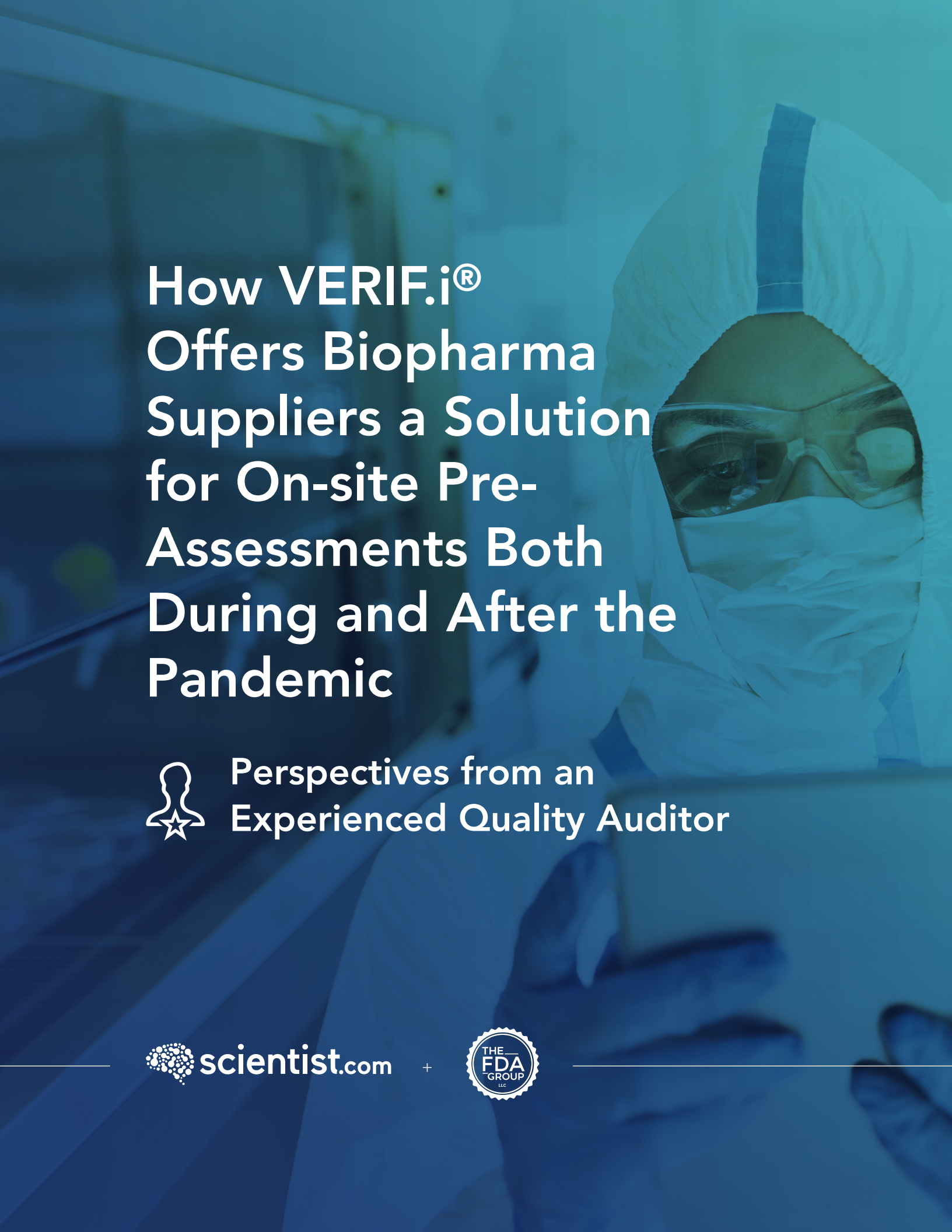

How VERIF.i® Offers Biopharma Suppliers a Solution for On-site Pre-Assessments Both During and After the Pandemic

Perspectives from an Experienced Quality Auditor

scientist.com + THE FDA GROUP LLC

Introduction

Supplier pre-assessments, while a critical part of the R&D lifecycle, have long been the source of headaches for suppliers and biopharma companies alike. The combination of understanding applicable regulations, developing assessment criteria and managing the complex logistics of conducting or hosting largely similar pre-assessments can be exhausting and frustrating for everyone involved. It's no wonder, then, that pre-assessments have gained a reputation among suppliers as an increasingly expensive and time-consuming activity—often requiring dedicated audit handlers to manage a steady stream of assessments from prospective clients.

