GMP Auditing and COVID-19:

A Guide to Remote Auditing and Workforce Recovery

Strategies and Expert Advice for Ensuring GMP Compliance Now and Later

THE FDA GROUP LLC

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Meet the Contributor

Neal Siegel

Neal is an independent Quality/Regulatory consultant (IVD/Med Device/Pharma) with 25+ years of experience and a particular interest in quality statistics and understandable, practical application in instances of compliance shortcomings. He has extensive, successful experience from lab bench to C-suite and welcomes opportunities to mentor and teach sustainable skills for the industry. Neal has participated on assessment and remediation teams for companies with severe Warning Letters and Consent Decrees and is knowledgeable in successful recovery from these types of regulatory actions.

Introduction

The coronavirus (COVID-19) pandemic has prompted worldwide travel restrictions and remote work policies, disrupting routine in-person auditing and official inspection activities throughout the regulated life science industry.

In March of 2020, The U.S. Food and Drug Administration (FDA) announced it was scaling back foreign and domestic surveillance facility inspections and relying instead upon, among other measures, reviewing records remotely—an authority granted in section 706 of FDASIA amendments of 2012 to the FD&C Act.

For quality and compliance teams, the sudden workforce disruption is complicating—and often preventing—in-person quality audits led by qualified third parties. To avoid compounding delays due to canceled or deferred audits, firms are increasingly turning to remote or "virtual" audits to maintain their assurance activities until normal operations can resume.

This guide examines the challenges of remote auditing and offers strategies and best practices for overcoming them throughout each phase of the assessment process: planning, document review, process review, facility review, interviews, and closing meetings.

This guide also calls attention to a few challenges that teams may encounter when transitioning back to "normal" operations, such as backlog management, scaling up resources, and prioritizing auditing projects.

Since the pandemic is a constantly-changing situation, the contents of this paper should not be considered comprehensive or definitive. We intend to add to these considerations as the environment evolves over the coming weeks or months.

Note: *This PDF has fillable fields for digital note taking. Download and open it on your computer to use it as an interactive planning tool.*

A Brief Review of Audit Requirements

The standards, regulations, and guidance that establish and govern good manufacturing practice (GMP) present several internal audit program requirements.

In addition to establishing, implementing, and maintaining quality audit procedures and clearly defining the criteria, methods, scope, and scheduling involved, regulated firms must ensure audits are conducted objectively by competent individuals as determined through education, training, or experience.

To help augment their internal audit program, firms routinely contract with third-party consultants who bring objectivity, experience, and practical knowledge to conduct mock audits and infuse teams with best practices informed through field experience.

Experienced third-party auditors not only plan and conduct audits fast and effectively, but help firms meet other audit requirements by sharing insights with management and transforming reports into corrective and preventive action (CAPA) plans—often leading remediation efforts themselves.

Remote GMP Auditing

Remote audits enable quality and compliance teams to continue delivering ongoing assurance activities without disrupting critical operational areas when traditional in-person audits aren't feasible.

Currently, GMP regulations do not expressly prohibit remote auditing, nor do they offer specific guidelines on proper conduct or expectations. Without official guidance, firms must determine the appropriateness and feasibility of a remote audit based on a risk assessment that considers the nature of their products and service, their technical capabilities, and factors such as compliance histories and quality trends. A remote audit may not be appropriate if the firm hasn't resolved issues observed during previous audits requiring an on-site visit.

> ***"If problems were identified during a recent on-site audit—a facility issue, for example—and they require an on-site follow-up, it could impact the eligibility for a remote audit. Running through that checklist is important to know you're not doing the assessment a disservice by going remote."***
>
> **— NEAL SIEGEL**

This risk assessment should also factor in the QMS's readiness for such an assessment, as there may be policy or procedural barriers that must be identified and addressed. For example, SOPs and specific auditing policies may be written specifically to assume in-person assessment, possibly complicating or restricting a remote auditor from certain activities, such as accessing documents.

All firms should conduct an initial risk assessment and document the outcomes achieved through remote auditing, including plans that will go into effect when current restrictions are lifted to ensure on-site audits can resume in a timely manner.

From a process perspective, remote audits largely reflect in-person audits with some obvious and not-so-obvious differences in planning and execution. When these points aren't identified and planned for at the outset, they can present frustrating surprises along the way. This guide is intended to put these considerations on your radar. We've gathered expert insights from experienced auditing professionals who have seen and overcome the challenges of remote auditing firsthand.

