



REPORT

Is Remote GxP Auditing Here to Stay?

Arithmos analyses remote GVP audits during the pandemic and what industry leaders are saying about its future potential in a post-pandemic world.

Will remote audits be the new norm?



ARITHMOS



s e Q u r e

A business unit of Arithmos

INTRODUCTION

The world is getting ready to settle (hopefully) into a post-pandemic phase where there seems to be an outcry for a return to normalcy, but at the same time several lessons and experiences acquired, mostly those forced upon us by circumstances beyond our control, have proved convenient and beneficial to the point that they will most likely remain habitual.

Many organisations shifted towards remote work, and it comes as no surprise that companies with effective project management, processes and technology capabilities are those which thrived the most.

Arithmos, alongside its business unit seQure, adapted efficiently and quickly to be able to support clients in conducting Good Vigilance Practices (GVP) audits remotely given restrictions on travel and physical proximity. However, what looked like a quick fix to a temporary problem may just be a more permanent solution.

Could the remote shift increase pharma productivity while improving both employee and auditor satisfaction?

Remote regulatory inspections are also becoming more recommended, even in conjunction with on-site visits, for the GxP environment. In a recent report*, the International Coalition of Medicines Regulatory Authorities (ICMRA) recommends the use of remote inspections as a complementary tool to on-site inspections beyond the Covid-19 pandemic.

After performing several remote audits in the GVP environment, Arithmos decided to dive deeper into whether it's just a trend or here to stay. Through in-depth interviews with several of its clients, Arithmos breaks down the benefits, considerations, doubts and points still open when it comes to auditing.

Now that restrictions are almost entirely gone, is remote GxP auditing still hanging around?

Carrying out Remote GVP Audits

While remote audits do not require logistical arrangements such as travel, there are many other factors to take into consideration like business processes, regulatory requirements and, of course, the human factor. Large pharmaceutical players weigh in on their experiences in switching to remote audits.

We interviewed some of our customers who asked us to conduct remote audits, and we summarised their answers and experiences in the following report.

* <https://www.europeanpharmaceuticalreview.com/news/166504/regulators-recommend-remote-inspections-for-use-post-pandemic/>

What are the three main benefits you have found in conducting audits remotely?

Several key advantages emerged from our sit-dows with our clients:



Convenience in terms of organisation and management.



Reduced costs.



Optimisation of time which leads to audits being conducted more efficiently.



Better preparation.

The benefits highlighted here are mostly obvious: remote audits reduce travel and logistical costs, time is better spent on the audit instead of possible socialising and easy distractions in an office setting, and they are definitely easier to organise.

In terms of preparation, our clients cited the ability to share documents beforehand in shared online folders as a primary benefit.

A more surprising benefit that emerged was that remote audits can actually be more inclusive as it gives more people the chance to be involved.

“It is a great convenience. Remote audits don’t require travel and there is no need to plan. It allows you to better manage your personal and work life. Remote audits also provide the ability to share the audit experience with more people, including people who are training”.

What business processes and procedures did you have to evaluate to make sure they fit the remote model?

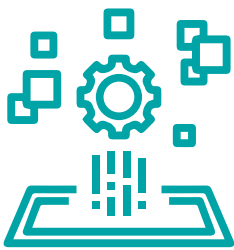
Most companies had remote auditing drafted into their internal processes as backup methods or in cases where travel to a certain country or region was difficult.

With respect to other GxP environments, GVP is an area that doesn't necessarily require on-site visits and can be carried out remotely with less complications.

Some organisations updated business continuity plans to include remote auditing in their risk mitigation measures. However, the general consensus is that remote auditing was always considered in governance procedures, however processes were simply reviewed, and possibly revised, to include remote auditing as a primary method option.

“We revised our business procedures anyway due to the governance process in the procedures. The remote audit process was already present in the auditing procedure, but it was not present as a defined process for audits in general, that is, it was not defined that all audits could be conducted remotely.”

