




**VIRTUAL INSPECTIONS:
NAVIGATING THE
NEW PARADIGM**

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thermo scientific | applied biosystems | invitrogen | fisher scientific | unity lab services | patheon

**Our mission is to enable our customers to
make the world healthier, cleaner and safer**

75,000 employees	5,000 R&D scientists/engineers	\$1B invested in R&D	\$25B in revenues
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Thermo Fisher Organization — How the Viral Vector Services Business Fits In

Life Sciences	Analytical Instrument	Specialty Diagnostics	Customers Channels	Pharma Services
Genetic Sciences	Chemical Analysis	Microbiology	Research and Safety Market Division North America	Clinical Trials
Clinical Next Generation Sequencing	Chromatography and Mass Spectrometry	Anatomical Pathology	Research and Safety Market Division Europe	Drug Product Division, North America
Biosciences		Clinical Diagnostics		Drug Product Division, Europe
Life Sciences Solutions and Laboratory Products	Materials and Structural Analysis	ImmunoDiagnostics		Drug Substance Division and Biologics
BioProduction	Instrument and Enterprise Services	Healthcare Market		Softgel Products
Laboratory Products		Transplant Diagnostics		Viral Vector Services
Laboratory Chemicals				



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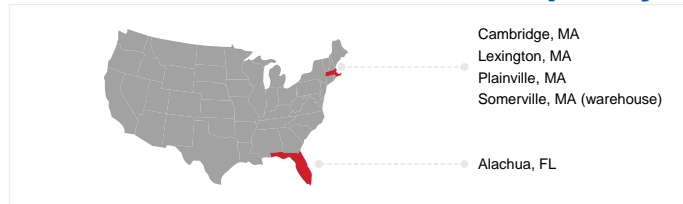
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Viral Vector Services: Unrivalled Track Record and Capacity

Experience

- 14+ years cGMP Track Record
- 60 Viral Vector Products Produced
- 150 Viral Vector cGMP Clinical and Commercial lots – 30+ lots each AAV and LV in last 12 months
- PLI and Commercial license expected in 2020



Technical Expertise

- 750+ team members
- ~100 PD / PS Scientists with >5 years average experience

Facilities

- 600,000 sq.ft.*
- 37 drug substance / 6 drug product suites
- Available capacity



> \$360M Invested in facilities / laboratories over the last 3 years



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Virtual Inspections: Navigating the New Paradigm

ISPE 2020

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Agenda

- 1 Current regulatory landscape
- 2 Virtual inspections: Advantages
- 3 Augmented reality technology for virtual inspections
- 4 Strategies to implement virtual inspections
- 5 Considerations



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Global Health Authorities Scale Back Onsite Inspections During Pandemic

FDA STATEMENT

Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections

“Importantly, during this interim period we’re evaluating additional ways to conduct our inspectional work that would not jeopardize public safety and protecting both the firms and the FDA staff. This can include, among other things, **evaluating records in lieu of conducting an onsite inspection** on an interim basis when travel is not permissible, when appropriate.”

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic>

EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINE. HEALTH.

Update to guidance on regulatory expectations in the context of COVID-19 pandemic

News 20/04/2020

“Current national and international safety measures and travel restrictions affect or prevent the conduct of onsite inspections related to good manufacturing (GMP) and distribution practice (GDP). The mitigation measures have been taken to ensure the continued availability of medicines while making sure that good practice standards are being adhered to. This is achieved through proportionate approaches to verification of standards by **enabling remote assessments** of compliance.”

<https://www.ema.europa.eu/en/news/update-guidance-regulatory-expectations-context-covid-19-pandemic>



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Virtual Inspections Enable Mission Critical Activities

Regulatory Focus™ News Articles > 2020 > 4 > Asia Regulatory Roundup: TGA begins virtual GMP inspections of domestic manufacturers

Asia Regulatory Roundup: TGA begins virtual GMP inspections of domestic manufacturers

Posted 28 April 2020 | By Nick Paul Taylor

“Performing a fully virtual assessment, using “agreed communication tools” and doing a desktop review of information to gauge the compliance of a site with GMPs...”