Remote Auditing from The FDA Group

Are you encountering difficulties in carrying out routine GMP audits in your organization? The FDA Group's auditing service can help you continue operations in a fully-compliant state. Our quality professionals can be utilized on-site or remotely to bring their direct experience in pharmaceutical, biotechnology, combination, and medical device development and manufacturing to help you understand and address quality assurance needs at every stage of product development.

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Stakeholder Planning

Like a traditional in-person audit, remote audits must be planned and scoped. However, since making a contemporaneous change in a remote setting is typically more difficult than it is in person, and each audit activity may demand more time due to technical limitations, a remote audit should be fully choreographed in as much detail as possible from the start.

Both parties should budget additional time for conducting planned activities and working through unforeseen technical issues that may arise. If an audit is typically completed in two days, for example, an additional half day may be needed to conduct the same activities remotely.

Given that most organizations may not have a formal preparation plan for remote auditing projects, the following items may be of particular importance during the planning phase:

Legal agreements barring electronic recordings:

A legal document should be produced and signed by both parties to prohibit any recording of screen-shares, livestreams, or other media transmitted remotely. The risks of recording in a remote project will likely not be mitigated by existing contractual clauses.

IT service preparation:

The technical components of a remote audit can be fraught with IT issues that may not be apparent, such as firewalls, software limitations, and security risks. IT resources should be included in the planning process to identify potential problems in the project plan and make any necessary policy or technical adjustments. Both parties need to have the appropriate safety features in place.

Connectivity and A/V checks:

If a live facility walkthrough is included in the audit, the route should be checked with devices that will be used to livestream the audit prior to audit day to ensure wi-fi dead spots don't threaten the process. This guide offers more detail on this point during its discussion of facility reviews.

Deliverables from the initial stakeholder meeting should include a full project scope and schedule with details for each activity. Knowing that even the most experienced audit participants may not be accustomed to remote auditing, an effective auditor—whether working as a certified external auditor or third-party consultant—will explain the relevant similarities and differences as well as any special actions that need to be taken.

Here are a few additional matters to consider and capture in the project plan during the initial planning phase:

- ***How both parties will share information,***
- ***Which technologies will be used to conduct or support the audit (such as cameras and teleconferencing systems),***
- ***What authorizations need to be obtained in advance to collect media such as photos or videos, and***
- ***What private or restricted areas need to be considered or avoided.***

The audit schedule should allow for any additional time auditors need to explain the remote auditing approach to participants and take other planning steps. Also, extra coordination may be needed to accommodate for time zone differences, which can complicate the concept of an "audit day."

As part of the initial plan, stakeholders should identify the limits of remote auditing and acknowledge that future on-site work may be required based on the remote audit findings or, in the case of a pandemic, once travel bans are lifted. Given that the stakeholder meetings may be conducted remotely, it's reasonable to expect twice as much time (or more) to complete them compared to an in-person meeting.

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Document Review

A remote document review largely reflects the process of a traditional on-site review with the expectation of a few important differences, which we've summarized below.

Time:

Most facilities are organized to make documents easy to find and reference on site. It may take more time to prepare and upload documents to a platform suitable for sharing materials with an auditor versus paper record storage organizers or digital database storage. Carefully determine how and how long it will take to convert your documentation into a reviewable file format and make them available for auditors to view.

Review workload:

Remote auditing is rarely as efficient as on-site auditing, so consider whether sampling may be necessary. Especially in areas where a full data review is traditionally conducted, be sure to coordinate a sampling strategy with the auditor and review the strategy with audit participants so sampling can be done accurately.

Accessibility:

In the interest of time and convenience, remote auditors should be flexible in accepting the sharing system you prefer. If you currently use digital database storage, determine whether the software allows you to grant temporary direct access, as this can save time and effort.

Questioning:

While a livestreamed document review should allow for live back and forth communications, auditors may need to present questions during remote interviews instead—a requirement that should be accommodated for in the project schedule.

> ***“As an auditor, I can’t know exactly which procedures I’ll need to review with any given firm. As a result, a firm preparing for a remote audit needs to make sure they can scan a copy of something when it’s requested or have it all ready electronically. With paper copies, it’s possible to flip through and find different sections and make notes for reference. But in a remote audit, this is much more difficult and can take far more time if accessibility becomes a problem.”***
>
> **— NEAL SIEGEL**

Copies of key documents should be prepared ahead of time for remote review, including the quality manual, procedures, complaints log, nonconformance log, CAPA log, deviation log, validation master plan (VMP), certificates, and any other essential records. Again, accessibility is a critical aspect of the audit that should be coordinated ahead of time with the auditor.

