getting Started</i></p> <p>So what happens when a bunch of auditors are brought together and told that they need to standardize their auditing? Using the auditors as types: the strict ISO constructionist, the wide-eyed novice, the Best Practice seeker, and the Baldrige Examiner, I will compare and contrast them one to another.</p>

<p>5E Application of Risk Management in Audits of Biomedical Co. Regulatory Issues and Compliance <i>Bruce Haggart</i> <i>Intermediate</i></p> <p>This talk summarizes the requirement for risk management in Biomedical Technology Companies both by international regulatory bodies and by the Federal Drug Administration providing a path to compliance by outlining methods for application of risk mgmt. throughout the development, manufacturing, quality, and post-distribution business processes.</p>	<p>4F Ten Essential Audit Questions <i>Craig Cochran</i> <i>Getting Started</i></p> <p>All experienced auditors have their favorite audit questions. I have a short, punchy list of the questions that I always seem to ask while evaluating a management system. What are truly the most important audit questions?</p>	<p>3G How to Cheaply Implement an Effective Internal Audit Program Jeffrey Stephens <i>Getting Started</i></p> <p>In this case study of a \$50M international medical device manufacturer, repeated ISO observations lead the quality management team to doubt the effectiveness of their internal audit program.</p>
<p style="text-align: center;">Concurrent Sessions F Friday 8:30-9:15 a.m.</p> <p>1F How to Audit the Difficult Areas <i>Larry Whittington</i> <i>Intermediate</i></p> <p>The applicable ISO 9001:2000 requirements will be examined for each of these difficult areas and then suggestions made on how to more effectively audit them. In addition, participants will be encouraged to identify their internal auditing concerns for the instructor and other participants to suggest possible solutions.</p>	<p>5F Beyond Redlines; Creating a practice-based QM system <i>Cliff Moser</i> <i>Getting Started</i></p> <p>Identifying & measuring quality in the practice of architecture may seem to be elusive & difficult; identifying the ABSENCE of quality is not. Designing a Quality Management (QM) system for the architectural firm begins by creating processes that help inhibit & mitigate the absence of quality.</p>	<p>4G Improving Heart Attack Care through Chest Pain Center Accreditation <i>Tony Joseph</i> <i>Advanced</i></p> <p>As the work of planning for Chest Pain Center accreditation took form, it became clear that accreditation could be used for much more than separating true Chest Pain Centers from others. In light of the wide variation within true Chest Pain Centers, a process improvement based approach to accreditation was proposed.</p>
<p>2F Automotive Excellence - Toledo Audit Focus Group, Toledo ASQ Section 1010 <i>Maggie Jones</i> <i>Getting Started</i></p> <p>The purpose of the Toledo Audit Focus group is to provide a gap assessment /</p>	<p style="text-align: center;">Concurrent Sessions G Friday 9:30-10:15 a.m.</p> <p>1G Layered Audits <i>Bob Clark</i> <i>Intermediate</i></p>	<p>5G Building Information Modeling (BIM) and Construction: Virtual Building for a Construction Project <i>Tom Krajewski/DPR</i> <i>Intermediate</i></p> <p>Although computer-aided design is widely used in the architecture-engineering-construction (AEC) industry,</p>

<p>Internal Audit to ISO 9001, or TS 16949, to area businesses that would like a fresh look at their Quality Management Systems (QMS) or to verify that they indeed are ready for their third-party auditor.</p>	<p>Audits are part of every known quality system. The adage “You get what you inspect, not what you expect.” has been proven true numerous times. As such, a comprehensive audit plan should be established for any business.</p>	<p>the exchange of information is still largely a manual process, where 2D paper drawings are reviewed to identify conflicts. Obviously, this process is time consuming and inefficient - not only do many conflicts go undetected but it's nearly impossible to quickly determine how design changes will affect the project's cost and schedule. Thus, an average project will lose 8 to 15 percent of labor costs due to mistakes that cause change</p>
<p>3F Simultaneous Quality Systems Registration <i>Scott VanElls</i> <i>Advanced</i></p> <p>Presenter will discuss the best practice for implementing additional International Quality Standards using the tools you already have. With a standard specific Gap Analysis, a strong Internal Quality Auditing program and of course the backing of Management.</p>	<p>2G Networking</p>	<p>Concurrent Sessions H Friday 11:00-11:45 a.m.</p> <p>1H Distance Auditing <i>Jose Luis Perez</i> <i>Getting Started</i></p> <p>Distance audits are audits carried out remotely - over the telephone and evaluating evidence online. Distance audits offer an excellent alternative to costly face-to-face audits.</p>



