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The Challenges of Remote Auditing Faced by the Pharmaceutical Industry

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The Challenges of Remote Auditing Faced by the Pharmaceutical Industry

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Abstract

On the 11th of March 2020, the World Health Organisation (WHO) declared the COVID-19 outbreak as a global pandemic. The way companies operated had to change and many people are now encouraged to work from home. Companies have had to adapt many of their work practices and in some cases adopt new ways conducting activities such conducting and hosting of audits. The paper seeks to investigate the challenges and potential benefits with conducting remote audits.

An industry-based survey was conducted to identify the challenges with conducting remote audits from the pharmaceutical industry's perspective. To overcome some of the challenges identified an action plan is proposed to facilitate companies in preparing for remote audits, as it appears this "new normal" may be something that we all have to adapt to in the future.

Introduction

On the 11th of March 2020, the World Health Organisation (WHO) declared the COVID-19 outbreak as a global pandemic(WHO, 2020). COVID-19 is a highly contagious virus that attacks the lungs and airways. There is currently (at the time of writing this paper, November 2020) no vaccine approved for COVID-19. Due to the fast spread of the virus throughout the world, governments are developing and enforcing plans to control the spread of the virus within their countries. The first case of the virus in Ireland was confirmed on the 28th of February. International travel bans for many countries were enforced in an effort to control the spread of the virus. This travel ban has impacted many industry sectors, including the pharmaceutical industry. One impact of this travel ban was the postponement of on-site 'Good Manufacturing Practice' (GMP) audits. Auditors would normally travel to

manufacturing sites to inspect facilities; this is no longer possible with such travel bans. Companies have had to come up with new approaches and ways of conducting such audits. Equally, regulatory agents have had to develop plans on how to conduct GMP compliance audits utilising staff in a 'remote working' environment.

The European Medicines Agency (EMA, 2020) has released updated guidance on audits and has deemed remote auditing acceptable. While travel bans are being rescinded by some countries, rules and good hygiene etiquette regarding social distancing will still apply into the future. Social distancing is defined maintaining safe space (typically about 2 metres) from someone not from the same household (Centers for Disease Control and Prevention, 2020). This is been termed the new 'normal'; furthermore, it is anticipated that social distancing will be in place until a successful vaccine is found. This 'social distancing' etiquette will have a major impact on GMP auditing on-site, even when all travel bans are lifted. This has resulted in companies within the industry, conduct risk management plans for all of their operations including auditing activities.

With such restrictions and operational requirements now in place, companies and regulators are now exploring the concept of remote GMP auditing to replace the traditional on-site audit. One possible solution is remote audits performed off-site through the use of information and communication technology (FDA, 2020). When the European Medicines Agency (EMA) issued guidance to assist the industry during the COVID-19 Pandemic; they extended the validity period of current GMP Certs and stated that 'If needed, inspections will be carried out remotely to support such extensions, with on-site inspections carried out as soon as feasible'(EMA, 2020).

Remote Auditing

Remote/digital auditing is a form of accessing a company for compliance by teleconferencing, phone calls and emails. Traditionally in the pharmaceutical industry regulatory and supplier audits are held on site. The COVID-19 pandemic has forced both companies and regulatory agents to think about the auditing process in a different way. With the advances in technology it is now possible for audits to be held remotely.

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Remote auditing is one of the audit methods described in International Standards Organisation (ISO) guidance document ISO 19011:2018 Annex A1(ISO, 2018). However, this was published before the outbreak of COVID-19. An updated ISO guidance document "ISO 9001 Auditing Practices Group Guidance on: REMOTE AUDITS" (ISO, 2020)was issued in April 2020 and gives extra guidance on remote auditing as a result of the global pandemic. The guidance document outlines different areas that need to be considered when conducting remote audits. It also details some potential risks and limitations with remote auditing.

> '*The first step to ensure feasibility is determining what technology may be used, if auditors and auditees have competencies and that resources are available'*
>
> (ISO, 2020)

Without the correct technology remote auditing is not possible. One pressing area of concern that must be addressed before remote audits are decided is that of data security and protection. In terms of data security and protection there should be appropriate agreements put in place between the auditee and the auditor. Before COVID-19 it is possible that the use of screensharing and video recording many not been covered in agreements and this needs to be rectified in any future arrangements. The ISO document states '*when analysing feasibility, the digital quality of the data to be reviewed should also be considered*' (ISO, 2020). This is an important factor to be considered as remote auditing may not be feasible if a company's documentation is not completely digitised.

Regulatory Audits

The EMA coordinates the inspections for medical products that are manufactured and sold within the European Union (EU). The EMA does not conduct audits itself, the competent authorities of EU member states must conduct these audits, in accordance with EMA guidance and regulations. The Health Products Regulatory Authority (HPRA) conducts Regulatory GMP audits on behalf of the EMA in Ireland. Typically, these audits are done every 2 to 3 years, using a risk-based approach.

The EMA have stated that current GMP certificates will be extended until the end of 2021 for companies in the European Economic Area (EEA). However, it should be noted; this does

not cover any changes to the GMP Certificate. If a company is located within the EEA but the facility has never been inspected before, there will be a need for a 'distant assessment'. This is identified as a remote audit, with the provision that '*on-site inspection should be conducted when circumstances permit*' (Medicines Agency, 2020). The EMA have stated that they will conduct 'distant inspection' if required so companies need to prepare to host these inspections if required.