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Facility & Process Review

Replicating an on-site facility and process walkthrough can be one of the most challenging prospects of a remote audit. Depending on the size and complexity of an operation, this review may simply not be feasible. If this is the case, it may be able to be deferred until travel restrictions are lifted if such actions are deemed appropriate following a risk assessment.

If full or partial facility and process reviews are feasible, auditors should receive a facility map of the inside and outside areas to help plan needs and identify areas where photos, videos, or a streamed walkthrough will be necessary.

While livestreaming may be possible, wireless internet coverage can be spotty in some regions of a facility. Noisy environments and the limitations of AV equipment can make real-time communication and peripheral observations difficult, if not impossible. If a live, virtual facility tour is conducted, be sure to test your technology on the route beforehand through a dry run to ensure the risks identified above don't pose problems.

When incorporating remote facility review into a larger remote auditing plan, auditors should note the areas they feel need to be captured through visual media like photos and video during document review. As part of this document review, auditors should note known or possible process problems, such as complaints, CAPAs, and deviations, so that they can be evaluated remotely.

As part of the planning process, both parties should discuss and agree to put the auditor in full control of the walkthrough—directing cameras and questioning to replicate the experience of an in-person tour. Expect any refusal or obfuscation to comply with an auditor's direction to trigger an immediate project termination.

> ***"During a remote facility tour, the auditor is like a movie director. They'll be requesting actions and camera movements throughout the process. It's important to keep in mind that they have to replace their peripheral vision by making the camera go where they need it to go—panning around rooms and coming in close to see numbers, words, and other fine details. Communication needs to be effective. That goes for the people and the technology."***
>
> **— NEAL SIEGEL**

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Remote Interviews

Remote interviews can be conducted much like in-person interviews through secure teleconferencing systems. Barring technical difficulties, interview times should largely match those of a traditional audit: 30 to 90 minutes with program owners, 15 to 30 minutes with implementation personnel, and shorter interviews with more general responsibilities.

Whenever possible, video calls should be used over audio-only calls so auditors can read non-verbal cues. While conducting a remote review shouldn't take more time than a traditional audit (again, barring any technical difficulties), auditors will likely need more time to prepare.

An effective auditor will "arrive" to a virtual interview with a list of questions and discussion points to obtain additional information. If multiple auditors are involved in the same interview, all parties should make process arrangements to avoid talking over one another.

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Closing Meeting

A remote closing meeting shouldn't be substantively different from that of an in-person audit. These should typically be scheduled a day or two following interviews—a timeframe that enables auditors to review their findings and meet as a team to gather preliminary audit results.

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Benefits and Pitfalls of Remote Auditing

Remote audits offer several advantages, especially in terms of cost and resource utilization. However, there are also barriers and limitations to be aware of. Whether you're responsible for deciding whether or not to conduct a remote audit or contribute to that decision-making process, the points below can help you contextualize the pros and cons within your organization.

The Benefits of Remote Auditing

No travel costs:

Depending on how many audits you conduct in a given period, remote audits can provide significant savings in logistical costs.

Better use of resources:

Rather than forcing staff to pause other work, internal specialists can connect remotely only when they're needed.

A larger auditor talent pool:

When location doesn't matter, the talent pool instantly expands to include those who may have cost too much or been too busy to bring in.

More thorough document review:

Remote audits enable auditors to work at their own pace, often contributing to a deeper review in a setting that's more conducive to great work.

Less operational burden:

Traditional on-site audits can be disruptive to normal facility operations. Remote audits, by contrast, reduce the overall impact on productivity that may already be hurt by the ongoing disruption.

Simultaneous coverage across sites:

The flexibility of remote auditing may allow for auditors to conduct reviews of specific QMS components at multiple sites in a single project rather than one-by-one.

Opportunity for document reorganization:

Since remote auditing likely requires personnel to review and gather the required documents, it offers a chance to organize and confirm that all documentation required for a regulatory inspection is readily available—perhaps in a way that saves time and effort going forward.

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The Pitfalls of Remote Auditing

Like anything that requires humans and technology to work in harmony, it's important to be prepared for inevitable hiccups and headaches. You may lose connection. People may have problems hearing others. You may encounter limits to software systems you didn't realize were there. For these reasons, it's good to consult your IT team ahead of time and make sure they're available during the audit. All these hurdles can be overcome with planning and patience.

