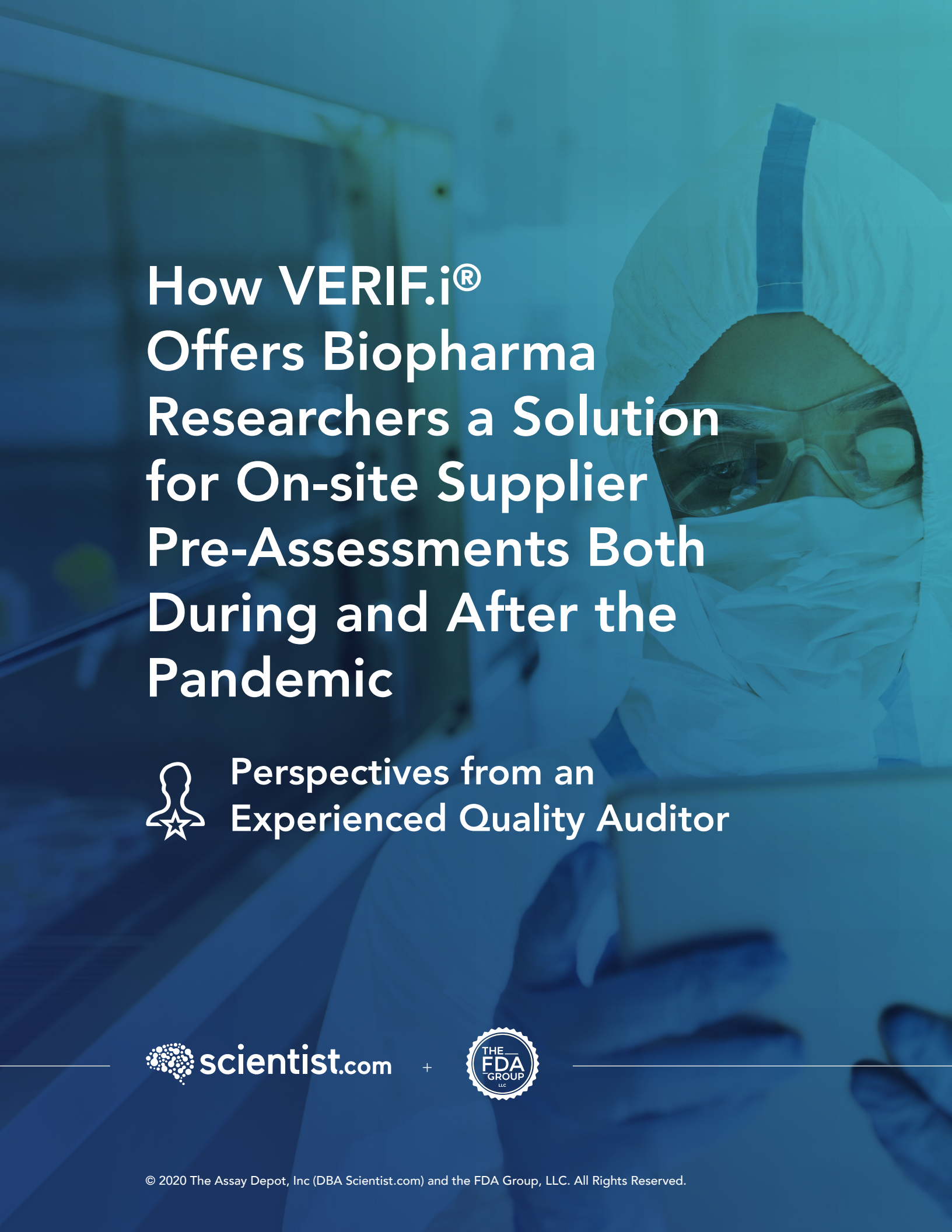

How VERIF.i® Offers Biopharma Researchers a Solution for On-site Supplier Pre-Assessments Both During and After the Pandemic

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 biopharma companies and suppliers 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 for being taxing to plan, expensive to manage, and an excessively time-consuming chunk of R&D project schedules.