Supplier Management

Even in the middle of a global pandemic the safety of drugs delivered to patients is a priority for the regulatory agents. This means companies must still ensure the competency of their supplier and contact manufacturers. It was made clear in the EMA Q&A document issued April 2020 that '*that the obligation of manufacturers and importers to comply with GMP is not waived*' (Medicines Agency, 2020)'. Companies have had to adopt new ways of working and still ensure they have oversite of their suppliers and contract manufacturers. The EMA also identify and explain some regulatory flexibility during the COVID-19 pandemic in relation to this aspect of supplier management. Temporary changes are permitted when required e.g. '*On sites re-audits of suppliers, and replacement by remote audits*' (Medicines Agency, 2020).

An assessment using an appropriate risk-based approach and the use of a Quality Risk Management system is recommended. '*Remote audits should provide confidence that the contracted party is fit-for-purpose and will not negatively affect the wholesale distribution process*' (Medicines Agency, 2020). This requires companies to develop remote auditing plans using a robust methodology and framework. To explain, each situation should be assessed, documented, and authorised using a risk-based approach.

In January 2009 ICH guideline Q9 on Quality Risk Management was released. This guidance document enables manufacturers to build in quality risk management to their process from development to packing and shipping within the stages of product lifecycle. The main focus of risk management is to produce a safe and effective drug for patients. The term Quality Risk Management is defined by the ICH as '*A systematic process for the assessment, control, communication, and review of risks to the quality of the drug (medicinal) product across the*

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product lifecycle'. The term 'risk' is described as '*The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51)*'. Risk assessments are used to determine the risks and how to eliminate or mitigate against them.

ICHQ9 identifies that quality risk management can be integrated into auditing and inspections planning '*To define the frequency and scope of audits, both internal and external*' Risk assessments consider different factors when determining the audit schedule such as: pervious inspection reports; and, the complexity of the product. Risk management is used by manufacturers and the regulatory agents to plan their inspections '*To assist with resource allocation. including, for example, inspection planning and frequency, and inspection and assessment intensity*' (ICH, 2015). Both manufacturers and regulators are advised to use risk management tools to assess the risk in conducting audits during the global pandemic. The goal is always to reduce the risk to patients but also during a global pandemic, the elimination or mitigation of this risk for inspectors to visit a manufacturing facility needs to be considered. While mindful of the recommendation that non-essential travel should be avoided; if the risk assessments can justify either extending the period until the audit or performing remote audits, this recommendation should be observed.

Remote Working

The COVID-19 global pandemic has impacted the working lives of people in many different ways. Some of these impacts include people encouraged to work from home, the Irish government as part of the 'Plan for Living with COVID-19' has stated remote working is encouraged where possible across all levels of the plan (Ireland, 2020) . Equally, many childcare facilities were forced to close or suspend services which in turn added greater pressures on parents. The workplace and the childcare facility were now the home for many people. Moreover, while difficult to have predicted a global pandemic; many people were not ready for this change in their daily lives of work and childcare. These changes in lifestyle conditions have affected personnel in terms of personal stress in their lives.

Studies looking into the psychological effects of remote working have found that it can lead personnel to feel overwhelmed, uncertainty and social isolation (Allen, 2020). It is suggested that those who primarily work from home face isolation and are less able to collaborate

effectively with colleagues (Allen, 2020). To overcome feelings of isolation people are coming up with new ideas such as a virtual coffee date; assigning 30 mins with colleagues to talk about issues other than work. Furthermore, it is found that often training for teleworking/ remote working is lacking, resulting in staff struggling to develop a competent level of efficiency (Grant, Wallace and Spurgeon, 2013). The global pandemic's swift spread across the globe further tested organisations' capabilities to deliver remote working training. The main issue with remote working for staff members is finding the balance between work and home life. More importantly, with technology there is a link between work and the home environment; boundaries are often blurred making it hard for workers to switch off (Grant, Wallace and Spurgeon, 2013).

There are also the technical difficulties with working remotely. Personnel need to have access to broadband while at home to be able to conduct their roles effectively. Companies also need to ensure that their staff have the correct technology at home such as screen, keyboards etc. Companies should also put in place procedures for security and confidentially agreements while working remotely, these procedures and policies should detail the correct process for working from home to ensure the confidentiality of work. The procedures should include detail on topics such as paperwork being removed from the manufacturing site and brought to a possibly less secure home. Risk assessments should be conducted to ensure risks of working remotely are captured and mitigated.

Non-Verbal Communication

Non-verbal communication involves the unspoken word, interactions between people through body language, facial expressions, hand movements and eye contact. This non-verbal communication is lost during remote audits. The existence of a visual channel while talking face to face increases the social presence by allowing for visual clues that can alter the meaning of the audio channel alone, often in unconscious ways (Short, J., 1976). Non-verbal communication has an influence over the whole communication process.