A global pandemic has only amplified all of these challenges. A flawed but functioning approach to assessing suppliers has rapidly become prohibitively difficult or simply infeasible due to travel restrictions and safety protocols that prevent in-person meetings. As project delays translate into bottom-line impact for biopharma and suppliers, the urgency to find a solution has never been greater.

This paper briefly unpacks both the long-standing and more recent problems plaguing the supplier pre-assessment process and presents a new solution from an experienced auditing professional's perspective. Scientist.com partnered with The FDA Group, a global life science resourcing provider specializing in an array of auditing services, to explore how Scientist.com's VERIF.i program addresses each of these challenges by establishing a global standard for supplier pre-assessments, thereby streamlining the process, reducing costs and saving time for suppliers.

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Meet the Contributor

Brian Dense brings over 25 years of industry experience, with more than 20 years working directly in quality systems and assessing compliance with FDA 21 CFR Part 820, Parts 210 & 211, Part 58, ISO 13485 and ISO 9000.

Brian is skilled in implementing, managing and maintaining complete quality systems to meet FDA regulations and ISO 9000 and ISO 13485 standards as well as regional and international supplier auditing, supplier controls, nonconforming product, complaint handling and investigation and corrective and preventive action (CAPA).

VERIF.i® at a Glance

VERIF.i is a supplier pre-assessment program offering standardized physical lab inspections that evaluate the facilities, personnel and processes supporting the sourcing of regulated services. Through on-site pre-assessments, VERIF.i saves both researchers and suppliers time, money and resources by allowing biopharma organizations to evaluate potential suppliers proactively.

Independent third-party auditors use a standardized checklist to confirm that a supplier's facilities, processes and systems meet a customer's research and regulatory requirements. For suppliers, the pre-assessments demonstrate quality and capabilities, enabling differentiation within the market.

Learn more about VERIF.i®

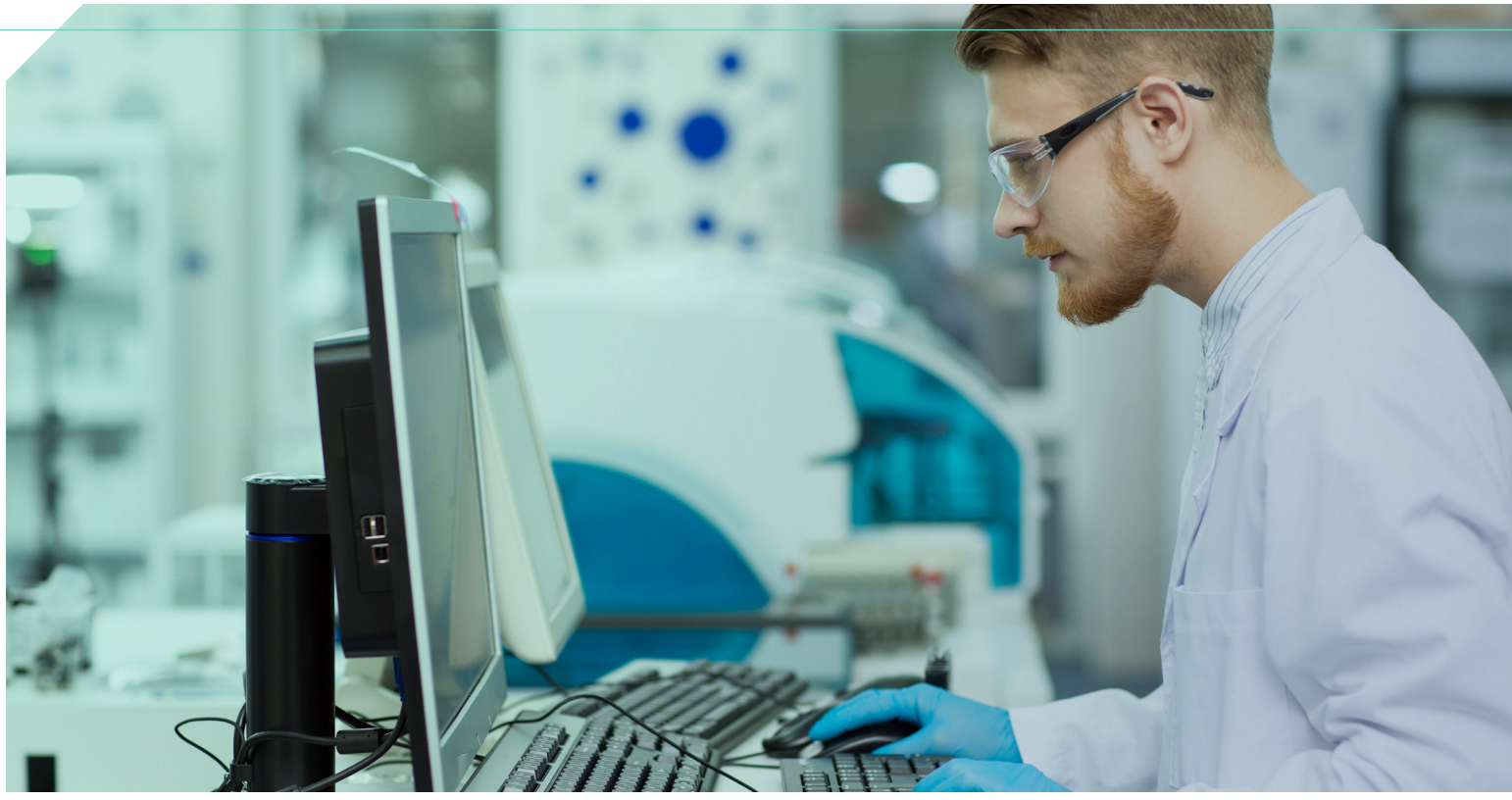
VERIF.i is a new approach to supplier pre-assessments that helps both researchers and suppliers save time and money by standardizing on-site assessments and presenting reports for convenient evaluation.