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 researchers, 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 biopharma organizations.

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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 biopharma companies, the pre-assessments help customers select suppliers faster with more confidence and less risk.

Learn more about VERIF.i®

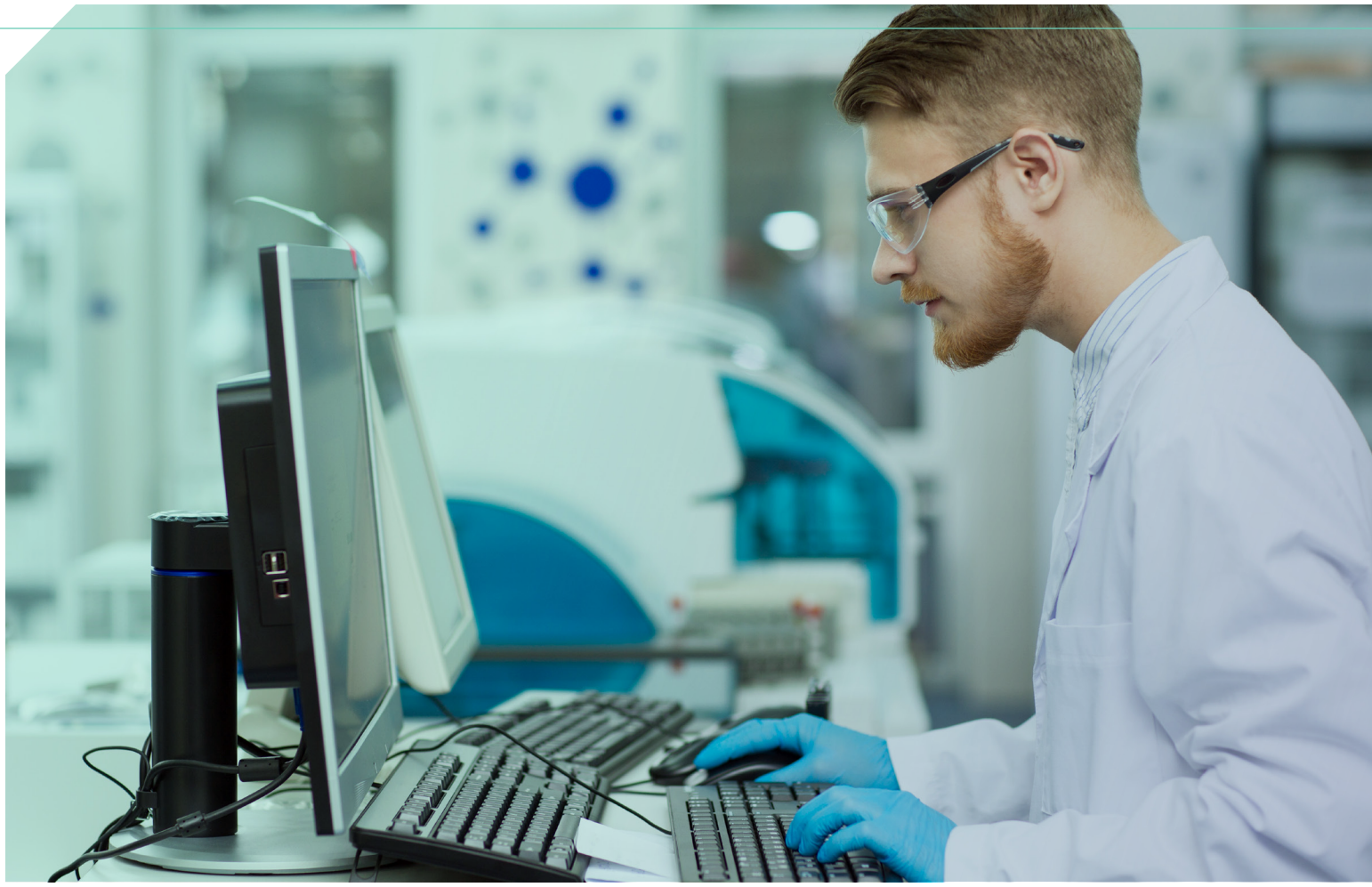
VERIF.i is a new approach to supplier pre-assessments that helps both researchers and suppliers save time and money by standardizing on-site assessments and presenting reports for convenient evaluation.