> *'People assume that non-verbal actions do not lie and therefore they tend to believe the non-verbal message when a verbal message contradicts it'(Besson et al., 2005).*

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Non-Verbal communication can give away details that may not be expressed during verbal communication. Body language is important during audits as it can relay or convey a message e.g. if someone's leg is shaking it may mean they are nervous. Or when an auditee is moving their hand when explaining a process, it may mean they are passionate and confident. Eye contact is another form of non-verbal communication and it is also particularly important during audits. The frequency of eye contact may suggest either interest or boredom or may even betray dishonesty (Besson *et al.*, 2005). Face to face audits by their very nature can reveal more non-verbal forms of communication to both the auditor and the auditee. However, not all non-verbal communication is lost during telecommunication.

The tone of an individual's voice is considered a non-verbal communication. Tone of voice can communicate if a person is aggressive, critical, nervous, disappointed, monotonous, friendly, enthusiastic, vivid, and persuasive; these different tones can be cues to the auditor about a situation in question.

Methodology – Industry Survey

A survey was created to provide both qualitative and quantitative data on perspectives held on this research topic within the pharmaceutical and biopharmaceutical industry. This survey was created using 'Survey Monkey'; it consisted of 10 questions that were designed to obtain the appropriate qualitative and quantitative data needed. Conducting this survey allowed the author to discover and identify current opinion held on remote auditing. Data gathered allowed a "snap shot" of opinion in the early stages of the "working from home" situation we have found ourselves in and to draw some preliminary conclusions on the impacts this is having on the pharmaceutical industry.

The survey was completed by seventy-six (76) personnel who work within the Irish pharmaceutical and biopharmaceutical industries. The survey was shared on LinkedIn, also a number of personnel who have experience in the area of 'Remote Auditing; were contacted directly to complete the survey. One aim of the survey was to identify their perspective on current challenges they are facing with remote auditing.

Results

1. **What industry are you working in?**

   From the responses received majority of people who responded worked in the Bio-pharmaceutical industry (46%) or the pharmaceutical industry (37%) the other respondents where in the medical device industry or other.

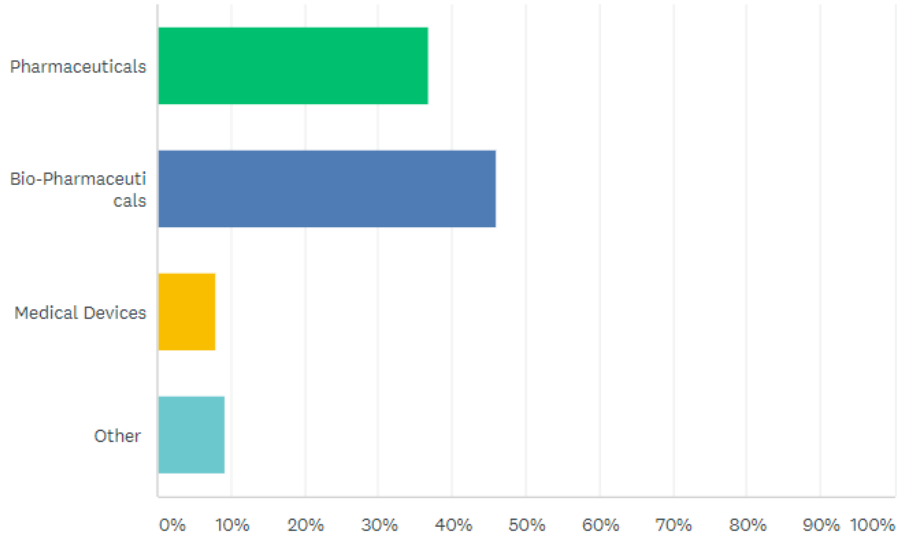

Figure 3: INDUSTRY SECTOR

2. **What department are you working in?**

   Of the 76 respondents 67 worked in the Quality Department in their company. The other 9 respondents worked between QC, Manufacturing and Validation.

3. **Has your company conducted/hosted any remote audits?**

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This was asked in order to determine the number of remote audits that have been conducted. From the responses, 67% of companies have conducted remote audits. 22% of respondents answered NO while 10% DID NOT KNOW if their company had conducted or hosted any remote audits.