Here are a few pitfalls and limitations to consider:

Technology woes:

Depending on what technology you use and where it's applied, you may be stymied by unreliable network connections or logins. If network issues occur, interviews and project meetings can be interrupted.

Awkward rapport:

In addition to being limited in what they can observe, remote auditors are also limited in how they can interact. Contemporaneous advice is hard to give. Poor microphones and speakers can make this worse.

Lack of firsthand observations and access:

No matter how sophisticated a remote audit can be, there's simply no way to replace the sensory experience of an in-person audit. Auditors can't read body language like they can when standing next to someone. They can't notice sights, sounds, and (certainly not) smells in the periphery. Access is another significant problem. You may not be able to take certain devices into sensitive environments like clean rooms or areas restricted by the use of chemicals.

Integrity risks:

Depending on how it's facilitated, a remote audit also keeps the door open for fraud if the proper precautions aren't taken. Without proper oversight, personnel can present altered documents and omit inconvenient or compromising information. These risks can be mitigated through proper planning and carefully-crafted procedures. A follow-up integrity audit may also be valuable when restrictions are lifted.

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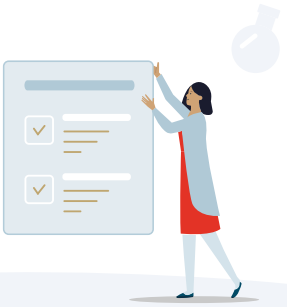
Worksheet

Key Considerations for Planning a Remote Audit



- Are we confident a remote audit is feasible and appropriate?
  Eligibility questions include:
  - Is our firm working through unresolved issues from past audits that require an on-site visit?
  - Has our firm recently been issued a Form 483 or Warning Letter from the FDA?
  - Is our QMS, along with company policy, restrictive around the needs of a remote audit?
- Have we planned to make any necessary contractual arrangements to mitigate risks around remote auditing, such as recording?
- Have we made arrangements to work with IT to review the project plan, identify risks and needs, and address them? Do we have sufficient infrastructure (e.g., bandwidth, access licences, software) to manage a remote audit?
- Does our project plan include some kind of dry run to test the technology and ensure the audit can run as smoothly as possible?
- Have we made electronic copies of key documents for review over the platform that will be used between our team and the auditor? If more copies are needed, is there a quick and easy way to make copies on the fly?
- Are we planning to take measures to safeguard the integrity of the audit if risks exist?
- Who will manage outreach to an external auditing firm that can resource and manage the project?

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Transitioning Your Audit Program to a New Normal

In addition to maintaining an audit program in the face of travel restrictions and stay-at-home orders, quality and compliance leaders also have to plan their transition back to "normal" operations after the immediate effects of the pandemic subside.

As of this paper's publishing, there are still too many unknowns to reliably predict when such a transition will take place in earnest. So, rather than prescribe a specific recovery strategy, we gathered general advice from experienced auditors looking to the future to anticipate challenges and handle them proactively at the appropriate time.

Considering the many project backlogs teams will inevitably need to work through once such a transition begins, the already highly-competitive life science labor environment will no doubt be shifted into an even higher gear as companies attempt to scale up their teams to deal with exceptionally large workloads.

Putting a plan in place now may provide a competitive advantage in finding the resources you need to recover and thrive in a more normal future. Consider the suggestions below as a starting point when formulating your own strategy.

1. Don't push QMS activities out even when regulators have other priorities.

It's no secret that COVID-19 has pulled the FDA's attention away from routine compliance activities to focus on other priorities. It's possible that some companies may not experience an inspection for an extended period of time. However, while resources are understandably tight, quality teams should continue to maintain and improve their QMS, especially when issues or opportunities are known.

If an SOP needs to be rewritten, get to it now. Firms that are discovered to have lingered on fixing known issues during the workforce disruption will only set themselves up for regulatory scrutiny in the future—something inspectors will certainly be looking for.

> ***"In a situation like this, budget naturally diverts from quality to maintaining equipment and production. But if quality loses out among competing priorities, risks are bound to emerge from several fronts. The costs of inaction may be hard to predict right now, but leaning away from quality as a short-term cost-saving measure will likely only compound into a much more expensive problem."***
>
> **— NEAL SEIGEL**

This is one area where auditors serving as "external internal" auditors play a unique role. Rather than a second party auditor, an auditing specialist serving in a consulting capacity can write the audit report as a gap analysis, which can be turned into a remediation project plan. Now, more than ever, quality teams should consider leveraging such a review—perhaps remotely—to ensure they emerge from this workforce disruption confident in their state of compliance.

