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# Audit Forum: Invitation To Participate

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# Invitation to Participate

**AUDIT FORUM**
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Audit Forum provides readers an opportunity to discuss information, experiences, and practices within the broad topic scope of audits. Discussions topics may include external and internal audits, best practices, problem situations, and other areas of concern. Traditional audit activities as well as virtual audit topics may be discussed. Journal submissions for publication in the Journal of Validation Technology and Journal of GXP Compliance are most welcome. Blog discussions posted on the IVT Network are more informal and are also very welcome. IVT "Voices in Validation" podcasts provide visual and verbal discussion by individuals and groups. Please respond in the comments section below with ideas, suggestions, or topics for discussion.

**Welcome to Audit Forum**

Audit Forum is a new IVT feature that will provide readers an opportunity to discuss information, experiences, and practices within the broad scope of audits. Audits are a part of daily life in pharma, med devices, and other regulated industries. Audits used to be relatively limited and generally routine in performance. In the "old" days (more than 2 years ago), audits were conducted face-to-face at the manufacturing site. Some audits began with facility tours and emphasized review of documented procedures; others were more process oriented as opposed to document reviews. Company personnel and auditors interacted directly – "face-to-face" -- without PPE masks. Other approaches have been tried over the years – checklists, telecons, and combinations thereof dictated by costs, efficiencies, and other factors. Since then, we have moved to virtual audits with Zoom technology in which auditors reside in their offices or at home and site personnel may also be offsite. Manufacturing facilities provide video technology for facility tours. Audits now require new considerations, skill sets, training, and preparation, and more changes are a certainty. What was originally intended (hoped) to be a temporary change in auditing will likely become routine practice depending on the application.

## WHY THIS FEATURE?

The idea for Audit Forum came from multiple sources. Validation and Quality Managers have often requested that audits topics be addressed in the IVT journals; there is universal agreement among industry personnel for the need to address topics related to audits. Regulatory agencies have been forefront in audit practice changes. FDA has recently issued Remote

Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency (1,2) describing methods and applications of audits. MHRA has also addressed virtual audit policies and procedures (3-5). IVT has recently published Digitization of Validation for Effective Off-Site Regulatory "Review" and "Inspection" and presented a Voices in Validation podcast of content with the authors (6-7). Any effort to increase the knowledge and awareness of industry personnel regarding issues associated with audits in daily work life will be useful to readers.

## AUDIT FORUM CONTENT

The potential scope of Audit Forum content is extensive. Companies have external audits, e.g., an external regulatory agency investigates, inspects, or otherwise visits a manufacturing site for a routine inspection or for cause – companies are audited. In turn, company personnel audit material suppliers and contracted organizations who service the company – companies are the auditors. The great increase in virtual or partially-virtual organizations has made auditing CROs, CMOs, laboratories, and other functional organizations a critical business and quality activity. Finally, and perhaps most important are internal audits in which audits are conducted on internal functions for multiple purposes. Pharma and Device GMPs require internal audit programs; management may review key business functions in the organization; "mock" audits may be conducted to develop infrastructure or train personnel in the audit experience. Successful organizations are proactive in preparation for audits and are continually prepared for an external audit. Audit Forum is intended to address topics associated with all of the above.

## WE NEED YOUR HELP

The title Audit Forum was selected to emphasize our desire for reader involvement as well as to represent the multiple communication methods available through IVT. We envision brief discussions of individual audit topics followed by example practical applications. Readers have opined their preference for case studies describing practical applications of theory; we intend to emphasize problem situations and successful practices to enhance audit readiness and performance. Journal submissions for publication in the Journal of Validation Technology and Journal of GXP Compliance are most welcome. Blog discussions posted on the IVT Network are more informal and are also very welcome. IVT "Voices in Validation" podcasts provide visual and verbal discussion by individuals and groups; information sharing through IVT podcasts has been very well received and very successful. Coupling written and podcast discussions have been effective methods of transmitting content and provide multiple preferred adult learning methods. The IVT Network is currently experiencing tremendous growth in each of our communication vehicles; applying their outreach will contribute to general website value as well as providing contributing individuals with global visibility and recognition. Audit Forum will be most successful when the validation and quality communities submit content for discussion. Please respond in the comments section below with ideas, suggestions, or topics for discussion.

## REFERENCES


1. Woodcock, Janet. FDA Provides Guidance on Remote Interactive Evaluations for Oversight of Drug Facilities During COVID-19. FDA In Brief, 4-19-21. https://www.fda.gov/news-events/press-announcements/fda-provides-guidanc... Accessed 4-18-21
2. FDA. Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency. Guidance for Industry. April, 2021. https://www.fda.gov/media/147582/download. Accessed 4-18-21.
3. .Churchward, David. MHRA Good Practice (GxP) Inspections during the COVID19 outbreak. MHRA Inspectorate, 23 Mar 2020. https://mhrainspectorate.blog.gov.uk/2020/03/23/mhra-good-practice-gxp-i... Accessed 4-18-21
4. MHRA. Guidance for Industry on MHRA's expectations for return to UK on-site inspections. 19 March 2021. https://www.gov.uk/guidance/guidance-for-industry-on-mhras-expectations-... Accessed 4-18-21.
5. Watson, Trevor. Maintaining control: Remote working and QP certification. MHRA Inspectorate, 25 February 2020. https://mhrainspectorate.blog.gov.uk/2020/02/25/maintaining-control-remo... Accessed 4-18-21.
6. Samy, Silva, Ajaz Hussain, and Alton Johnson. Digitization of Validation for Effective Off-Site Regulatory "Review" and "Inspection." JGXP, Volume 25, #1, January 2021. https://www.ivtnetwork.com/article/digitization-validation-effective-sit... Accessed 4-8-21
7. Hussain, Ajaz S, Alton Johnson, and Steven Thompson. Digitization of Validation for Effective Regulatory Inspections. Voices in Validation. IVT Network Podcast, 2-2-21. https://www.ivtnetwork.com/article/digitization-validation-effective-vir... Accessed 4-18-21.