Remote audits – The new normal

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The COVID19 pandemic is presenting unprecedented challenges to healthcare, the pharmaceutical industry's supply chain and the ways in which companies operate "business as usual". Quality and compliance activities have been particularly affected, areas that are crucial to ensure the long-term safety and efficacy of treatments.

Quality audits and inspections are essential aspects of the checks and balances in a pharmaceutical Quality Management System (QMS). With new guidance's, constrained travel and limited access to buildings, suppliers, records and people, manufacturer, regulatory and quality personnel must now explore methods and techniques to evaluate quality and compliance in light of these restrictions. To meet these challenges, regulatory agencies and companies alike are adapting to the situation, relying heavily on remote mechanisms to continue delivering lifesaving medicines and products globally.

In this whitepaper, we will provide tips and good practices for remote audits as an alternative method to conducting traditional on-site audit. This paper will also cover circumstances in which remote audits may be necessary and preferable to an on-site audit. Furthermore, we will discuss potential challenges and benefits when auditing remotely and how to adapt your processes and systems to prepare your company for remote audits.

Potential COVID-19 impacts

For most companies, the standard type of audits and inspections are on-site audits. For this type of event, Auditors or Inspectors (from this point forward we will use these terms interchangeably) are on site and conduct reviews which assess compliance with standards, regulations, and guidance's; adherence to requirements and specifications; evaluating process and system performance; evaluating the adequacy and effectiveness of the QMS; and confirms conformance. Auditors also conduct interviews and perform facility tours to view and evaluate production processes being conducted. But what happens when circumstance prevent in person audits?

Whether by design or by happenstance, companies and Health Agencies are starting to consider alternate auditing methods to traditional on-site audits. One consideration could be a remote audit - which could be equally insightful as traditional on-site audit if the required information and resources are available and established.

Remote audits are sometimes referred to as distant audits, virtual audits, online audits, desktop audits, or e-audits; however, the purpose remains the same: to evaluate and obtain evidence to determine if the established processes and QMS are effectively supporting the organization's overall quality objectives. While traditional on-site audits take place on site, remote audits utilize different techniques, tools, and technology to evaluate processes, systems, and procedures remotely.

Remote Audit Readiness - QMS and Organizational Perspective

As you consider Remote audits, you will need to look at three aspects QMS, Technology and Security and Organizational (People and Process) closely. All three areas need readiness plans and all three must support each other in a way that provides value. Let's take a look!

QMS

In general, a QMS documents processes and practices that have been implemented in a company. A company's QMS will need to describe the types of audit (supplier audit, QMS audit) and methods (on-site or remote audit) that are suitable for use. The QMS should allow for alternatives or a combination of audit methods to enhance the effectiveness and credibility of the audit performed. To avoid non-compliance with the company QMS, you will need to ensure that all audit methods defined are described in the audit procedures and any other relevant documents. The methods identified should also describe a risk-based audit approach to help identify opportunities for when and how to use a remote audit.

One of the factors driving the move towards more remote auditing is the postponement of on-site audits, either by Health Agencies or the company itself due to COVID-19 or other unexpected events. There is also the desire to make things as easy as possible and still met the internal requirements of the company and regulations. Moreover, companies and Health Agencies are becoming more open and comfortable with the increased virtualisation of business functions.

Technology attributes and security

As a company, you should always consider the security of your assets. Each and every company needs to assess, with their IT team, risks that may be introduced through the performance of remote audits.

Remote audits require both auditee and

Health Agencies to have resources, tools and infrastructure established for the audits. By taking advantage of well-established technology principles, organizations and Health Agencies are transforming audits that once depended on being in-person. The technologies supporting remote audits continue to evolve at lightning pace. As long as they are secure, there is no limitation as far as available technologies are concerned. Advances such as secure file sharing, video chats, and virtual private networks can facilitate remote audits that create flexibility and ease for both a company being audited and the audit team.

All of these technologies will have their own benefits, limitations and risks. It will be up to the companies and auditees to explore each of them in detail to determine what is and is not appropriate for use. However, one factor that will always be relevant is data protection and data privacy.

Here are some of the main considerations:

- Appropriate IT security policies and standards must be established e.g. Policy or SOP on the use of video or other technologies.
- The company will need to determine the necessary security requirements for the audit. This must include the security and confidentiality of electronic or electronically transmitted or received during the audit.
- Necessary training / introduction to company hard- and software for the Auditors should be considered. The same applies to internal staff that participate in the audit activities.
- Guidance and support from your IT department or an external IT security specialist are invaluable.

