Whitepaper

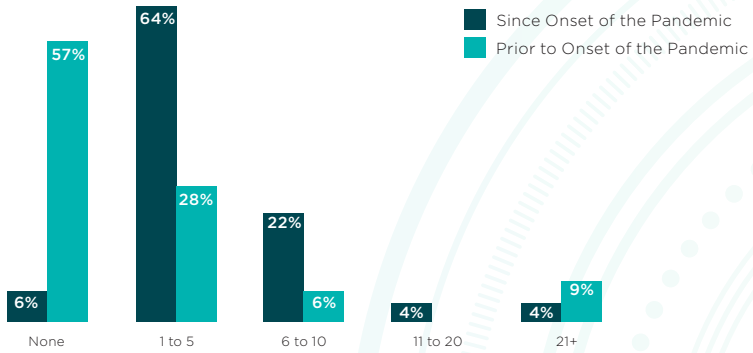
Digital Transformation In Regulatory: Achieving Excellence Virtually

The COVID-19 pandemic demanded significant pivots in how life sciences professionals and regulators carried out their responsibilities. Remote working was imposed in many regions to minimize the spread of disease, so technology became critical for continued regulatory operations, including carrying out virtual inspections to assess drug safety and adherence to good manufacturing practices (GMP).

This was a substantial change, as a recent survey conducted by Informa Pharma Intelligence and Cambrex showed that before the onset of the pandemic 57% of respondents had never undertaken a virtual inspection (see Figure 1).

Such rapid digital adoption was a direct reaction to continue operations and would undoubtedly have taken longer to become widely accepted without the catalyst of the pandemic. Nonetheless, this implementation has largely been successful, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) stating it sees "added value in retaining these practices beyond the pandemic."[1] Additionally, the FDA has indicated support of virtual GMP inspections, announcing the development of guidance on the topic.[2] As the industry looks forward, key decision-makers in pharma and biotech companies were surveyed to assess their views on undertaking regulatory processes virtually.

Figure 1: Number of virtual inspections undertaken



Question: How many virtual inspections have you or your outsourcing partners undertaken?

Base: Respondents with virtual inspection experience (organization of outsourcing partner) (n=47)

Why Cambrex?

Cambrex provides drug substance, drug product and analytical services across the entire lifecycle.

We deliver quality in every aspect of our work, across all of our facilities, systems and teams.

About Cambrex

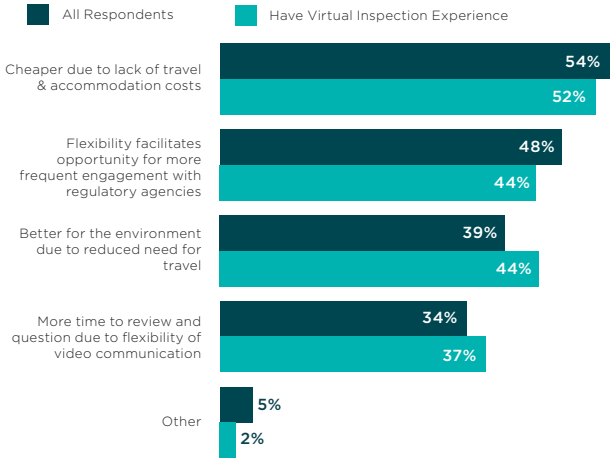
Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

Building Sustainable Relationships

Relative to in-person inspections, 54% of respondents regarded saving travel and accommodation costs as one of the main advantages of virtual engagement with regulators (see Figure 2). It was also recognized that reduction in travel had notable benefits for the environment, with this chosen as a primary benefit by 39%. This is a priority in the pharma industry and the wider world, with bodies such as CPhI calling on companies to utilize the COVID-19 pandemic as an opportunity to create more sustainable processes.[3]

Figure 2: Top-2 benefits of virtual inspections (compared with in-person inspections)

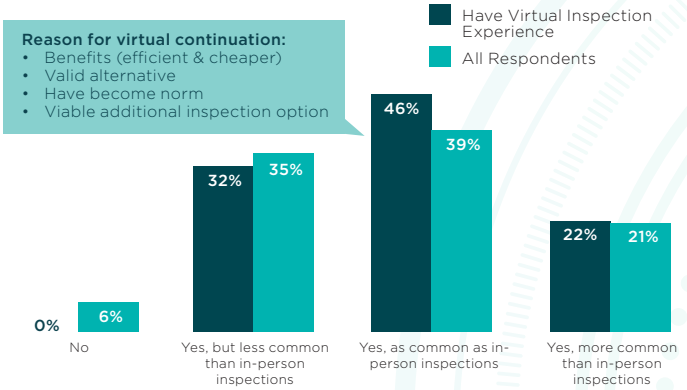


Question: What are the main benefits of virtual inspections in comparison with in-person inspections? (Please select up to 2 main benefits)