Read our other white paper for a comprehensive guide to transforming a finished quality system gap analysis into an actionable project plan.

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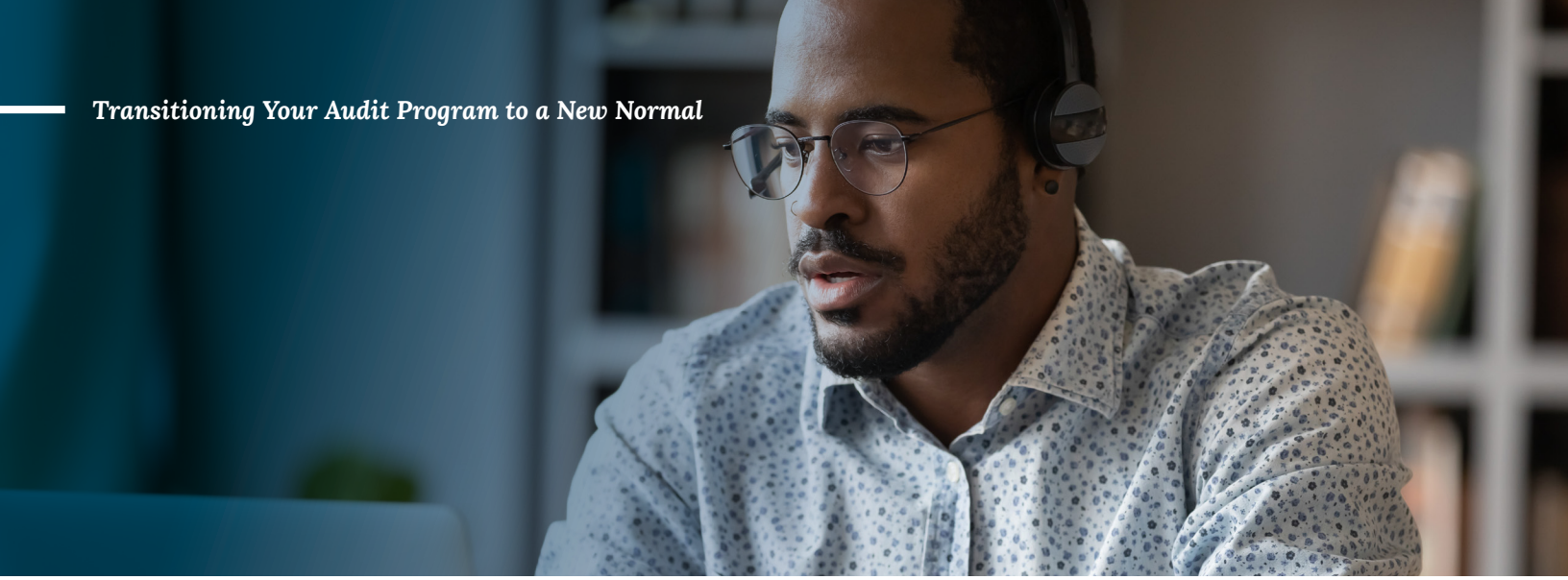

2. Plan now to avoid needing to deliver auditing projects later when capacity is strained.

This unique moment represents a massive opportunity to make life easier once operations return to some semblance of normal through planning.

Consider the following points to craft a plan that won't overwhelm your resources.

Determine which aspects of your audit program can be handled remotely.

Work now to prepare amended scopes of work that can be finalized and deployed as needed when the time comes. When in-person meetings are required, consider whether some elements of that work can be handled remotely in the interim and arrange for in-person projects when restrictions are lifted.

Prioritize backlogged compliance and quality assurance activities by risk.

If deferred work has led to a backlog, it needs to be structured, organized, and arranged before work can begin. Identify known and potential emerging risks and use these insights to prioritize audits in sequence. This sequence can then be applied to a schedule once dates for "re-opening" are known with confidence.

Understand the implications of deferred or canceled assurance activities.

If audits or other assurance activities must be deferred or canceled, the repercussions should be immediately discussed with all impacted parties so any necessary downstream effects can be identified and managed.

Communicate with external resourcing firms early and often so resources can be secured.

As the demand for resources (especially experienced consultants who serve as third-party auditors) becomes highly competitive as auditing programs come back online, it's incredibly important to make resourcing needs known to staffing and recruitment firms as early as possible. Contact us to secure auditing resources when and where you need them.