While the potential of technology and its use are undisputed people need to be pragmatic in their expectations. Things will happen! Networks go down. Software freezes in the middle of the site tour. Have a contingency plan for technology malfunctions or hurdles. While audit practitioners have technology at their disposal, they have the same obligations to comply with standards and deliver the same high-quality products and services as they would when working on-site.

Training and skills

A final aspect to consider is that technology cannot be more competent than the person who uses it. Remote audit programs and their necessary technical infrastructure present challenges - now add the human element to the equation. It is in the best interest of the company to ensure that personnel are properly trained in receiving, conducting, and managing remote audits from clients, suppliers or Health Authorities before it happens and not as a reaction to the news of an audit. Remote audits may require you to employ tools and resources that you have not used before and any training given will need to include the use of technology, ensuring there is fluency in their use for all involved.

A remote audit team must also actively communicate more than an on-site team. It goes without saying that communication skills to support an effective remote audit is paramount and should not be overlooked as an element of any training for your teams.

Now that we have outlined areas that should be ready to support Remote audits, here are some pros and cons for you to consider.

Pros and Cons with remote audits

In many cases, circumstance force a switch to a remote audit rather than a conscious, strategic or tactical choice. With the advent of remote audits as a natural part of the monitoring and compliance activities of companies it is however important to realise that

remote audits are meaningful and valuable tools of the QMS and could be selected tactically rather than by chance. To make such a decision it is important to understand under what circumstances remote audits are more advantageous than an on-site audit.

These are several reasons why conducting remote audits can be beneficial:

- Provide flexibility when unplanned event happened
- Reduces audit overhead
- More flexibility with companies with geographically dispersed
- Great option for QMS audit – documentation is easier to review remotely than actual behaviours or machinery
- More flexibility in planning without the need to account for travel time
- Multi-site organizations can be audited jointly without unnecessary repetition
- Minimizes disruption to the organization

When it comes to the challenges that an organization may need to consider with remote audits, we find the following:

- Remote audits are not accepted by all Health Authorities
- Not an option for site certification audits (First time audits)
- Longer audit timeframes – Auditors will not be constrained by travel or accommodations, which may mean remote assessments of more facilities than traditionally inspected and longer
- Time Zone differences
- QMS document update needs
- Fully electronic document management system required
- Different in terms of logistics and planning
- Challenges with technology
- Infrastructure adjustment
- Process Owner involvement
- Trusting the audit

When should Remote audits be used?

When regional, national, or global issues restrict or otherwise prohibit travel, traditional on-site audits may not be an option- thus exposing the organization to compliance challenges. As a company you will need to develop measures to mitigate the impact of disruptions caused by COVID-19 or similar events where the conduct of audits and inspections are impacted at manufacturing facilities, distribution centres, or other sites relevant for medicinal products.

Alternative ways and flexibility, where applicable, will be key. Remote audits provide an organization with a viable alternative to ensure continued compliance with regulatory requirements. Considering the global COVID-19 events Health Agencies are finding and implementing different strategies to maintain compliance and making sure that good practice standards are being adhered to.

If you need flexibility- Remote Audits may be the answer. With the current social distancing measures and business closures, remote audits have become a necessary alternative. This give the company flexibility of its resources while meeting required standards and meet regulatory requirements.

QMS audits are a good candidate for remote audits. Companies put enormous effort into developing processes and systems and use metric measurements to confirm their adherence to the standard. The QMS documents

such as records and protocols can provide good insight into the control of QMS systems and processes. Coupled with other compliance reviews a remote QMS audit is another opportunity to review and confirm compliance with internal and external requirements.

Trusted Partners are another candidate when it comes to remote audits. It takes time to build a relationship with your Supplier and Contract Manufacturing partners. Partners who have established trust with the agencies and or customers are good candidates for remote audits and likely to receive remote audits. For NEW Contract Manufacturer or Supplier, the audit should be an on-site audit, even with a high trust component, a remote audit should not be considered as an option. However, as you build trust and as the relationships becomes more established with the New Suppliers and Contact Manufacturers then a remote audit should be considered.

Global companies with multiple sites located across the world are another candidate for remote audits. Remote audits give an organization the flexibility to audit multiple sites jointly without the unnecessary repetition of reviewing common processes and systems. Remote audits also provide **flexibility in planning** without the need to account for travel time therefore reducing audit overhead cost. It means that companies don't have to pay for travel & lodging. Joint remote audits also **minimize disruption** to the organization by reducing the number of meetings, meeting spaces needed, and the resources used further **reduce overall** cost.

