Remote Audits:
New Challenges and Opportunities

Remote Audits: New Challenges and Opportunities
Moderator: Gerard Pearce, Executive Vice President , SQA Services
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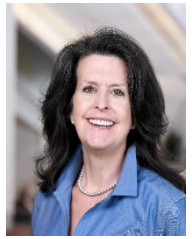
Featured Topic

Remote Audits: New Challenges and Opportunities

Without notice, companies have been forced to consider alternatives to traditional on-site audits and face new challenges with remote auditing. Where to begin, and how to plan and prepare for a remote assessment will be the topic of this webinar. Perspectives by a finished product manufacturer, supplier, and auditor will be shared with strategies to address:

New Approaches to Consider
Planning and Scope
Communication
Technology Considerations
Secure Collaboration for Information Sharing
Limitations of Being Off-Site

Featured Speakers



Panelist,
Donna Gulbinski
Chief Quality & Regulatory Affairs Officer
Civica, Inc.

Panelist,
Laurel Hacche, Ph.D.
Field Engineering Director
SQA Services, Inc.

Panelist,
Jennifer Darr
Quality Assurance Supplier Qualification
Civica, Inc.

Moderator,
Gerard Pearce
Executive Vice President
SQA Services, Inc.

Panelist,
Tony Thesing
Senior Manager, Quality Systems & Compliance
American Regent

Agenda

- Background
- Quality Management System Perspective
- Supply Chain (Auditee) Perspective
- Auditor Perspective
- Panel Discussion and Q&A

Background

- **Drivers**
  - Feasibility and necessity
  - Flexibility to achieve audit objectives by auditing in a new way
- **Benefits**
  - Low-touch environment, travel savings, flexibility, reduced 'face time'
- **Challenges**
  - Security/confidentiality, quality of objective evidence, tech maturity
- **Guidelines for Remote Auditing**

Guidances and Standards

- ISO 9001 Auditing Practices Group, QMS Audit Topics for ISO 9001:2015, 2 Auditing General, Remote Audits: https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html
- ISO 19011:2018, Guidelines for auditing management systems, A.16 Auditing virtual activities and locations: https://www.iso.org/standard/70017.html
- European Medicines Agency, Guidance on regulatory requirements in the context of the COVID-19 pandemic (April 2020): https://www.ema.europa.eu/en/news/guidance-regulatory-requirements-context-covid-19-pandemic
- United States Food and Drug Administration (USFDA), Medical Device Single Audit Program, MDSAP AU P0036.001, Remote Audit Pilot Program, 13 January 2020: https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-audit-procedures-and-forms

Definitions

- **Questionnaire**: A document that is submitted to a facility to gather data prior to an audit or when it has been determined that an on-site or remote audit is not required via risk assessment
- **On-site Audit**: When an auditor is on-site at a facility conducting a "face to face" inspection
- **Remote Audit**: Refers to the use of Information Communication Technologies (ICT) to gather information, including interviewing an auditee when "face to face" methods are not possible or desired and all data is exchanged in electronic formats.
- **Desktop Audit**: Refers to a review of documents and records only. A desktop audit would not routinely include auditee interviews. Desktop Audits may include the use of hard copy and/or electronic records.

Quality Management System Perspective

Donna Gulbinski
Jennifer Darr

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At Civica We Must Deliver Quality Medicines in a Reliable Manner at Fair and Sustainable Prices





This Privilege Comes with Significant Responsibilities

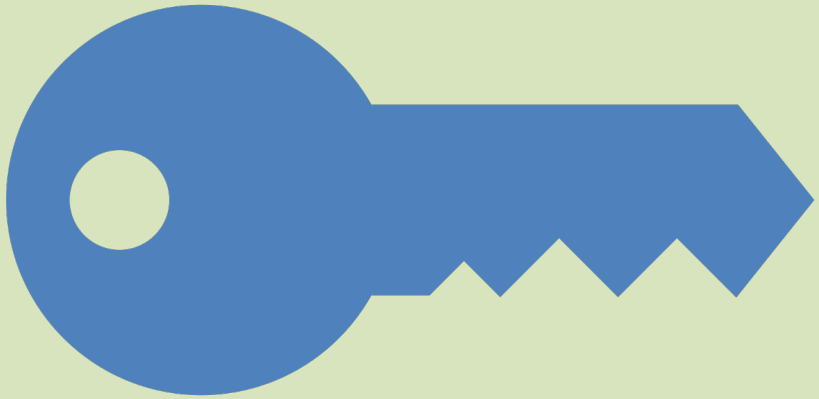




Virtual Audits Aren't Just A Good Idea … they may become the way we do things for a while