Base: All respondents (n=128)

As well as being positive from practical and environmental perspectives, respondents also saw opportunities for virtual inspections to improve their interactions with regulators. Some 48% considered that the added flexibility would allow for more frequent engagement with regulatory agencies and that this was a key benefit. GMP inspections are critical to ensure that drug safety and quality standards are met, so any opportunity to increase their frequency offers reassurance to regulators and patients alike that medicines are efficacious.

Figure 3: Will virtual inspections still be utilized after the COVID-19 pandemic?



Question: Do you expect virtual inspections to still be utilized after the COVID-19 Pandemic?

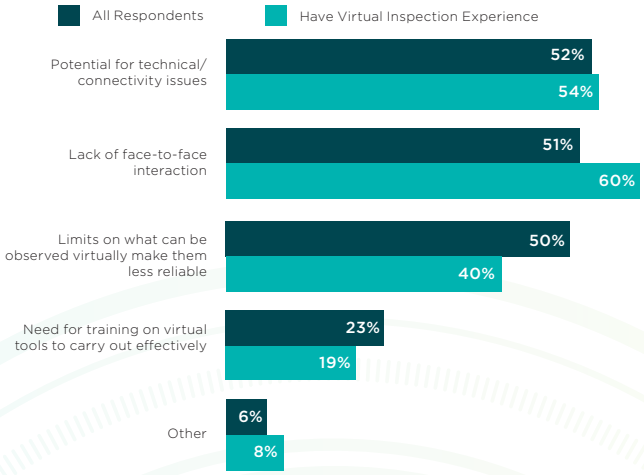
Base: All Respondents (n=109)

While 91% asserted that COVID-19 had greatly accelerated the digital transformation of regulatory inspections, respondents also stated that they believed these changes would remain. Almost all (94%) expected virtual inspections would still be utilized after the pandemic, with 68% believing they would be at least as common as in-person inspections (see Figure 3). This is a testament to the benefits that have been realized following their execution, with supporting verbatim comments including that they had proved to be a valid alternative and were now considered the norm. The wider industry sentiment reflects this, with regulators across the globe predicting that there is room for "hybrid" assessments combining virtual and on-site inspections, with virtual being particularly useful for international inspections.[4]

The Limits Of Technology

Despite the recognized benefits of virtual inspections, changes of this magnitude can also cause complications when implemented. Overall, respondents stated that the main disadvantage compared with in-person inspections was the potential for technical or connectivity issues (53%) (see Figure 4). This is an issue that all remote working environments have had to adapt to, as opposed to an isolated problem with virtual inspections in life sciences.

Figure 4: Top-2 disadvantages of virtual inspections (compared with in-person inspections)



Question: What are the main disadvantages of virtual inspections in comparison with in-person inspections? (Please select up to 2 main disadvantages)

Base: All respondents (n=122); multiple answers permitted.

In its live document on best practices in virtual GMP inspections, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) advises having an IT Redundancy and Back-up Plan for unforeseen circumstances, such as loss of WiFi connection or mobile signals.[5]

Other key disadvantages were the lack of face-to-face interaction (51%) and concerns that there were limits on what could be observed virtually, which could make these inspections less reliable (50%). Notably, there were clear differences in perception between respondents who had already experienced a virtual inspection and those who had not. With regards to face-to-face interaction, those

who had undertaken a virtual inspection saw this as the most significant drawback, with 60% ranking it in the top two disadvantages. Nevertheless, given that respondents expressed a clear willingness to continuing these practices in the future, this indicates that face-to-face engagement is a matter of preference as opposed to a fundamental barrier to adoption. Also, reliability concerns were expressed much less by respondents with virtual inspection experience (40%). This demonstrates that it is more likely a preconception, and one that is found to be unsubstantiated once a virtual inspection has been undertaken.

Partner Prioritization

While some larger pharma companies may manufacture their products in-house, there is an increasing trend toward outsourcing drug development and manufacturing to specialist contract development and manufacturing organizations (CDMOs).[6] Success with regulators on both the clinical and manufacturing sides is pivotal to achieving market access and bringing products to patients, so unsurprisingly, respondents placed great emphasis on this when choosing outsourcing partners. Some 96% stated that regulatory excellence was important when their business assessed CDMOs, with a clear majority viewing it as very important (65%).