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<p>2H Data Mining and SPC Demystified <i>Jay Author</i> <i>Intermediate</i></p> <p>Perhaps the hardest part of Lean Six Sigma is turning reams of data into a simple but elegant improvement story. In this session, Jay will demonstrate tips</p>	<p>2I Virtual Audits – Integrating technology into the audit process <i>Ron Fishman, Olivia Morgan</i> <i>Getting Started</i></p> <p>This presentation will highlight our experiences with virtual auditing and provide insight into how virtual audits</p>	<p>2J How Annual Product Reviews Facilitate Process Auditing or How To Save Money On Auditing <i>Stéphanie Peika</i> <i>Intermediate</i></p> <p>By conducting APRs, an organization can better control its processes and/or suppliers, and reduce the frequency of</p>
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<p>and techniques for mining information from Excel spreadsheets and graphing it.</p>	<p>can be integrated into your overall audit program while maintaining the quality of your audits.</p>	<p>audits. Also, the company can use an APR to shorten a third party audit and make better use of audit time.</p>
<p>3H Using Internal Auditing to Mitigate Risk from the Sarbanes-Oxley Law <i>Sandford Liebesman</i> <i>Intermediate</i></p> <p>This presentation includes: a description of the key sections of the SOX law, the system of internal control commonly used, support provided by quality and environmental management systems and improvements obtained in corporate governance.</p>	<p>3I A best practice approach, to simultaneous implementation of more than one quality model or standard. <i>Raghunandan Reddy</i> <i>Intermediate</i></p> <p>Adapting a Portfolio approach to simultaneous implementation of various models and standards so that efforts and direction are integrated towards to the common goals and objectives of the organization.</p>	<p>3J Beyond Conformance: Benchmarking Regulatory Compliance© <i>Walter Hekala</i> <i>Intermediate</i></p> <p>Concepts for private sector auditing for regulatory compliance within the context of three foundational rules. These rules are the result of work on regulatory reforms within developing countries for the past ten years.</p>
<p>4H Networking</p>	<p>4I Effective Internal Audits: Is Outsourcing the Answer? <i>Denis Devos</i> <i>Intermediate</i></p> <p>A growing trend among ISO 9001 and ISO/TS 16949 registered companies is toward outsourcing their internal audits. A survey was conducted to explore attitudes toward this issue between September 2006 and April 2007.</p>	<p>4J Audit This! Auditing Made Simple <i>L. Blandford and Kenneth Leamer</i> <i>Getting Started</i></p> <p>Typical Auditing Practices, Auditing Made Simple with an Audit Management System. An Audit example in Motion, Benefits of an Audit Management System, Audit Management Systems simplify audits</p>
<p>5H Creating a Balanced Scorecard for the Architectural Firm <i>Cliff Moser</i> <i>Intermediate</i></p> <p>Few design firms understand how intangibles drive and control their capacity for successful growth and strategic development, helping win exciting work and create innovative designs. Creating and designing metrics for performance assessment will provide tools for organizational sustainment, and improvement as well as growth and advancement.</p> <p>This presentation will help the design</p>	<p>5I Performance Management Systems: New Thinking for Design Firm Leaders Part 1 <i>Jack Reigle</i> <i>Intermediate</i></p> <p>For many in the design industry, traditional performance measurements such as utilization rate, overhead rate, etc. represent the level of formal analysis a firm undertakes in tracking performance. Benchmarking data may also be added to provide a sense of how you're performing in relation to other firms. Learn about a system designed to merge</p>	<p>5J Performance Management Systems: New Thinking for Design Firm Leaders Part 2 <i>Jack Reigle</i> <i>Intermediate</i></p> <p>For many in the design industry, traditional performance measurements such as utilization rate, overhead rate, etc. represent the level of formal analysis a firm undertakes in tracking performance. Benchmarking data may also be added to the mix to provide a sense of how you're performing in relation to other firms. Learn about a system designed to merge performance</p>

<p>firm recognize balanced performance and help it create and implement new performance and quality metrics.</p>	<p>performance management for on-going business operations, new innovations, and strategic initiatives.</p>	<p>management for on-going business operations, new innovations, and strategic initiatives.</p>
<p style="text-align: center;">Concurrent Sessions I Friday 1:45-2:30 p.m.</p> <p>11 Applying ISO:9000 Concepts to Performance Based Contracting <i>Chandru Idnani</i> <i>Advanced</i></p> <p>ISO:9000 is the structural framework of a business system that specifies the necessary components of a quality management system.</p>	<p style="text-align: center;">Concurrent Sessions J Friday 2:45-3:30 p.m.</p> <p>1J Auditing Principles: In Auditing as in Life <i>JP Russell</i> <i>Intermediate</i></p> <p>Current best-practice solutions for organizations supplying the mobile environment; drawn from in and outside the design and construction industry.</p>	 <p style="text-align: center;">ASQ 16th Annual Audit Division Conference</p> <p style="text-align: center;">Innovation Strategic Auditing Implementation Interaction</p> <p style="text-align: center;">Atlanta Georgia, October 11-12, 2007</p>