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. Research organizations use VERIF.i to improve supplier quality management, decrease costs and reduce risk. 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 **Researchers**

On-site supplier pre-assessments are expensive, resource-intensive and time-consuming for biopharma research organizations in search of trusted suppliers. We gathered firsthand perspectives from an experienced auditor to identify and explore a few of the major challenges researchers face and how the VERIF.i program offers a solution to each of them.



CHALLENGE

Non-standardized pre-assessments mean costly management of multiple similar pre-assessments.

Although many pre-assessments contain similar or even identical assessment criteria, no significant effort has been made to realize the opportunity to radically streamline the pre-assessment process by standardizing a global set of pre-assessment criteria.

> **"Companies often devote a lot of time and energy to creating what is largely the same pre-assessment criteria over and over again. In biopharma research, pre-assessments can look largely the same. There's a huge opportunity to develop a global standard so we can seize that opportunity, reduce superfluous on-site assessments, and reallocate that time and money to assessments that are unique to the product or study."**
>
> **— 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. Following a VERIF.i pre-assessment, detailed findings are made available to prospective research organizations via digital report. Pre-assessments can be conducted simply by reviewing the report, eliminating the need for an on-site visit.

> **"Rather than having to develop criteria and go on-site to conduct a pre-assessment, researcher organizations could simply view suppliers' VERIF.i reports and ascertain everything they need to know for initial qualification. Knowing how long the pre-assessment process can take with planning and travel, researchers could condense a week or more into a few hours, depending on how many suppliers they were considering. It can all be done from behind a computer in less than a day."**
>
> **— BRIAN DENSE**

CHALLENGE

Internally led supplier pre-assessments can undermine objectivity.

Natural relationship building in the early phases of a possible supplier engagement can subtly undermine an assessment's objectivity when conducted directly between researcher and supplier.

> "As a research organization, it's important to recognize the two incentives at work at the outset of a supplier engagement. One is to objectively evaluate possible candidates. The other is to build relationships and rapport with those who may go on to be partners. The second incentive can slyly affect the first when a certain distance isn't strictly maintained."
>
> — BRIAN DENSE

SOLUTION

VERIF.i protects the integrity of every assessment by ensuring trained, external auditors conduct third-party pre-assessments.

> "It's critical that a qualified third-party step in to conduct that assessment to ensure the assessment findings have no undue influence. By opting for third parties rather than, for example, building an internal team of auditors in-house, VERIF.i bakes that objectivity in by design."
>
> — BRIAN DENSE

CHALLENGE

A lack of centralized reporting hinders cross-functional visibility.

The current non-standardized approach to supplier pre-assessment means it's up to each researcher to plan and conduct pre-assessments and distribute the findings to all the necessary stakeholders so informed decisions can be made as efficiently as possible.

> "Depending on the size and scope of the research or product, researchers and manufacturers might have a sizable group of people that need to access the pre-assessment report and come together to make decisions to stay on schedule. That process can get messy when technology gets in the way of collaboration instead of helping to improve it. Visibility is an under-appreciated problem, especially in larger organizations that may need to get the same data in front of busy Quality Assurance, Procurement and Governance teams and make a decision."
>
> — BRIAN DENSE

SOLUTION

VERIF.i centralizes pre-assessment reporting, thus guiding sourcing decisions and streamlining supplier selection by making reports easily accessible for all stakeholders within an organization via the Scientist.com platform.

> "Putting the pre-assessment report in one secure place for everyone to access could mitigate the effects of poor visibility and avoid frustrating delays. It could also help researchers spot potential issues within their own R&D lifecycle that they otherwise wouldn't have had brought to their attention until they traveled to a supplier. Having a detailed, digital report at your fingertips means you can conduct those critical checks to validate your own readiness much faster and less expensively than you could have otherwise. That's huge."
>
> — BRIAN DENSE

CHALLENGE

Limited internal resources and shrinking budgets lead to longer timelines and overworked teams.