<https://www.raps.org/news-and-articles/news-articles/2020/4/asia-regulatory-roundup-tga-begins-virtual-gmp-ins>

FiercePharma

MANUFACTURING MARKETING PHARMA VACCINES COVID-19 SPECIAL REPORTS

Manufacturing

Indian pharmas call on FDA to perform 'virtual' facility checks during COVID-19 inspection lockdown

by Kyle Blankenship | Apr 30, 2020 6:09pm

“Major Indian pharmaceutical companies are asking the FDA to conduct ‘desk reviews’ or virtual facility inspections during the pandemic in order to ‘ensure the continuous supply of much-needed drugs in the United States’...”

<https://www.fiercepharma.com/manufacturing/indian-pharmas-call-fda-to-perform-virtual-facility-checks-during-covid-19-inspection>



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Virtual Inspections Option at Thermo Fisher Scientific VVS

Thermo Fisher Scientific Pharma Services Tech Ops developed the Mixed Reality (MR) platform

- This has allowed VVS to provide a virtual inspection option for both clients and regulatory health authorities
- Remote assessments are in line with FDA and EMA COVID-19 response plans
- Use of Microsoft Teams software
 - Review of quality documents in a SharePoint site via the Microsoft Teams software during the inspection
 - Video conferencing for discussion and review
- Real-time online video streaming tour of the GMP facilities using a 360° camera using Avatour software



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360° Camera With Avatour Software

- Real-time streaming video: 360° camera connected to a cell phone (or iPad) on an IV pole
- Allows remote Q&A and direction to the operators and remote viewers
- Adjustable viewing angles by remote VVS camera operator at inspector's direction



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Virtual Inspection Can Occur In All GMP Spaces



- 1** Progress 1 Warehouse, Office Building, QC Labs
- 2** BB2 Process Development Labs
- 3** BB1 Clinical Manufacturing



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Virtual Inspection Technology – Microsoft Hololens



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Virtual Inspection Technology – Matterport 3D Mapping

Matterport 3D mapping



Photo credit: www.matterport.com

- Great for showing facility layout
 - Collects accurate depth, data, and imagery
- Creates highly realistic virtual environment
- First-person POV
- Gives a 360° view of the space



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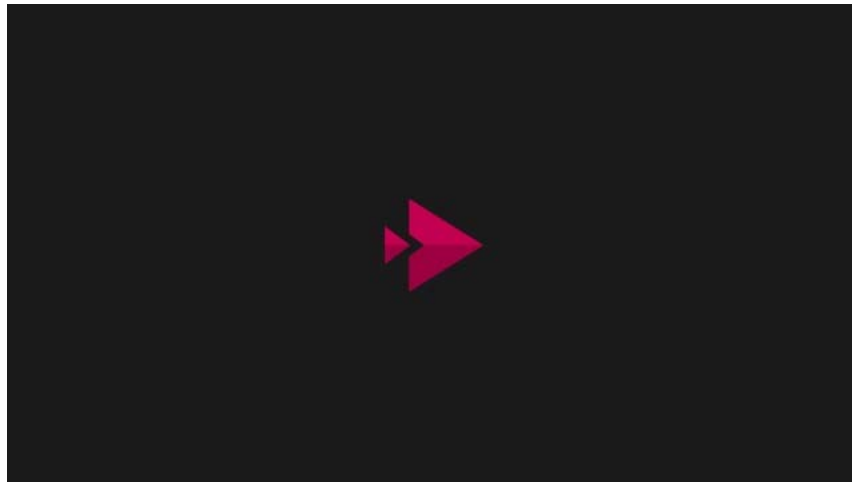
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Matterport 3D Mapping



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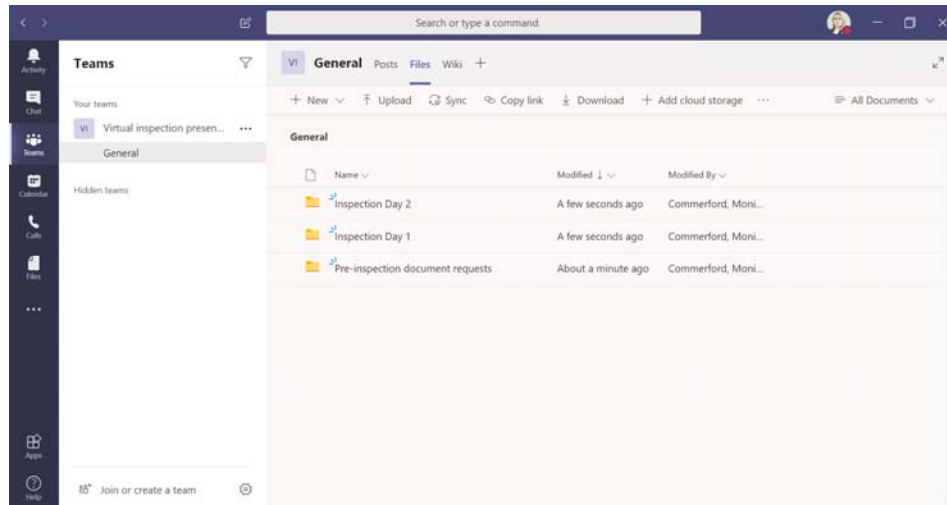
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Using Existing Software to Enhance the Virtual Inspection