VERIF.i offers standardized on-site inspections to evaluate the facilities, personnel and processes supporting the sourcing of human biological samples and research services involving animals. Suppliers use VERIF.i to meet a client's regulatory requirements while differentiating themselves from other suppliers in the market that offer similar services.

Contact Scientist.com at compliance@scientist.com for more information or to schedule a free platform demo and consultation.

Addressing the Long-Standing Challenges of Supplier Pre-Assessments for **Suppliers**

Hosting traditional pre-assessments, whether in-person or remote, forces suppliers to contend with a number of challenges. The time, effort and resources spent supporting individual one-off client evaluations that largely comprise the same pre-assessment criteria can become a significant operational burden for suppliers looking to innovate and stay competitive. We gathered firsthand perspectives from an experienced auditor to identify and explore a few of the major challenges suppliers face and how the VERIF.i program offers a solution to each of them.



CHALLENGE

Non-standardized pre-assessments mean a constant cycle of hosting largely identical pre-assessments.

Although many pre-assessments contain the same assessment criteria, no major effort has been made to seize the opportunity to standardize a global set of pre-assessment criteria—a step that would reduce the number of pre-assessments suppliers would have to host.

> **Suppliers are inundated with assessments. When I worked for a large life science manufacturer, some of our suppliers would tell me there were times they'd have three or four customers in the building at the same time doing assessments and audits. There are so many going on these days that some suppliers now have a staff of handlers. Suppliers are victims of their own success when it comes to assessment. The more prospects they field, the more assessments they need to host."**
>
> **— BRIAN DENSE**

SOLUTION

VERIF.i is the first program of its kind to acknowledge the opportunity to standardize supplier pre-assessments and capture that assessment criteria in a single template. Suppliers can dramatically reduce the number of pre-assessments they need to host by offering their VERIF.i report to prospects without them needing to step on site—reducing the time, effort and resources spent supporting individual one-off client evaluations.

> **For suppliers, there's a big opportunity here to cut down on the need for hosting pre-assessments that largely look the same, so time and attention can be spent engaging on study or product-specific assessments."**
>
> **— BRIAN DENSE**

CHALLENGE

Internally led supplier pre-assessments can undermine objectivity.

Biopharma organizations have come to expect every potential supplier to host independent third-party auditors who can be trusted to conduct objective assessments.