- Background for the basis of virtual auditing -
  - FDA FDASIA –
    - Allowing FDA to determine inspection frequencies based on risk and
    - to collect information that they would otherwise obtain during inspection
  - FDA's approach under COVID
    - May have suspended routine surveillance
    - They are conducting PAI for new therapies and for cause
    - Won't be surprised when FDA starts virtual inspections for the same reason we started virtual audits

Virtual Auditing- Key Points



- Overall Approach- End to end coverage
- "Live" Access- Allows for efficient interviewing of SMEs and site engagement
- Audit thoroughness compared to traditional audit setting
- Technology enhances virtual success

Supplier Qualification in a COVID-19 World

What stays the same?

- Auditing of the facilities
- Routine meetings to establish product set-up, serialization and launch
- Pre-shipping authorization to review batch information until qualified
- Civica release of each batch

What changes?

- Facility audits are conducted via video/teleconference vs in person
- Audit process does not change with regard to systems reviewed
- Limited ability to observe the physical facility – will mitigate with video review
- Will reserve the right for a follow-up site visit

Supply Chain (Auditee) Perspective

Anthony Thesing

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Supply Chain (Auditee) Perspective

- Have CDA in place to allow sending documents ahead of the Audit and/or sharing live – suggest use of a virtual Doc Sharing service or room
- Ask for agenda with specificity at least as week prior
  - Find out if pictures and/or walk through videos will be requested by Auditor
  - (have someone on site able to do it live if necessary, with the means to connect to the conference)
  - Conference ahead of audit call to clarify any items
- Separate auditors into different tracks
  - Extremely difficult to manage multiple auditors, questions, talking, ambient noise
- It's a slow process and technology issues can happen
- Be prepared for surprises, be ready to improvise, and be able to make adjustments/changes on a moment's notice

Supply Chain (Auditee) Perspective

Preparation is key

- Like in person audit, have support room (physical or virtual) in place
- Compile all required documentation in a central place (that the whole team is familiar with) for easy and quick access
- Create a catalogue system in virtual room request numbers to agenda for easier traceability
  - Save requests in identified locations by assigned number rather by time slot
- Separate electronic locations for SMEs to deliver requests and for inspection/audit lead to "store" before delivery to auditor
- Have representative SME's on a "call list" to be fully participating in the Audit or be readily available upon request at any time during the Audit, including

Auditor Perspective

Laurel Hacche

Audit Preparation:

- A pre-audit meeting should be scheduled with the auditee to verify the IT systems available and the content that can be shared via a web interface (Zoom, WebEx, or alternate).
- Trial runs for the web interface are recommended.
- A comprehensive Agenda with detailed timelines should be provided. The Agenda should also include the required Documents and Records for specific time slots.
- Current experience has shown that use of a web-based data repository, such as Box or Datasite to be successful with the exception that Documents and Records must be downloaded for effective auditing.

Audit Execution:

- Use of video conferencing is recommended, such that it is clear when the auditor/auditee are present. It also adds an opportunity for person to person contact.
- Staying on track with Agenda timelines can be challenging, especially if there is an over abundance of Documents and Records provided for a specific topic.
- Use of video presentations for facility tours and line function activities is recommended.
- Challenges have been noted for auditing smaller facilities that have limited resources and limited IT infrastructure.
- If multiple auditors are involved, off-line meetings (separate WebEx connection) should be scheduled prior to daily close out meetings to ensure that discussions with respect to potential audit findings can be conducted.