Resource allocation can profoundly affect the timeline of an R&D project. Whether it's limited personnel, budget or both, supplier pre-assessments might have to be conducted in a series rather than simultaneously. This can extend the pre-assessment phase considerably and impact the overall timeline of the project.

> "So much rides on available resources when it comes to R&D. Typically, the fewer resources available to plan and manage pre-assessments, and the more supplier candidates there are to assess, the longer and more drawn out you can expect that process to be. Ideally, a team can conduct multiple pre-assessments at once. But very often, resource constraints mean, again, longer timelines because they must be done one after another."
>
> — BRIAN DENSE

SOLUTION

By creating a global standard across the biopharma industry, VERIF.i eliminates the need to conduct individual on-site supplier pre-assessments, leading to a potentially massive reduction in the annual resources a supplier must devote.

> "What Scientist.com has done with VERIF.i is allow one person to do the job of five in a single day. So much of that process and expense in time and money is reduced to simply looking over their suppliers' VERIF.i reports. It lifts the resource burden so you can focus your energy on the study-specific assessment."
>
> — BRIAN DENSE

CHALLENGE

Priorities compete between supplier pre-assessments and study-specific assessments.

Allocating adequate resources for both pre-assessments and study-specific assessments can be a frustrating balancing act, especially when those resources are tight. When either activity is under-resourced, it can have significant consequences on the broader project in terms of risk.

> **Those who plan and manage supplier assessments are put in the tough spot of having to balance the time spent conducting on-site pre-assessments with other things they're doing in research, like running tests and doing other work back at the home office or lab."**
>
> **— BRIAN DENSE**

SOLUTION

VERIF.i eliminates the need to conduct individual on-site supplier pre-assessments, enabling biopharma companies to reinvest those resources elsewhere.

> **Again, the efficiency advantage is pretty clear here. If you don't need to go on-site, you can reinvest all of those resources in the study-specific assessment or other areas of the project."**
>
> **— 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 assessments 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 audits and 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 has presented some of its own unique challenges that complicate assessment and pose new risks to the process.