Microsoft Teams



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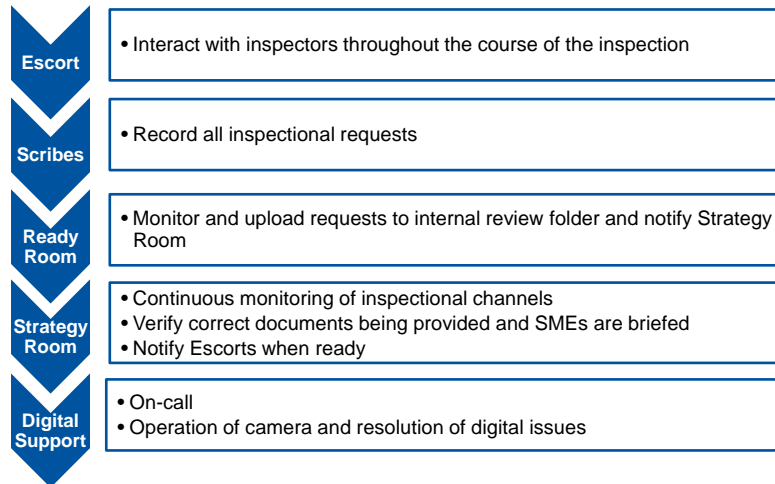
Strategies for Implementation

- 1 Inspection roles
- 2 IT and logistics requirements
- 3 Training
- 4 Pre-meeting with auditors/inspectors



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Inspection Roles are the Same as a Traditional Onsite Inspection



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Ensuring a Smooth Experience: Requirements

IT requirements

- Wireless access point data mapping
 - To understand the signal strength in all rooms in the facility
 - Determine whether equipment is insulated against microwave cell phone signals (older equipment may not be)
 - VVS has a long history of using cell phone communication devices in sealed bags (little risk for VVS)
 - **Recommendation:** Use cell phone during non-operational periods (i.e. power outage)
- 360° camera and Avatour software
 - **Recommendation:** Have multiple cameras (3 – 4) ready and placed throughout the facility (and don't forget the extra batteries)
 - Cameras can be staged ahead of time to reduce cleaning and transition times during the inspection
 - Reduces cross-contamination risk
- Using 5G LTE
 - Associate a 5G puck for use throughout the facility

Logistics

- Evaluating cleaning of camera, stand, and equipment
- Providing an understanding between the host and inspector that this is a live inspection and a live tour
 - No recordings or screenshots (unless this is a regulatory agency)
- Preparing the tour route and site map



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Training for a Virtual Inspection

What does training look like in a virtual environment?

- Training on the platform and software prior to inspection
 - Helps teams to understand platform
 - Practice using the software (e.g. Microsoft Teams) for uploading documents, etc.
 - Increases understanding of inspection rules and responsibilities
- Perform a mock virtual inspection with your teams
 - Checks audio and visual quality
 - Allows for resolution of digital issues prior to inspection
- Tackles any technical issues prior to the inspection
 - Can files be accessed?
 - Are there any technical issues with the software?
 - Helps to ensure the additional layers of security are in place



Photo credit: www.sessionlab.com/blog/train-the-trainer/



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Consider Holding a Pre-meeting with the Regulatory Inspectors

- Builds credibility for working within the platform
- Chance for inspectors and hosts to meet ahead of time
 - Builds to establish a rapport and inspection environment
- Advantages to holding a pre-meeting:
 - Help to build trust and credibility in the platform and in your ability to use the platform
- Pre-meeting requests
 - Can be discussed and the file directory can be shown
- Agreements and schedules can be discussed ahead of time
 - Naming convention for file directories
 - How to handle follow-up questions



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Traditional Onsite Inspections Versus Virtual Inspections