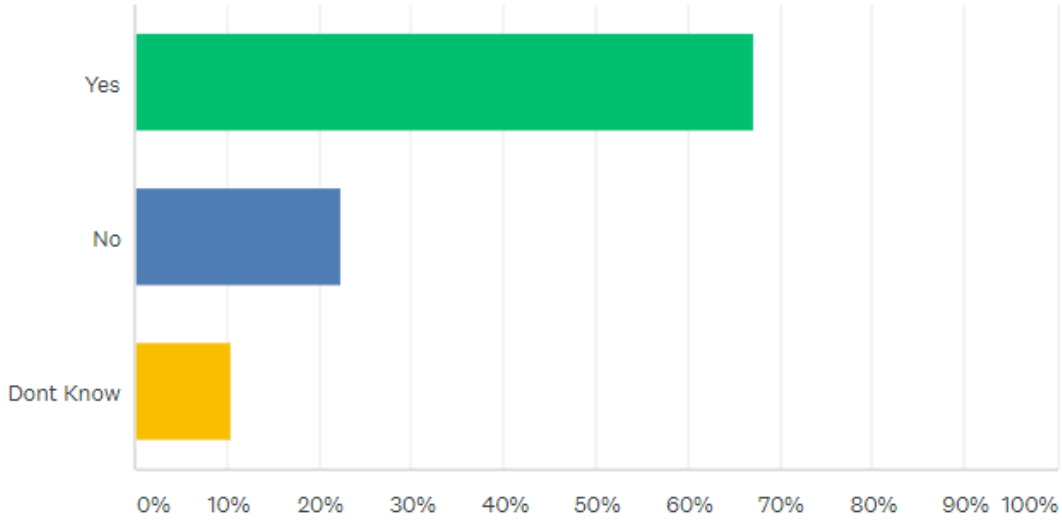

Figure 4: FREQUENCY OF REMOTE AUDITS

4. **Have your company's auditing procedures been updated to manage remote auditing?**

Question 4 was asked in order to determine if the industry had considered remote auditing before the COVID-19 pandemic. 25% ALREADY HAD INFORMATION on remote auditing. While 37% said YES, their procedures needed to be updated and 37% said NO their procedures have not been updated.

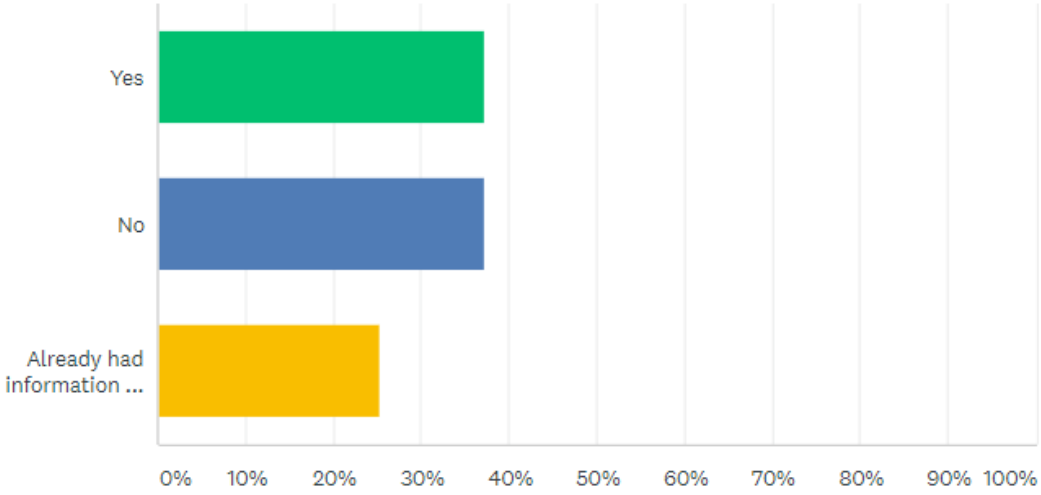

Figure 5: UPDATE OF AUDITING PROCEDURES

5. Rank these remote auditing challenges in order of what you think are the most challenging 1 being the most challenging 5 being the least challenging

This question was asked in order to determine the industry's opinion on the challenges with remote auditing. The following challenges were ranked from 1- 5.

a. Conducting Virtual Tours
b. Sharing of Documentation
c. Data Security Concerns
d. Insufficient IT Platforms
e. Conducting Personnel Interviews

All of the challenges provided were identified with by all respondents. Conducting of virtual tours was ranked the most challenging by 29 respondents, while Data Security Concerns was identified by 22 respondents as being most challenging. Furthermore, the least challenging aspect was identified by 35 respondents as Conducting Personnel Interviews. Overall, the priority of challenges by their Score Marking was identified as:

1. Conducting Virtual Tours. 3.67.
2. Data Security Concerns. 3.49.
3. Sharing of Documentation. 2.86.
4. Insufficient IT Platforms. 2.81.

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5. Conducting Personnel Interviews. 2.16.

*The score marking is calculated by calculating the average ranking for each answer choice