The Drawbacks of Virtual Assessments

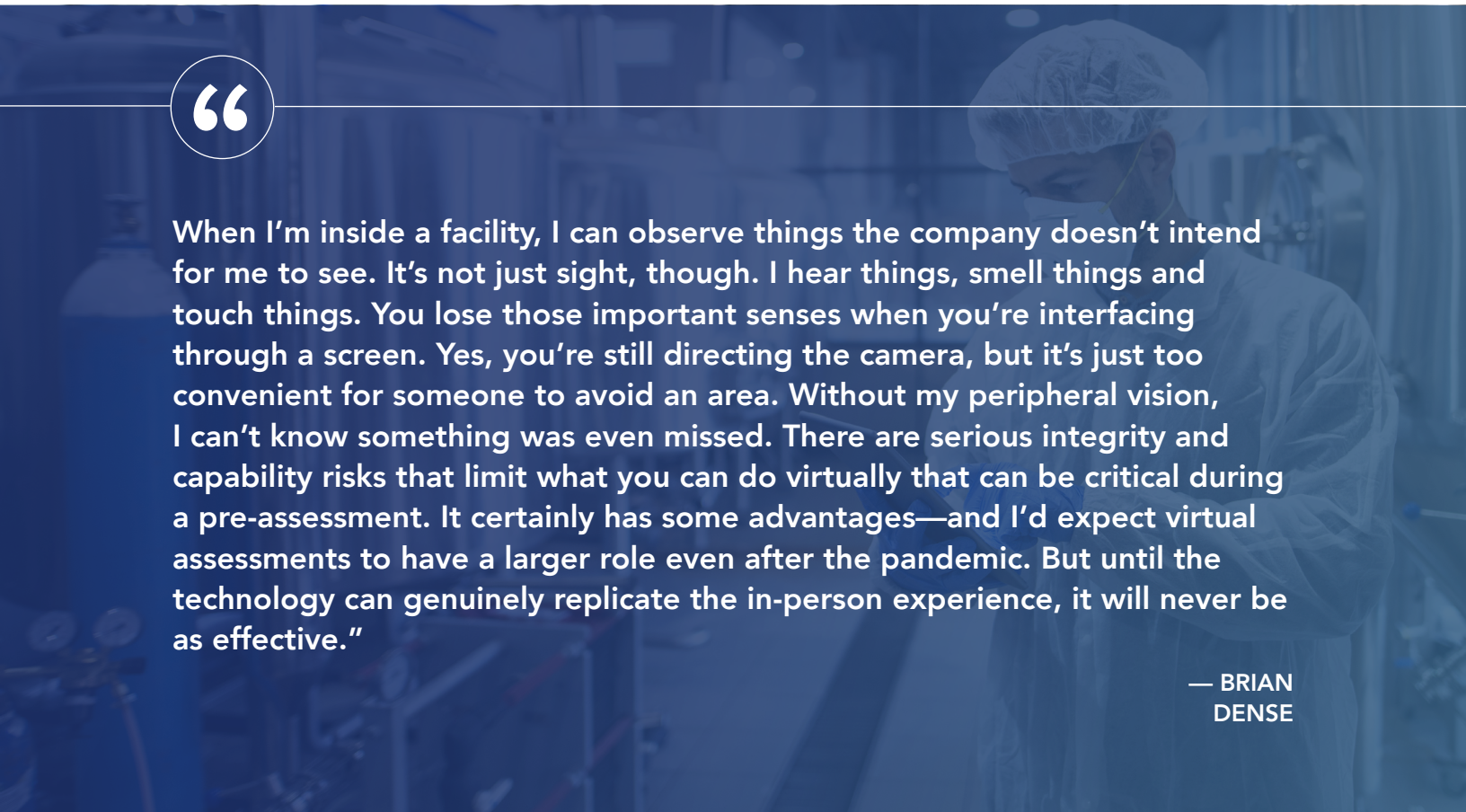
The rapid transition from in-person to virtual assessments has brought both advantages and disadvantages. The benefits largely boil down to cost-savings and efficiency. Travel expenses and operational burdens evaporate. Screens force each person's attention on the tasks at-hand—reducing distractions 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 meet the biopharma industry's needs when sourcing in vivo services or acquiring human biological samples 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, skills, policies and procedures to support these services.

Save time, money, and other resources: The current supplier pre-assessment system forces researchers to invest their own time and resources to evaluate potential suppliers. Beyond the direct cost savings of their own pre-assessments, researchers can remove the risk of potentially exposing their staff to the current dangers of travel. In short, by establishing a global standard for supplier pre-assessment, VERIF.i reduces—and often eliminates—the need to conduct these pre-assessments on site.

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.

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Reduce risk when conducting supplier pre-assessment: The risks associated with supplier qualification and selection can be massive. In both the human biological sample (HBS) and in vivo spaces, issues with supplier selection can cost potentially millions of dollars in lost development and jeopardize the company's reputation. As we've seen firsthand, many organizations don't realize their due diligence processes are lacking until it's too late. Failing to properly qualify a supplier before beginning work can lead to problems further down the line if that drug candidate continues toward trials.

All prior work, and the supplier(s) who completed it, are put under the microscope. A failure to follow proper procedures and regulations can result in the work needing to be redone, delaying critical projects.

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. This streamlined approach to pre-assessment helps 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 to what degree your R&D lifecycle could benefit by radically reducing the resource commitment for supplier pre-assessments.

If a biopharma company wanted to know how much they stood to save and gain from VERIF.i, I'd suggest they look back on the time and resource commitment required for supplier pre-assessment and consider how R&D could have been improved if that was reinvested elsewhere. I think the answer for a lot of organizations will 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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