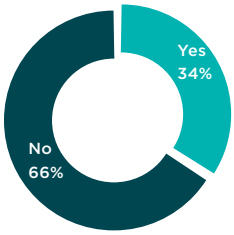
Now that sponsors are aware of the opportunities and support of the continued use of virtual GMP inspections, it is of the utmost importance that partners have the technology to facilitate these. According to IFMPA, key technologies necessary to ensure a faultless, reliable inspection include document sharing and video capabilities.[5] Respondents were aware of this, with 41% viewing the former as the most important and 34% choosing the latter, followed by 22% seeing technical staff who can effectively deploy and maintain these tools as crucial. The reality is that all three are critical, so upon deciding to outsource to a CDMO, sponsors must ensure that their partners can prove they have these capabilities.

Project Management Potential

Beyond its use for regulatory processes, this technology also has added benefits for partnership selection and management. Of respondents from pharma and biotech companies, 31% thought visibility on project progress with existing partners was the most important use of virtual tools, and a further 24% thought virtual site visits with potential new partners was the primary benefit. The value of a sponsor's drug development is extremely high, and partnering with a CDMO places a great amount of responsibility on them for these projects. The opportunity to regularly observe progress through video communications increases the accountability of the vendor and offers reassurance to their partners.

Despite this, only a third of respondents had conducted virtual site visits of this nature (see Figure 5). When compared with the higher frequency of the virtual inspection experience, it would appear that the use of video technology has not been commonly extended by some CDMOs to more widely benefit their partnerships.

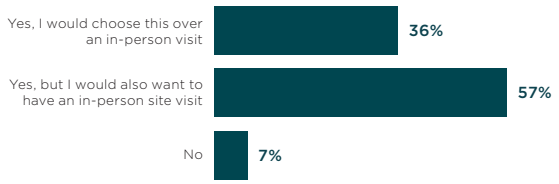
Figure 5:
Conducted any virtual site visits with existing or potential partners?



Question: Have you ever conducted a virtual site visit with an existing or potential outsourcing partner?

Base: All Respondents (n=93)

Would you consider a virtual site visit with an existing or potential outsourcing partner?



Question: Would you consider a virtual site visit with an existing or potential outsourcing partner?

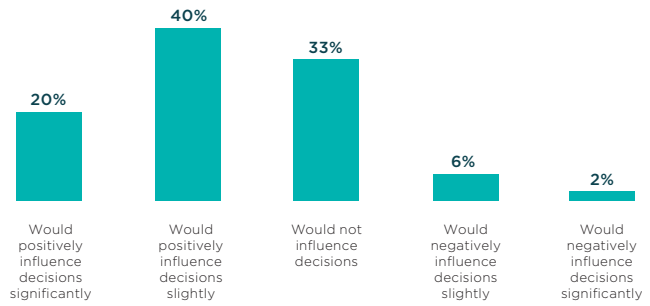
Base: All Respondents (n=88)

There is a clear appetite for this to change, with the vast majority of respondents (93%) stating they would consider a virtual site visit with their existing or prospective partners (see Figure 5).

Nonetheless, it would appear that in-person visits are by no means redundant, with 57% indicating they would still want face-to-face interaction with their partners. Given the impact these relationships have on a sponsor's business prospects, it is understandable that virtual means alone may not be satisfactory for peace of mind. However, the results clearly show that the option of additional oversight through improved technology is welcomed by sponsors.

As this technology becomes more common, those looking for new CDMO partners will be prioritizing it in their searches. Some 60% of respondents stated that the opportunity to conduct virtual audits would positively influence their outsourcing partnership decisions (see Figure 6). CDMOs must react to this to ensure they meet the expectations of their clients and provide the best service possible.

Figure 6: Impact of virtual site audit opportunities on outsourcing partnership decisions



Question: How would the opportunity of conducting virtual site audits impact your outsourcing partnership decisions?

Base: All Respondents (n=114)

From Crisis To Opportunity

While COVID-19 has caused substantial upheaval in the pharma industry, there is a silver lining of digital transformation. The pandemic has accelerated the implementation of technology in regulatory processes, making them more sustainable and efficient. While in-person inspections by regulators and site visits to new and existing partners will continue to be important, virtualization offers opportunities for increased communication and oversight, which can only benefit the success prospects of drug products. The immediate need for this technology may wane as the world recovers from the pandemic, but sponsors will and should continue to expect state-of-the art processes from their CDMO partners to continue this momentum.

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