The regulators' response to COVID-19

All major regulatory authorities have responded to the COVID-19 crisis by suspending part, most or all of their on-site audits. These are gradually being replaced by remote audit alternatives. Below we have summarised the responses of the EMA, the MHRA, FDA and MPA.

European Medicines Agency (EMA)

The EMA plays a key role in coordinating the EU's Good Manufacturing Practice (GMP) inspections of pharma manufacturing sites. In cases where on-site audits are not currently possible, the EMA suggests that "a risk-based supplier qualification process can be supported by a remote or virtual audit." And while the benefits of on-site tours of facilities, warehouses, and laboratories are impractical at this time, the Health Agencies suggest other audit procedures – such as interviewing personnel and reviewing documents – could still be handled remotely.

In addition, the European Commission, EMA and the Heads of Medicines Agencies (HMA), are extending the validity of GMP certificates and time-limited manufacturing and import authorizations, as well as the validity of GDP certificates and time-limited wholesale authorizations until the end of 2021. If needed, inspections will be carried out remotely to support such extensions, with on-site inspections carried out as soon as possible.

Medicines and Healthcare Products Regulatory Agency (MHRA)

MHRA announced in March 2020 that it would only be conducting "essential" on-site inspections, and that it expects pharma companies to maintain GxP compliance. In other cases, alternative approaches such as office-based assessments will temporarily replace some aspects of on-site inspections.

U.S. Food & Drug Administration (FDA)

In-person visits to most facilities inside and outside the U.S. have been postponed

indefinitely and periodic updates are being communicated via the FDA website (Updated COVID-19 information from FDA). FDA is preparing to resume domestic audits, beginning the week of 20 July 2020, with a new risk assessment system. FDA has developed a rating system to help companies understand when and where is it safest to conduct prioritized domestic inspections. FDA has introduced "alternative tools", such as remote assessment, which means an increased focus on document review and decreased review on the review of the facility.

Swedish Medical Product Agency (MPA)

MPA's mission is to ensure that patients and healthcare professionals have access to pharmaceuticals and medical devices products that are safe. In the current situation, MPA has stated that on-site audits should be avoided or postponed. If audits are needed, they should only be conducted, if permitted, under national, local and/or organisational social distancing restrictions. On-site audits as well as remote audits can be considered for clinical trials and only after agreement between the authorities and the investigator. If the audit is essential (e.g. triggered audits with the purpose of investigating serious deviations from the trial protocol or from the applicable legislation). MPA is collaborating with the other Health Agencies in Europe to share their experiences about distant GMP audits we other agencies1 to develop strategies and guidance's for audits that are considered essential to ensure the continued supply of medicines to patients during the corona virus pandemic.

Conclusion

2020 has been an unprecedented year for the drug development industry and for people all over the world, due to the COVID-19 pandemic, and remote audits are here to stay. With the introduction of novel approaches to auditing assessments and conformance reviews we as an industry will need to learn, adapt, educate, and transform. This is not a very fast process, but once we've absorbed the experience, we will have taken another important step forward for patients around the world.

It is clear that remote audits provide essential advantages to on-site audits; hence it is crucial for successful quality monitoring to have a clear strategy for when to apply them. Doing it right will save money and improve operational efficiency, while maintaining product quality and patient safety.

While the global COVID -19 pandemic is an extraordinary situation, for all of us, extraordinary situations call for extraordinary actions to ensure patient safety. Health Agencies all over the global are designing more strategies, providing flexibility, and adjusting, as needed, when it comes to remote audits.

And while the pros of a remote audit outweigh the cons, companies should always ensure that the necessary infrastructure, personnel, and technology are appropriate and available to handle the remote assessment.

As an expert consultancy in novel drug development, therapies, and regulation, NDA continues being at the forefront of these new developments. We are ideally and uniquely positioned to support development of appropriate risk mitigation and audit strategies as well as supporting companies in the transition to an environment where remote audits are becoming the new normal.

NDA's mission is to bring medicines to the world without unnecessary delay. To learn more about Remote audits and find out how we can help you. Contact us: info@ndareg.com

About the author

Helen joined NDA in 2019 as Global Head of Quality. She is a leader in Quality and compliance operations for global corporations specializing in pharmaceuticals, biopharmaceuticals, medical devices, healthcare, and life sciences. Helen has over 20 years of success developing and implementing global Quality Management Systems that drive an organizational focus on good manufacturing practices (GMP), good distribution practices (GDP), Quality system regulation medical devices and compliance to support business objectives.

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