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3. Rethink work and workforce resiliency.

The pandemic has forced rapid shifts to virtual and remote work—a move that while incredibly disruptive, has led to innovative ways of working that improve flexibility, teaming, and adaptability. Looking to the future, consider how these new work priorities can be used to reconfigure your workforce to better reflect business needs.

Whether you're returning to work with new priorities or goals that are largely the same, don't return to business-as-usual if better methods and approaches are apparent. Take this moment to assess which earlier work processes are still ideal and where new methods may be advantageous. This shift in perspective, while challenging, will be critical in workforce recovery, especially in the areas below.

Tools, technology, and systems:

During the initial response to COVID-19, many organizations accelerated their adoption of digital technologies to work smarter. Consider which changes should be carried over to mitigate new risks and seize new opportunities for speed and effectiveness.

Resourcing and workforce:

The pandemic has prompted many organizations to rethink their workforce and reinvent how teams are composed in ways that better reflect budgets, project lifecycles, and a globalized talent pool. For several years, life science firms have increasingly embraced an augmented workforce, reducing traditional employees and adding more off-balance-sheet workers such as consultants and contractors who bring specialty experience for pre-determined periods of time.

All teams, including quality and compliance functions, should see the recovery period as an opportunity to pivot towards a more resilient workforce—one that moves faster, makes more meaningful contributions in line with the company's mission, and can adapt to shifting priorities. Consider how you can capture the resourcefulness and agility of your recovery and maintain it well into the future.

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Conclusion and next steps

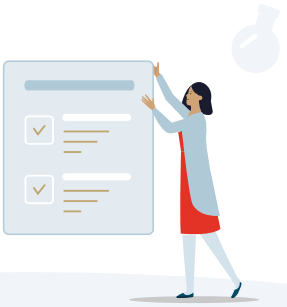
The COVID-19 pandemic has given rise to risks that are both unpredictable and unprecedented. Quality and compliance teams face unique challenges, but they're also in a position to work collaboratively and use this opportunity to improve the ways they work.

By embracing alternative auditing approaches like remote auditing to continue operations in the short-term—and codify changes that make them more agile in the long-term, teams can mitigate the cancellation and deferment of audits scheduled in 2020 and emerge from this crisis more capable and prepared for uncertainty.

Below, we've included a worksheet with important questions to ask when formulating your long-term auditing plans (and assurance functions more generally).

Worksheet

Key Considerations for Workforce Recovery



- What steps are required to continue or restart our auditing program? How should we position those steps on a one, two, and three-month timeline? How will we communicate these plans to leadership?
- Where do we continue to have critical skill or capability gaps in the auditing program?
- How have the effects of this crisis altered future skill requirements?
- How are we thinking about our workforce in a way that provides us with the greatest flexibility, sustainability, and resilience going forward?
- How might we more holistically rethink the composition and size of our workforce into the future (e.g., contractors, consultants)?
- If more work will be done remotely, what support will the organization provide?
- Is the organization prepared for the increased cyber risk that comes with a dispersed and remote workforce?
- What tools can we adopt for virtual work and for adapting to the new practices and ways of work that will make teams and workplaces more effective in the future?
- How can we capture and scale the productivity that can come with new ways of working specifically, new combinations of virtual and on-site work?

NOTES:

Join the thousands of life science companies resourcing their projects with The FDA Group.

Considering a remote audit and need to find an experienced auditor? We bring direct experience to assist you with all aspects of compliance, including but not limited to, GMP, GCP, and GLP.

We perform detailed assessments of your existing quality system, identify current and potential problems, recommend corrective and preventive actions, and work closely with your staff to implement these improvements to your quality system.

Whether you need a single resource or an entire team of on-site or remote resources, we connect you to the skilled professionals you need to build, scale, and efficiently manage projects through a flexible contract staffing/staff augmentation model that better reflects cyclical or project-based demand while infusing new skills and experiences into your team.

We fully understand your resourcing needs and employ our proprietary talent selection process to provide the resources you need, at a competitive rate, with dedicated account management every step of the way. All of our services are backed by a **Total Quality Guarantee**.

Get rapid ***access to qualified personnel*** in an increasingly competitive labor environment.

Free up time and attention within your internal teams.

Find cost efficiencies in recruiting, screening, and onboarding staff.

Learn more and **connect** with us to learn how we can help you assess your quality system and maintain strong, resilient teams now and in the future.

Contact us » ***Learn more*** »