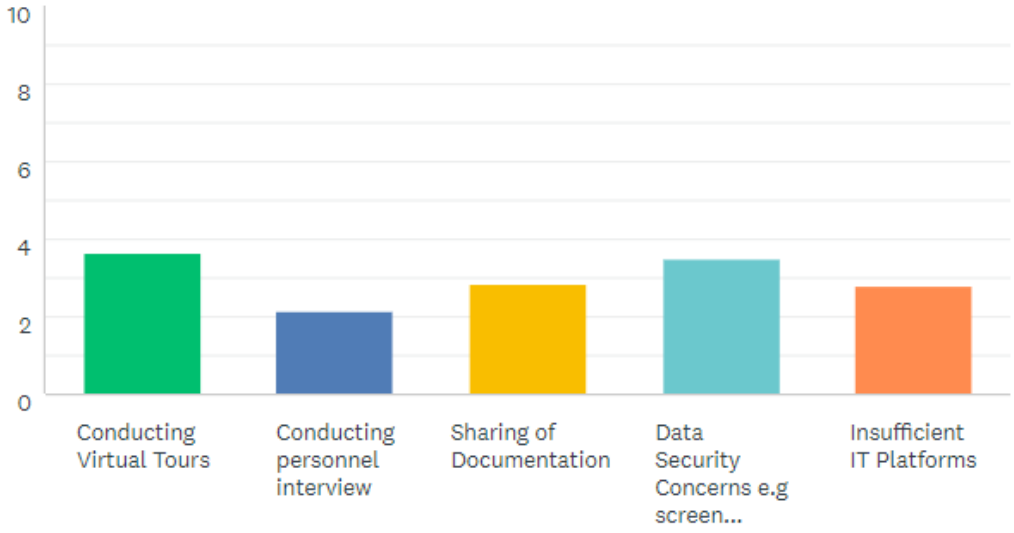

Figure 6: RATING OF REMOTE AUDITING CHALLENGES

6. Do you think there are any benefits of remote auditing?

This question was asked to identify the industry's attitude towards remote auditing and if it could return benefits. Respondents were asked to choose 'Yes' or 'No'; if they chose 'Yes' they were asked to identify the perceived benefits.

61 respondents answered YES to this question. Of the 61 that responded YES, 55 commented to what they thought were the benefits to remote auditing. Of these 55 comments, 21 respondents stated that 'Reduced Travel' as a benefit. There were also respondents believing the benefit of easier pre-planning for remote audits exists. Another respondent stated that a benefit was: that it *'Allows a more focused review and make optimal use of auditors time thereby potentially increasing the sample size for audits.*

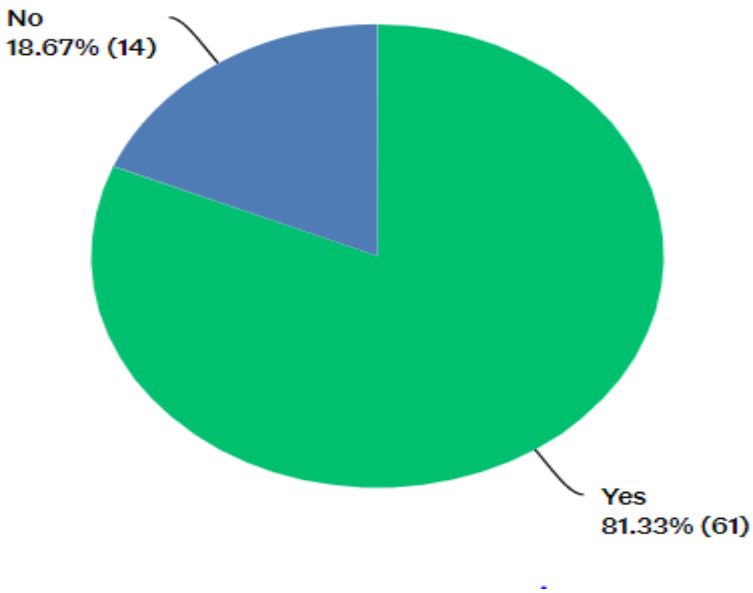

Figure 7: BENEFITS TO REMOTE AUDITING

7. Is all your company's documentation available electronically?

This question was asked to determine how much of the industry was paperless. Remote audits can by their nature involve no paper and relies on the review of electronic documents, so if companies do not have these available it will be harder to plan for these audit types. Of the 75 respondents only 3% have no documents available electronically. A majority of respondents, 54% identified their company as having a hybrid of both paper and electronic copies; 43% of responds identified all documents are available electronically.

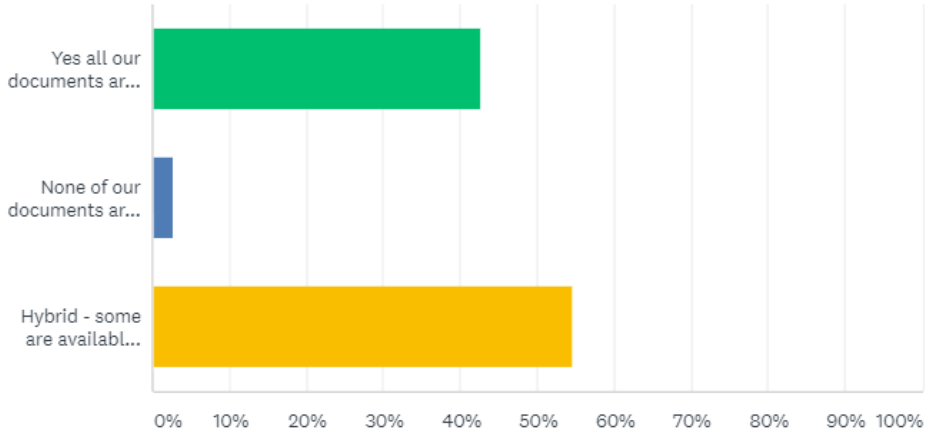

Figure 8: AVAILABILITY OF ELECTRONIC DOCUMENTS

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8. Do you think there are compliance risks to remote auditing?

This question was asked to gain the industry's opinion on compliance risks. 53% of respondents believed there are compliance risks associated with remote auditing. With 46% believing there are no compliance risks. Respondents that answered yes, were asked to identify these compliance risks.