> Researchers and manufacturers both expect every assessment to be carried out by qualified external auditors to ensure they can trust the integrity of the report."
>
> — BRIAN DENSE

SOLUTION

VERIF.i protects the integrity of every assessment by ensuring third-party assessments are conducted by trained external auditors.

> The fact that Scientist.com is powering VERIF.i with external third-party auditors rather than building an in-house team of auditors means objectivity is built into the system. Both sides can have full confidence in the report."
>
> — BRIAN DENSE

CHALLENGE

A never-ending cycle of assessment leaves little time for continuous improvement.

With so much time and energy devoted to hosting assessments—sometimes multiple assessments at once—suppliers can struggle to focus their attention on identifying opportunities for forward-thinking improvement.

> "Supplier assessments are incredibly important, but when a company is overwhelmed with hosting these assessments, it can start to steal valuable time away from day-to-day work."
>
> — BRIAN DENSE

SOLUTION

VERIF.i offers suppliers a unique opportunity to improve quality by freeing up more time to identify potential process improvements while providing a robust set of assessment criteria to guide improvement projects and innovate their services.

> "With standardized pre-assessment, researchers can evaluate without doing their own assessment. Suppliers are going to save a ton of time and money hosting what's essentially the same pre-assessment over and over again. I think their clients would be pleased to know they're able to reinvest those resources in their products and services. I can see this giving a competitive advantage to suppliers who could use that time to improve their products while others are stuck in an endless audit cycle. Also, while I would anticipate some companies might get worried about a lack of face-to-face interaction, knowing this isn't a substitute for a study-specific assessment, researchers are just shifting that engagement one step later in the process, where it's arguably more appropriate. Both sides can have a more informed conversation about the development project after pre-assessment."
>
> — BRIAN DENSE

CHALLENGE

Committing resources to pre-assessment without the guarantee of a relationship.

Suppliers often devote a significant amount of resources to hosting pre-assessments that do not result in working relationships with researchers despite clear signals at the outset of the qualification process.

> **"Without a way to see pre-assessment information unless they go on-site to collect it each time, both researchers and suppliers end up spending a lot of time and resources figuring out that, for whatever reason, they're not the right fit for a project."**
>
> — BRIAN DENSE

SOLUTION

VERIF.i gives suppliers' new and existing clients confidence and insight into their organization's capabilities, all while enabling them to conduct initial assessments without coming on-site.

> **"From a supplier's standpoint, having that standardized VERIF.i report available to prospects either through or outside of Scientist.com will likely result in more qualified opportunities since researchers can conduct that qualification themselves just by evaluating the report. Suppliers can focus their energy on viable opportunities."**
>
> — BRIAN DENSE

The Heightened Challenges Brought by a Global Pandemic

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

The wide-scale transition to remote work has had an enormous impact on R&D's frontline. The sudden workforce disruption is complicating—and often preventing—in-person activities, including all types of assessments. To keep R&D projects moving forward, firms are increasingly turning to virtual assessments to maintain supplier qualification and other quality and compliance assurance activities until normal operations can resume.

However, the switch to virtual assessments has presented some of its own unique challenges that complicate assessment and pose new risks to the process.

