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# Best Practice for **Remote Auditing in a GMP Environment**

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by **Martina Forristal**

## Introduction

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As the coronavirus pandemic continues to spread and organisations have no choice but to have employees work remotely, auditors face the challenges of completing audits remotely to make deadlines.

Audits, and remote audits in particular, are now more important than ever to ensure that standards are being upheld, GMP manufacturing processes are being adhered to and quality is being delivered, so now's the time to ask if your organisation is remote audit-ready?

In Perigord, as a global company, we are fortunate to have championed and prepared for remote auditing for quite some time. We recognised the benefits of remote auditing in minimising costs, enabling more flexible scheduling, speeding up the process and now, more recently, in meeting the added need to safeguard our staff and clients. Having been through the process ourselves, we also know firsthand the challenges and limitations of remote auditing and how to overcome them.

Today remote auditing is no longer just an option to be considered, it is an absolute necessity. Rather than asking ourselves if we should do it, we now need to ask ourselves how we should do it to ensure we can continue business.



## About the Author

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Martina is responsible for maintaining Perigord's Integrated Management System(IMS) which is certified to ISO 9001:2015/ISO 27001:2103/PS 9000:2016. She also has responsibility for promoting recognition of Perigord's quality programs among clients and staff, as well as developing and implementing employee communication and training programs regarding Perigord's quality objectives, strategies and processes. Martina is passionate about patient safety and has 30 years experience working in senior quality roles in pharmaceutical/GMP environments. She holds a degree in Chemistry and also in Quality Management.

# 01

## How can we make sure that remote auditing supports GMP compliance?

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### 1. Establish whether remote auditing is permitted for your organisation

First, you need to ensure that remote auditing is allowed for your organisation and meets your client's validation criteria. The GMP regulations allow the use of remote auditing techniques but specify that their use "must be balanced based upon the relative risk posed by the organisation and the products and services produced or supplied".



### 2. Perform a risk assessment via your change control process

To convert to remote auditing, a change control should be opened within your organisation. The change control process is a systematic approach to managing all changes made to a product or system. The purpose is to ensure that no unnecessary changes are made, that all changes are documented, that services are not unnecessarily disrupted and that resources are used efficiently. The coronavirus outbreak has disrupted businesses and will have lasting effects that may result in more or new liabilities and risks. Your organisation's risk profile could look very different post-pandemic. Consider how your processes have changed to accommodate this new way of working, what issues you have identified and what new tools you have adopted to ensure you can carry on your usual activities. Make sure that all risks for noncompliance with remote audits are identified and assessed, and that your processes are updated to meet remote auditing requirements.



### 3. Assess your suitability and readiness

Some organisations are easier to remote audit than others. For example, manufacturing plants, where auditors need to see certain areas, need to work out how these can be inspected remotely, versus service organisations, where the audits are more documentation evidence based and, therefore, easier to audit. Depending on the nature of your business, you will need to consider whether, by live video stream or photos, you can take a virtual tour of your sites, and also how best to make your documentation available to the auditor digitally. Also, your suppliers (potential and existing) will have to be assessed for suitability.



### 4. Update your Integrated Management Systems (Quality and Security) and make them remote audit-ready

You will need to be able to provide a complete overview of all stages of a project or process from start to finish in a format that can be remotely audited. Making all files and documentation easily accessible and readily available for a remote audit is key and digitising the process is essential. You need to manage your requirements for Quality, GMP, Security, Data and Sustainability with integrated management systems that will work for remote auditing.



### 5. Achieve more Certifications

If your organisation is not certified to standards you should consider this. Perigord is certified to three standards (ISO 9000, ISO 27001, and PS 9000) and is the most certified artwork solutions supplier globally. Certification enhances professional credibility, customer satisfaction and improved customer loyalty leading to repeat business. It gives our clients/auditors a comfort factor that Perigord is audited by a reputable certification body and has achieved its certifications.

# 02

## How can we make a remote audit as close as possible to an in-person experience?

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### 1. Identify the best technology for the task

Remote auditing is not a one-size-fits-all approach, as different organisations will have a variety of processes, activities and systems that may need to be audited, so you'll need to consider what technologies will work best for your organisation. Whether the auditor needs to see your manufacturing facilities in operation or access documentation, you need to be able to facilitate that.



### 2. Facility Inspection

From virtual reality walk-throughs to drones providing 360-degree views of facilities, there are many ways to give a live action walkthrough of a facility. If the inspection does not need to be live or in-person, an auditee could walk the auditor through a facility using the video on their mobile phone or photos may even be enough.



### 3. Document Sharing Platform

If the auditors need to access your files, you need to choose a data secure file sharing method that works best for everyone. Agree on the time frame the files need to be available, the format they need to be in, who will access them and how they will be stored or deleted. Make sure that the technologies you use are secure so your data can be protected and ensure your data-sharing methods meet all confidentiality requirements.



### 4. Prepare your audit agenda

It is essential to create an audit agenda as it allows the auditor to assure that specific circumstances and transactions are properly recorded and documented, and the auditee can prepare accordingly. Always define the audit criteria, scope, interval, and methods before the audit. Make sure that nondisclosure agreements (NDAs) are executed prior to the audit.