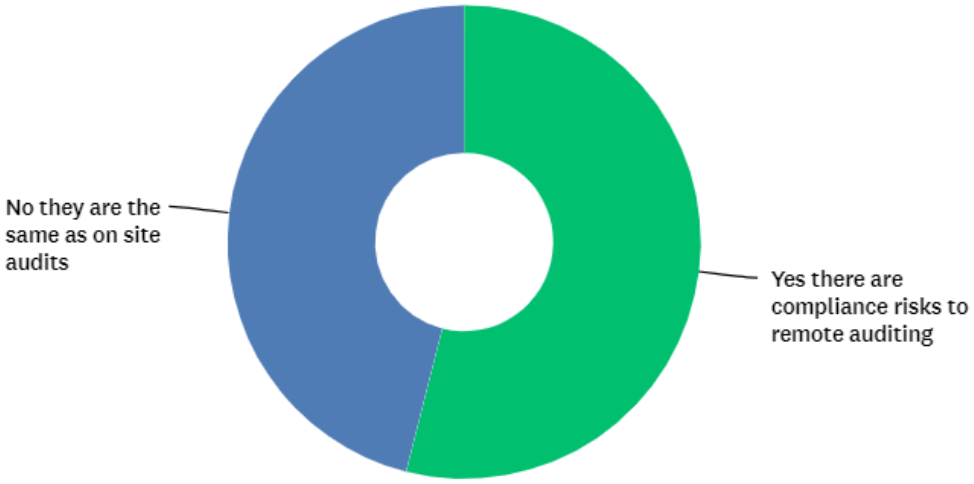

Figure 9: COMPLIANCE RISKS WITH REMOTE AUDITING

Many of the respondents believe it is difficult to gain an overall impression of a company via remote auditing. While clear that review of documentation is easier remotely, other aspects of auditing are not and therefore considered a risk for the following reasons.

> *'Audit sample is more controlled by auditee'*
>
> *'It is easier to hide issues in a remote audit'*
>
> *'You only see what you are shown with remote auditing' 'Some things could be hidden from camera that company doesn't want to be seen by auditor'*
>
> *'Virtual tours reliant on the auditee to provide a true representation of the area under review'.*

9. Do you think your company has the IT capabilities to conduct/host remote audits?

The main factor to a remote audit is the IT capabilities without such technology remote audits are not possible. When identifying how many of the respondents believe their company has the capability, of the 76 respondents that answered 67 believed their company had the capabilities while only 9 believed that they did not. The respondents who answered 'No' to this question were further asked why they believed this to be the case. Of the 9 that answered 'No', 3 common responses identified the lack of virtual tour capabilities.

- *'Virtual tours need work in my company'*
- *'Virtual Tours capability'*
- *'Capability to perform a live tour of our facilities. I would also be concerned about poor quality of video-calls which could make interviews a little more difficult.'*

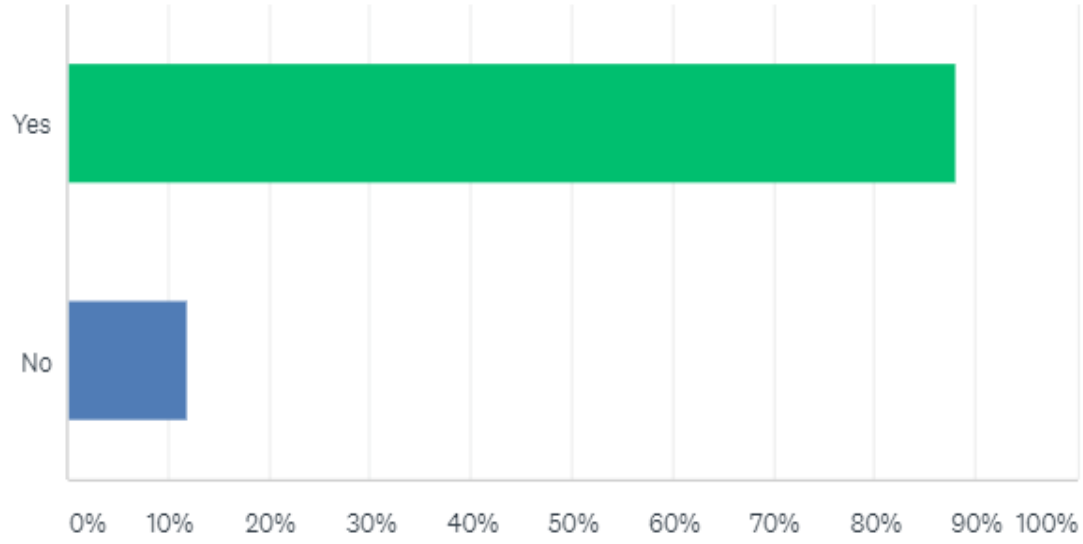

Figure 10: IT CAPABILITIES FOR REMOTE AUDITING

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10. How do you think virtual tours should be conducted?

This question was used to determine what respondents considered how to conduct virtual tours. This question provided 4 identified options and provided an opportunity for respondents to identify a specific opinion. Of the 76 respondents, 62 identified that 'Live video walking around the site' is the best way to conduct a virtual tour. 12 respondents selected 'pre-recorded videos' as a way of conducting virtual tours.