The Drawbacks of Virtual Assessments

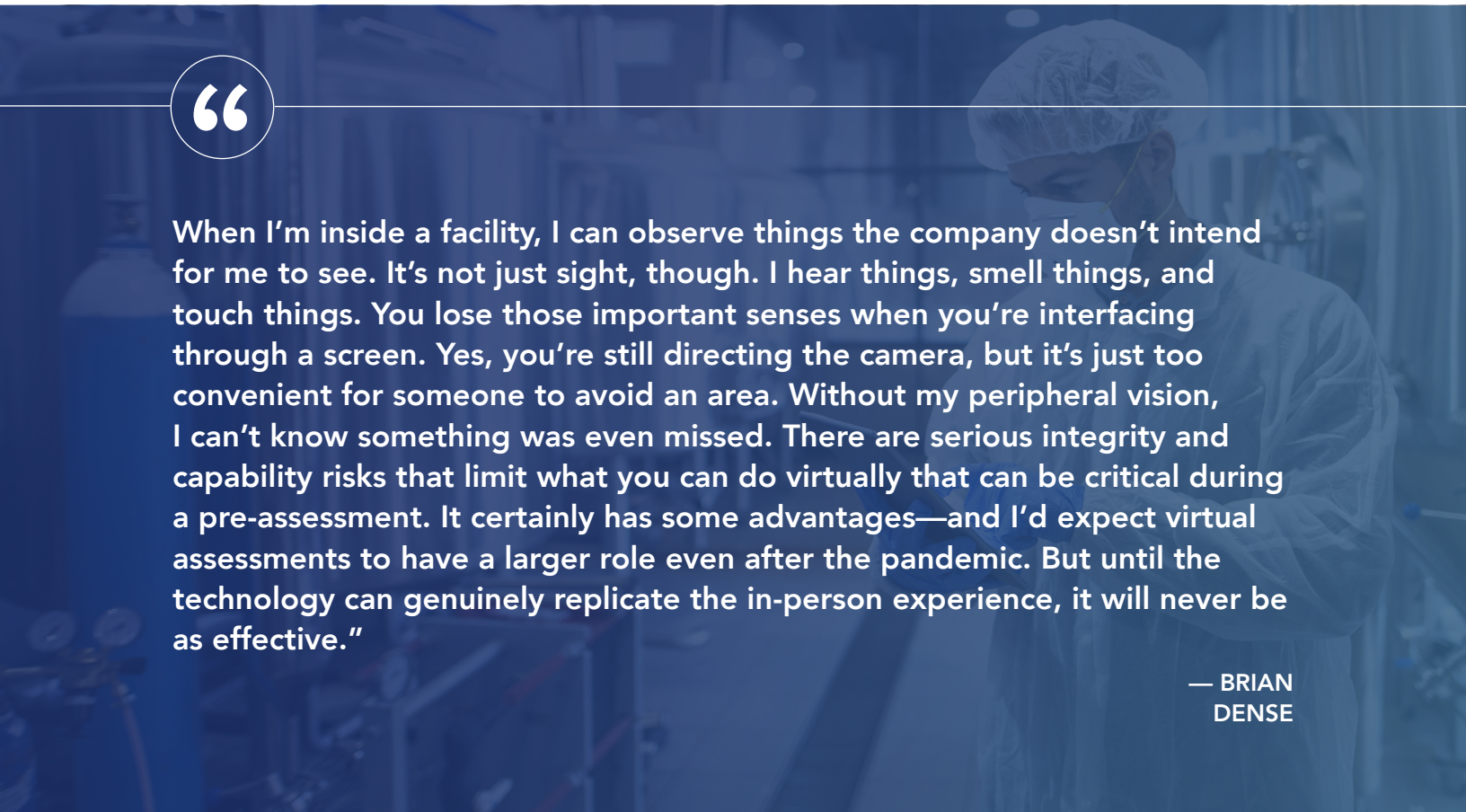
The rapid transition from in-person to virtual assessments has brought both advantages and disadvantages. The benefits largely boil down to cost-savings and efficiency. Travel expenses and operational burdens evaporate. Screens force each person's attention on the tasks at-hand—reducing distractions and wait time. Auditors can assess multiple sites in a single project with the right planning and orchestration rather than one-by-one.

But removing the physical, in-person component of an assessment has brought new challenges and risks that can threaten the mission of an objective assessment itself:

Technology issues: Teams using new technology systems for the first time may find themselves stymied by unreliable network connections or run into software limitations that can threaten the process. Poor audio and video equipment can make communication difficult or impossible.

Lack of sensory inputs: Even the most sophisticated technologies cannot replicate an in-person assessment's sensory experience. Subtle indicators, like body language, may go unnoticed. The frame of a camera may limit visual fields. Soft sounds may not register through the microphone.

Integrity risks: Virtual platforms can pose significant risks to the integrity of an assessment. Without proper oversight, personnel can present altered documents and omit inconvenient or compromising information. While some of these risks can be mitigated through appropriate planning and carefully crafted procedures, current technologies' inherent limitations can invite temptations that would otherwise be mitigated on-site.