	Traditional onsite inspections	Virtual inspections
Advantages	<ul style="list-style-type: none"> Faster paced than a virtual inspection Typically inspection duration is over a period of consecutive days Instant communication and discussion 	<ul style="list-style-type: none"> Decreased travel time and costs Enables business continuity during challenging times Similar "total" time as a traditional inspection Provides a chance to meet prior to the start of the inspection Option for non-consecutive inspection days Inspectors can "work on their own time" to review documents outside of the inspection Typically stays on task and schedule Increased verbal communication between site and inspectors SMEs from multiple sites can participate <ul style="list-style-type: none"> Available online and in real-time during tours Virtual inspection can occur in <u>all</u> GMP spaces
Disadvantages	<ul style="list-style-type: none"> Increased travel time and costs Can get behind or off schedule Site personnel often work beyond business hours SMEs may potentially need to travel onsite 	<ul style="list-style-type: none"> Daily lists of questions are provided to the site Lack of body language and context Tours may take longer than expected Additional preparation associated with training



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Considerations

Virtual inspections:

- Use cutting edge technology to provide a unique inspectional experience
- Provides many advantages over traditional onsite inspections
- Can be seamlessly incorporated into standard operations

Future considerations

- Virtual inspections have the ability to revolutionize the inspection experience
 - Allows for business continuity during a pandemic (or even during day-to-day activities)

"This has been a new thing for us and has been a positive experience...you may not realize it, but I have this on a bigger screen, and the audit is almost life-size!"

EMA inspector



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Mixed Reality as a Strategic Automation Opportunity



Engage-Vision

Make it easy for employees to be successful



Educate-People

Enhance the operator's ability to execute by providing tools that ensure performance



Enable-Performance

Reduce risk associated with human error from complex, incomplete or unclear process steps

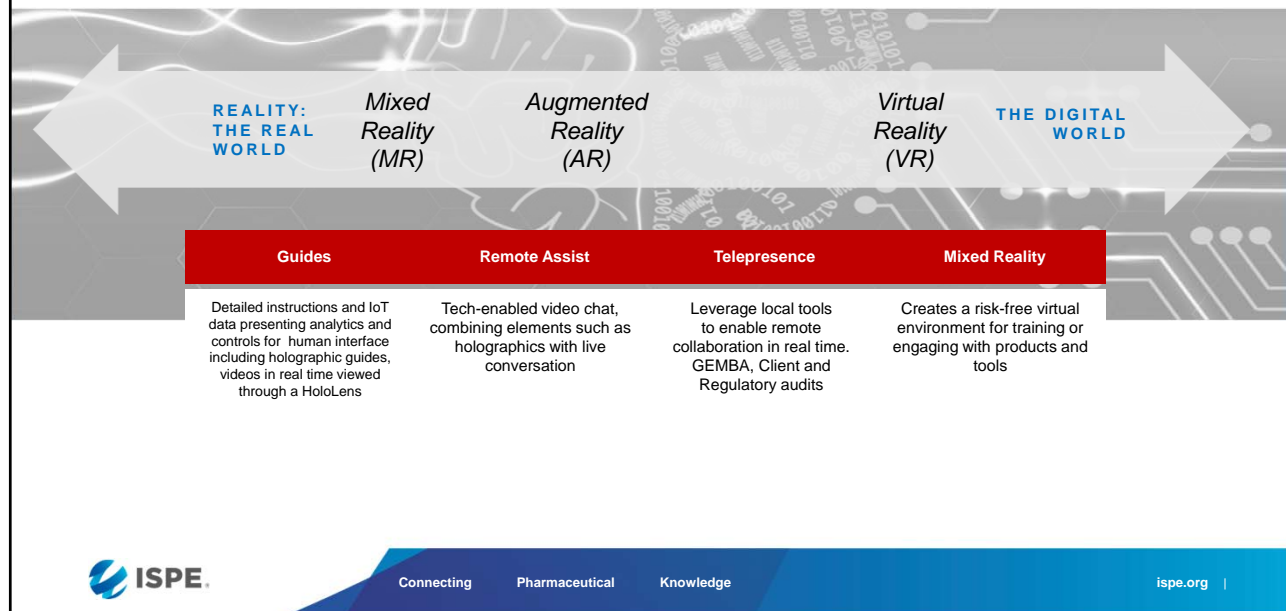


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Mixed Reality as a Digital Enabler



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