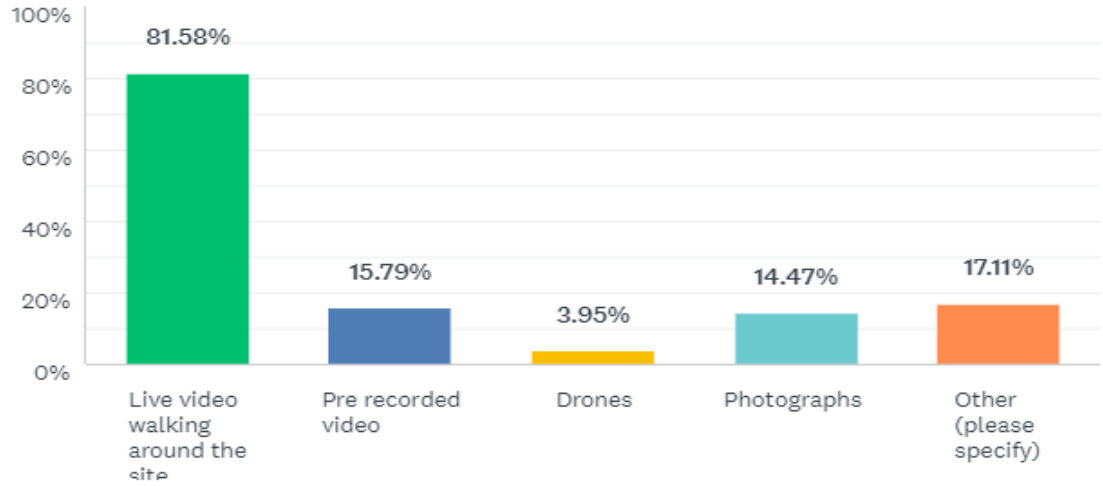

Figure 11: THE CONDUCT OF VIRTUAL TOURS

Of the 13 specified opinions, 7 suggested using a combination of methods to conduct that virtual tours while 4 suggested the use of 'smart glasses' as a means of 'live tour' to see the operators performing.

11. Do you think there is enough guidance documents on remote auditing?

This question was asked to determine the industry's perspective on remote auditing guidance documents. Of the 76 people who answered this question 47 believed there is not enough guidance documents for the industry. While 21 of the respondents did not know if there were enough guidance documents. Only 7 of the respondents believed there is enough guidance documents on remote auditing.

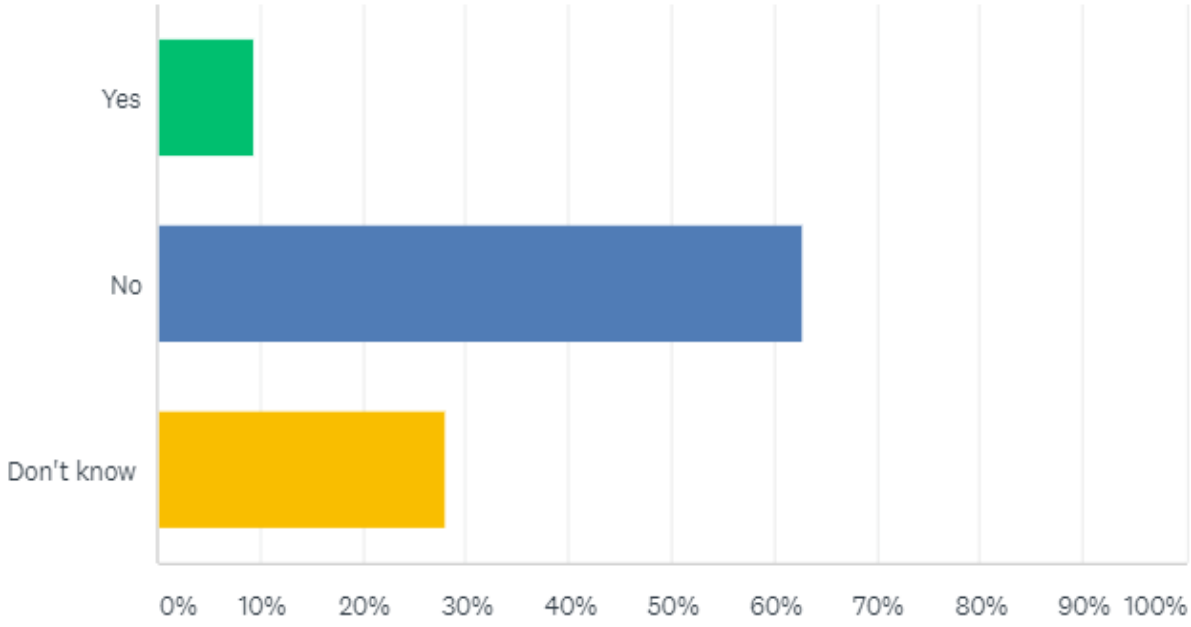

Figure 12: REMOTE AUDITING GUIDANCE

Discussion

Remote auditing has become more relevant since the onset of the global COVID-19 pandemic. Regulations on auditing in relation to GMP audits by regulators and the regulations in relation to outsourced activities identifies the legal requirement for audits to ensure the safety of drugs. However, the traditional approach of onsite audits is not possible at this time. This requires companies and regulators to adopt new ways of working and auditing for compliance. As a result, much of the guidance on remote auditing for the Pharmaceutical Industry was published the past year as the industry grappled with the situation it found itself in.