### 5. Make the remote audit as personal as possible

It's hard to beat personal face-to-face interaction for audits, as non-verbal cues and body language are an essential part of communication. That is why it is important to use videoconferencing during a remote audit. Ensure that all of your key team are standing by and available to take a call to answer any questions the auditor may have during the audit. In a global organisation you may need to take different time zones into account when scheduling.



### 6. Highlight any limitations of the remote audit

If any new tools were used in the remote audit, you will need to assess if they were effective in meeting the audit objectives. If some processes were not able to be remote audited, this should also be highlighted, as they may require an in-person visit later. Some clients request the master documentation list in advance and then request specific documents before the audit. They complete a desktop audit on the documents that may identify any limitations beforehand.

## Top Tips for a Smooth Remote Audit:

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### — Check eligibility.

Make sure that your organisation's auditing procedures allow the use of remote auditing techniques. Review the previous audit report and update the audit agenda as required.

### — Planning is key.

Always define the audit criteria, scope, interval and methods before the audit. Make sure that nondisclosure agreements (NDAs) are executed prior to the audit.

### — Choose the best technology.

Agree on what video conferencing software will be used (E.g. Skype, Zoom, Microsoft Teams etc.) and what file sharing method works best for everyone. Most of the current file-sharing software systems are cloud-based, also giving storage services, and thus provide accessibility from anywhere, and any of your devices. Make sure that these are secure so your data can be protected.

### — Practice makes perfect.

It's a good idea for the auditor and auditee to have a trial run of the virtual technology platform before the audit so that any potential problems can be anticipated and resolved beforehand and make sure that the document and record sharing method is also working properly. Have a technical person on standby to help with any technical issues.

### — Embrace video.

When face-to-face meetings are not possible, opt for video calls over voice calls and let auditees/auditors know that they will need to turn on their cameras.

### — Be prepared.

Try to anticipate the questions that will be asked in advance. Make a list of possible questions and have your answers ready.

### — Break it down.

Remote audits are best done in segments. This allows time for the auditor to review records and prepare suitable questions and the auditee to gather evidence, organise interviews and communicate responses.

### — Ensure objectivity.

Make sure the audit process is objective and independent. The auditor cannot have a vested interest in the subject they are auditing, impartiality is a critical requirement.

### — Be honest.

Be completely open and honest with auditors and auditees.

### — Audit and Re-audit.

Generate your audit report and ensure corrective action(s) are taken and, if required, re-audit the deficient matters until all deficiencies are dealt with adequately and the audit is closed.

# 04

## Remote audits are here to stay

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### Remote audits are here to stay

The coronavirus pandemic may have forced us into remote auditing but it has now become established in a GMP environment and many of our clients have seen how much easier it is and have switched to it already. Remote auditing has proven itself to be a valid way of doing things for many reasons. It saves money and hassle, cuts down on travel and even allows audits to be run more efficiently. There are challenges like maintaining data security, varying Wi-Fi connections, fraud risks and the lack of a personal touch but if we understand these and work to overcome them, remote auditing may well become the method of choice for the future. So activate that drone, brush up on your video conferencing skills and embrace a new way of auditing. Remote auditing will soon become second nature.



## We're here to help

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At Perigord, we are remote audited continuously, so we know what it takes. Patient safety is paramount to us and we are always fully committed to maintaining quality standards. We are currently certified to three standards: ISO 9001, 27001 and PS 9000, which is fundamental to our continued growth.

If you have any questions or would like some advice or guidance on remote auditing, get in touch and we'll be happy to help.

### Martina Forristal

[martina.forristal@perigord-as.com](mailto:martina.forristal@perigord-as.com)

[www.perigord-as.com](http://www.perigord-as.com)

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## About Perigord

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Servicing the Life Science industry from our Global Centres of Creative and Packaging Excellence in Europe, Asia and North America, Perigord helps Life Science companies design, manage and deliver their packaging, marketing communications and digital assets around the globe, from centres of "Creative and Packaging Excellence" across Europe, Asia and North America.

Our services cover six core disciplines: Strategic Consultancy, Packaging Artwork and Labelling, Creative and Digital, Strategic Outsourcing – BPS, Managed Services and Software Solutions.

Patient safety and risk mitigation are our primary focus: our culture of operational excellence, GMP/GAMP compliant processes and the development of our Integrated Management Systems are all guided by this principle.

### Global Centres of Creative and Packaging Excellence

#### HEADQUARTERS

Perigord  
Unit 1, Lyncon Court  
IDA Business and Technology  
Park, Snugborough Road  
Blanchardstown Dublin 15,  
D15 N283 Ireland  
+353 1 440 3222  
[info@perigord-as.com](mailto:info@perigord-as.com)

#### EUROPE

Faller Perigord  
Fabrik Sonntag 4b  
79183 Waldkirch  
Germany  
+49 7681 49393-10  
[info@perigord-as.com](mailto:info@perigord-as.com)

#### ASIA

Perigord  
10 A, B, C and D 10th  
Floor Vaishnavi Cynosure  
2-48/5/6 Telecom Nagar  
Extension Gachibowli,  
Hyderabad Telangana,  
500 032 India  
+91 40 2980 1699  
[info@perigord-as.com](mailto:info@perigord-as.com)

#### NORTH AMERICA

Perigord  
4 Pin Oak Drive  
Branford, CT 06405  
USA  
+1 203 433 4054  
[info@perigord-as.com](mailto:info@perigord-as.com)