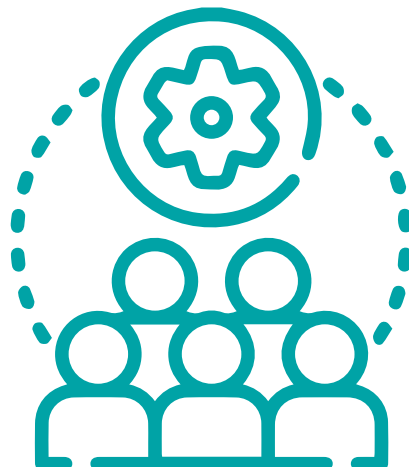
From a technology perspective, were you ready to conduct audits remotely or did you make any internal changes?



There seems to be a shared agreement that companies quickly adopted communication and document-sharing tools like Zoom, Teams, Sharepoint, etc., however the main challenge was people's comfort level in using these technologies.

While most companies also used these technologies pre-pandemic for communication purposes, they found it relatively easy to scale up the usage.

“The ease with which people use these means has changed, unlike ever before, and now they are used to these technologies.”



From a human resources perspective, how have the people involved in the audit reacted to the new model?

Audit participants saw only positive changes on the human side of things from remote auditing. Most professionals working in pharmacovigilance were already used to using digital tools because many are required for business continuity.

One surprising find was that participants saw a more positive presence from the auditor who was a bit more “refreshed” rather than having to always travel.

“Those working in PV, who are mainly the ones being audited, were already using these tools during Covid because they had to ensure business continuity, so they were already prepared.”



Did the audit executive timelines meet your expectations?

In terms of timelines, this is where there was some difference of opinion and maybe a small shadow of a doubt, but in general none of the companies found significant delays in conducting audits remotely.

Remote audits helped reduce or meet timelines due to the following:



Requesting documents in advance in order to be better prepared.



More focused agendas and questions: in on-site audits agendas are planned around a classic 8-hour day with breaks and lunch scheduled and there are time wasters such as general company presentations. Remote audits allow for more flexible agendas and more focused questioning.



More focused interviews.

Companies expressed some concerns over organisation in a remote environment with elements like technology interruptions or alignment with participants located in diverse locations. However, it was noted that this may occur in the first remote audit conducted, but usually adjustments are made from “learning on the job”.

“Time has really been reduced significantly with remote audits. When you activate a remote audit, you don’t just have the audit to fill an 8-hour day. The questions become more focused. You don’t see this in a physical audit, they are not static: they tend to magnify the questions as to solicit a response. It is a different technique.”

Up until this point, remote auditing in the GVP environment has provided significant benefits to pharmaceutical companies in terms of costs, time and resources. Therefore, the real question is whether they are here to stay.

Remote auditing has been a necessary practice since the start of the Covid-19 pandemic, and may become a permanent trend for the future. What is your opinion? Will you continue to adopt this model?

The overall consensus is yes, but not everyone is ready to completely give up on-site audits, especially since a lot of times it can be up to the Inspector to decide the format.

In general, companies are in favor of remote auditing, or at least a hybrid approach, especially for the GVP environment since they don't require specific requirements for necessarily being on site.

They have built remote audits into their procedures, ensured business continuity, mastered the technology tools and have seen the benefits.

“The idea is certainly to continue, and probably integrate the two models, certainly for pharmacovigilance because that is where remote audits succeed more.”



What is the aspect you appreciated the most during your remote auditing experience with Arithmos?

Our clients agree that the most important element is to have a good relationship with the auditing partner.

Each client was able to establish a good, trusting relationship with the Quality Assurance department in Arithmos and its business unit seQure.

More importantly, they needed a partner they could trust during the difficult transition into the Covid pandemic in terms of efficient and dedicated project management and exceptional technology capabilities, and Arithmos proved to fit the description.

“The auditors are very knowledgeable, good, helpful people who always try to meet our needs.”

“Arithmos, with its business unit seQure, was given all of our audits for a key study at a time when auditing was particularly difficult because of Covid restrictions. We needed a secure partner with skilled people.”

“We appreciated the efficiency, the proactivity towards problem-solving and the respect for timelines.”