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This research has shown that the industry believes that there is a lack of guidance on the topic. Due to an unexpected global pandemic, regulators and companies may have been ill-prepared in their contingency plans to deal with its impact on auditing operations. Regulatory agencies responded in short-term and published Q&A documents to address some of the industry concerns.

Sharing of documentation during remote auditing was one of the key challenges highlighted by the industry. From the results of the industry survey 42% of respondents identified their company having documentation available electronically, while 52% had a hybrid of paper and electronic copies. For the companies that have a hybrid format, they will still require time to be fully prepared for remote audits. This may involve scanning of any documents that are not available electronically.

Sharing of documentation links into the challenge of data security concerns for industry. 28% of the respondents identified this as their biggest challenge while 22% respondents identified this as their second biggest challenge. Companies need to ensure confidential information is not revealed unnecessarily through processes such as screen sharing. The regulations for outsourcing activities state that contracts are required between two companies, these contracts may now require an update to align with a remote auditing process. These contracts will require addressing items such as confidentially agreements and include information for the remote sharing of documentation.

Conducting tours of a facility is an obvious challenge with remote auditing. It was highlighted as a challenge in the industry survey. Conducting of virtual tours was ranked the most challenging aspect of remote auditing during the Industry Survey. From the industry survey ‘live video’ was expressed as been the best way to conduct a virtual tour. ‘Live video’ is put forward as a method to give a real time review of inspected areas and may allow for auditors to communicate with people who are on the tour.

Another aspect of the research was to highlight any benefits of remote auditing. The survey highlighted the obvious benefits such as no requirement to travel to different countries, reduction in cost of an audit and environmentally more friendly due to reduction in carbon footprint due to less air travel. Respondents during the survey also stated that remote audits can be more planned in nature, which can lead to more efficient use of time.

In summary, there are many challenges faced by companies required to conduct or host remote audits. Preparation will be key to minimising some of these challenges. To facilitate this an **'Action Plan'** is proposed, this action plan just focused on aiding companies prepare for remote audits. The action plan is discussed below. It is also evident that technology is a key enabler to conducting remote audits, without the correct technology and familiarity with this technology, remote audits will not be effective. Companies and regulators need to move forward with this approach as a priority to ensure patients continue to receive medicines while ensuring compliance.

Action Plan

In order to successfully conduct a remote audit on a service provider/contact manufacturer the following key actions detailed below need to take place the key message is preparation is key to a successful audit.

Quality Risk Management tools such as risk assessments should be carried out before the remote audit. Risk assessments can be used to determine if an audit is needed e.g. when was the previous audit and what was the outcome? The risk assessment should also be used to determine the scope of the audit.

Once the scope is defined the audit team should meet and discuss the IT platforms to be used and if there needs to be a virtual tour. As discussed, Quality Agreements may need to be updated if time permits, they should be updated prior to audit. If needed a 'Memorandum of Understanding' should be in place to define the confidentiality agreement.

An important task to prepare for a remote audit is to ensure the training of staff on the technology to be used. Technical issues can happen, and the more familiar staff are with the IT platform the smoother the auditing process will be.

A full action plan can be seen below. The table outlines a rough estimate of timelines to adhere to when planning an audit. Ideally planning should start as soon as a notification of an audit is received.

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Action	Timeline
Risk Assessment ➢ Conduct Risk Assessment to determine if an audit is required or if an extension can be considered. ➢ Include the critically of the product ➢ Look at the last audit report.	At least **8 weeks** out from audit
Host Pre agenda meeting ➢ Discuss audit scope ➢ Discuss Logistic e.g. IT platforms ➢ Discuss if virtual tours are possible. ➢ Discuss Quality Agreements	**6 weeks** out from audit.
Update Quality Agreement ➢ Cover the scope of remote audits i.e Screensharing, sharing of documentation electronically. ➢ Include confidentiality agreement ➢ If specific detail is included on frequency of auditing update.	**6 weeks** or as soon as there is an agreement between both sides.
Prepare Audit Plan/Schedule ➢ Prepare a detail audit plan to provide to the auditee ➢ Provide the list of pre request documentation where possible	**4 weeks** out from audit.
Site Audit Team Meeting ➢ Host training session with audit team to discuss IT platform ➢ Discuss the scope in detail	**4/3 Weeks** out from audit.
Final Pre-Meeting ➢ Send Meeting invites ➢ Trial Technology – Demo any technology new to the auditee. ➢ Share detailed audit timetable	**1 week** out from audit.

Table 1: Remote Audit Action Plan

Conclusion

In conclusion, there are many challenges faced by the pharmaceutical industry when conducting/hosting remote audits. Within the pharmaceutical industry, the auditing process has had the same approach for many years and the sudden impact of the global pandemic forced the industry to adapt new ways of working. While remote auditing will not completely replace onsite audits, there will now be an option to conduct remote audits via a risk-based approach. It is likely that this will be the 'New Norm' until a vaccine is approved for Covid-19, additional guidance and legislation covering remote audits will be necessary for the pharmaceutical industry.

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