When I'm inside a facility, I can observe things the company doesn't intend for me to see. It's not just sight, though. I hear things, smell things, and touch things. You lose those important senses when you're interfacing through a screen. Yes, you're still directing the camera, but it's just too convenient for someone to avoid an area. Without my peripheral vision, I can't know something was even missed. There are serious integrity and capability risks that limit what you can do virtually that can be critical during a pre-assessment. It certainly has some advantages—and I'd expect virtual assessments to have a larger role even after the pandemic. But until the technology can genuinely replicate the in-person experience, it will never be as effective."

— BRIAN DENSE

Making the Case for VERIF.i® as a Solution to the Challenges of Supplier Pre-Assessment

VERIF.i is designed to help suppliers of in vivo services and biological samples reduce the time, effort and resources spent supporting individual one-off client evaluations by creating an impartial, on-site assessment process supporting our global network of clients and suppliers.

Scientist.com partnered with third-party assessment firms that use industry developed, standardized checklists to confirm that a supplier's facilities, processes and systems meet a customer's research and regulatory requirements. The assessment includes pre-work, documentation review, a one-day on-site inspection, inspection report and potential corrective actions.

These standardized reports are then made available within the Scientist.com platform, allowing suppliers to demonstrate to both potential and existing clients either on or off platform that they possess the appropriate knowledge, skill, policies and procedures to support these services.

Save time, money, and other resources: Hosting individual client assessments can be a time and resource-intensive endeavor for both large suppliers whose global business may require tens or hundreds of site assessments as well as small suppliers who may lack the Quality Assurance resources that these assessments require.

Creating a global standard for the biopharma industry means that individual clients no longer need to conduct on-site supplier pre-assessments, leading to a potentially massive reduction in the annual resources a supplier must devote. Suppliers can also enhance new customer acquisition as VERIF.i can differentiate their organizations from the competition and complement their business not supported by Scientist.com.

scientist.com + THE FDA GROUP LLC

Instill more confidence in supplier pre-assessments: Having a framework in place to evaluate suppliers against a global standard offers greater confidence that requirements are being met across not just one, but many customers. Conversely, biopharma companies know that when their researchers need to source highly regulated services, they can be confident that those suppliers uphold the highest industry standards, even beyond the individual requirements.

Reduce risk when conducting or hosting supplier pre-assessment: Suppliers reduce their internal risk by ensuring their facility, policies and procedures meet the highest industry standards. Additionally, because VERIF.i reports can be accessed by dozens of customers instead of just one, suppliers no longer have to go through the burden of individual client assessments that may still result in little to no work from that client.

Overcome the shortcomings of existing standards (and lack thereof): The existing on-site assessment system is splintered and unorganized. The rise of pandemic-related restrictions has left the biopharma industry in search of a solution as quickly as possible. Within the in vivo space, researchers' inability to conduct individual assessments can lead to a regression toward the existing standards such as AAALAC.

VERIF.i does not replace these broader standards but instead builds upon them to align with biopharma industry requirements and best-practice policies. With regard to human biological sample provision, this becomes even more important as there is nothing close to a global standard. Few, if any, companies currently have the capacity to conduct on-site assessments of human sample providers despite the potential risks. VERIF.i has been designed with industry to address this gap and ensure that the industry is proactive in driving up standards and ensuring donors are protected.

Summary, Key Considerations & Next Steps

On-site assessments are expensive, resource intensive and time-consuming for customers and suppliers. Scientist.com developed VERIF.i to provide a new approach to supplier assessments that helps both sides of the market.

Independent third-party auditors use a standardized checklist to confirm that a supplier's facilities, processes and systems meet a customer's research and regulatory requirements. As a supplier, the pre-assessments demonstrate your quality and capabilities, enabling you to differentiate yourself within the market. The pre-assessments help biopharma researchers select suppliers faster with more confidence and less risk.

The VERIF.i program currently supports animal welfare and human biological sample on-site pre-assessments, but it is currently expanding into additional regulated service areas.

When quantifying the value of a standardized pre-assessment program for your organization, consider how much time and money could be saved by radically reducing the assessment workload from prospective clients.

For suppliers, ask youself: how could you better utilize your resources, and save money, if you could reduce the number of assessments you host? I think the answer for a lot of organizations would be revealing."

— BRIAN DENSE

Want to learn more about VERIF.i and how much your organization stands to gain from streamlining its supplier pre-assessment program?

Find additional resources at scientist.com/verifi and email compliance@scientist.com to schedule a free platform demo and consultation.

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