Would you recommend our remote audit service to others, if so why?

“Absolutely. It is much simpler and more convenient in terms of management. The main driver for conducting audits remotely is technology. If you show the auditors they can see a bit of everything, they take notice. It's not easy moving things remotely, but we are comfortable with Arithmos.”

“Yes, and in three words: security, trust and transparency.”

Arithmos and Remote Auditing

Reflections from the CEO, Paolo Morelli

"When Covid-19 arrived unexpectedly and suddenly on our doorsteps in 2020, we were faced with two options: **wait out the storm or find a way to be resilient and carry on.**



Auditing is a fundamental part of our industry. Without the numerous international standards in place, we wouldn't be able to bring **safe and reliable therapeutics to the market.** Remote Auditing allowed us to **work alongside our clients** to conduct the necessary audits in the GVP environment without delaying drug or device pipelines.

We've seen that remote auditing works: **from a technological standpoint, from a regulatory perspective, from a practical and economic standpoint, and perhaps most importantly, from a human perspective.** I believe that remote auditing, or at least a hybrid model, is here to stay. If anything, this pandemic has demonstrated that superior knowledge and capabilities coupled with excellent technology solutions was a winning strategy for business continuity, and fortunately Arithmos, with its business unit seQure, was able to offer exactly this to its clients".

Arithmos Remote Audit Service

With a quality-driven culture and customer-oriented service management approach, we offer advanced solutions for Quality and Compliance in all GxP areas (GMP, GLP, GVP, GCP), supporting individual client needs.

We have created a network of experts with over 20 years of experience in the implementation of Quality Management Systems, Support for GxP audits and Computer System Validation.

In addition, our team offers training courses on Quality Assurance & Compliance for our customers to support the organisational strategies and the quality management culture in their organisation.

CONCLUSION

We have seen that remote audits, especially in the GVP environment, are not only a reactionary solution to external macro factors, but a viable method for conducting **efficient, cost-effective**, and perhaps even **more enjoyable, audits**.

Arithmos has seen a steady shift towards remote auditing as a choice. In 2020, around 80% of our audits were conducted remotely, in 2021 that number was 100%. With 2022 still ongoing, 92% of our audits have been planned remotely and 58% of those audits have already been completed while the rest are still in progress.

Remote auditing is here to stay.

Based on our extensive experience over these past three years, we believe the following factors can contribute to **remote audit success**:

- Allow for **adequate scheduling** and **preparation time**.
- Create an **audit checklist** for all the **important documentation**.
- Plan for an **English translator**, especially if **SOPs and documents** are mainly in **local language**.
- Prepare a **timed agenda** for both the **auditor and auditees**.
- Run at least one **pre-audit test call**.
- **Prepare your remote audit environment** (office or home workspace, opening necessary files and preparing all tools needed).
- **Organise evidence** while **drafting the report**.

ABOUT US

At Arithmos, we help pharmaceutical, biotechnology, nutraceutical, medical device, universities, hospitals and non-profit organisations to gain the best business value through technology-enabled solutions and, through the seQure business unit, Regulatory Compliance and Consulting services.

We deliver solutions and services for:

- ✓ Pharmacovigilance & Safety
- ✓ Regulated Document Management
- ✓ Reporting & Analytics
- ✓ eClinical
- ✓ Quality Management
- ✓ Computer System Validation
- ✓ Regulatory Affairs
- ✓ Cloud Services
- ✓ IT Services

Our industry-leading experts combine the knowledge of processes and technologies to implement digital strategy, enable rapidly scale-up along with fulfilling oversight, governance, and compliance requirements.

Through a holistic approach, we support the Life Sciences companies with:

- ✓ Digital Transformation
- ✓ Business Process Re-engineering
- ✓ System Integration
- ✓ Data-Driven Management

Are you interested in discovering more about our services?

Reach out to Arithmos to know how our Team can support your company to address your problems and improve your business.

To know more about our services, contact us at info@arithmostech.com

Our team will be glad to assist you.



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