Post Audit Follow Up and Final Report

- Access to the data repository post audit should be provided to ensure that key information is included in the final audit report.
- Ongoing communication with the auditee is key to ensuring that any follow up items can be addressed.
- Focusing on key points is imperative. As there is a lot of information shared via the data repository, the audit report should focus on critical to content information, including Records reviewed.
- Challenges have been noted with the use of multiple auditors for one audit, including combining auditor write ups and ensuring that all observations are reported accurately.

Panel Discussion Q&A

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Today's Speakers

Gerard Pearce

Gerard is a quality and supply chain expert with over 25 years of experience in combining the disciplines of quality, technology and supply management. His expertise spans a variety of quality-critical industries in a global manufacturing landscape. For the last 19 years, he has focused on defining the processes and infrastructure that provides managed supplier quality programs for numerous global leaders in the fields of personal care, pharmaceuticals, medical devices, aerospace & defense, electronics, consumer goods, and more. Central to this infrastructure is the technology required for effectively running global supplier quality operations by connecting all stakeholders in the supply chain. Currently the executive vice president and head of operations with SQA, Gerard is a regular industry commentator and contributor, and is closely involved in shaping and implementing the global supplier quality strategy for SQA's Fortune 500 clients.

Today's Speakers

Donna Gulbinski

Donna's expertise spans worldwide operations, quality, and regulatory experience across vaccine, biological, pharmaceutical and device technologies where she was an operational leader with a history of delivering exceptional quality, compliance and business performance.

Donna has a 30-year plus career where she held positions of significant responsibility for Quality and GxP Compliance, including various roles in drug discovery, operations, quality and regulatory affairs at both Merck & Co., Bristol Myers Squibb and Lachman Consultants. Donna is currently the Chief Quality & Regulatory Affairs Officer at Civica, Inc., a new independent not-for-profit company founded by health care systems and philanthropies to address critical generic drug shortages caused by market failures.

Today's Speakers

Jennifer Darr

Jennifer has worked in the manufacturing space for the pharmaceutical industry since 2007. Holding a Bachelor's degree in both Biology and Chemistry, Jennifer spent the beginning half of her career at a small molecule API facility operated by Roche/Genentech. Transitioning for the past several years as a Quality Manager with focus on virtual business model organizations, Jennifer as a certified ASQ Lead Auditor, has participated in an estimated 40 audits in the past 5 years. As a veteran auditor, inspecting facilities all over the World, Jennifer brings insight and perspective in this panel discussion.

Today's Speakers

Anthony Thesing

Since 2006, Tony's experience has spanned the sterile injectable, oral solid dose and Personal Care industries. In his current role at American Regent he is responsible for all activities related to Inspections/Audits, Complaint Management, Investigations, CAPA, Change Control and Annual Product Reviews. Prior to his role at American Regent, he has held various roles supporting Quality, Compliance, and Microbiology for Dow Corning (now Dow Consumer Solutions) in Midland, MI, as well as Teva Pharmaceuticals in Cincinnati, OH. He holds a Bachelor's Degree in Biology from the University of Cincinnati, and an M.B.A from the Florida Institute of Technology.

Today's Speakers

Laurel S. Hacche, Ph.D.

Laurel Hacche is a Senior Professional with over 30 years of experience in the pharmaceutical, device, cosmetic, and biologics industries. Prior to her role as SQA Field Engineering Director, she was the Senior Director of Third Party Manufacturing in the Global Sourcing & Procurement department at Allergan, Inc. During her tenure with Allergan, she also served as the Director of Worldwide Quality Assurance with oversight for the corporate CAPA system, annual product reviews, government agency communication records, third party manufacturers, the global audit and stability programs, complaint management, and R&D technology transfer. She has also served as the lead corporate QA liaison for the FDA and alternate regulatory agencies.

Prior to Allergan, Dr. Hacche served as a Postdoctoral Researcher in the Department of Biological Chemistry at the California College of Medicine at U.C. Irvine. She has also held an Associate Faculty position at Saddleback College and served as an Assistant Professor at the Joint Science Department for the Claremont Colleges. Dr. Hacche has a Ph.D. in Physical Polymer Chemistry from U.C. Irvine and an A.B. in Chemistry from Occidental College.

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