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VIRTUAL UTILIZATION IN THE PHARMA/BIOTECH INDUSTRY

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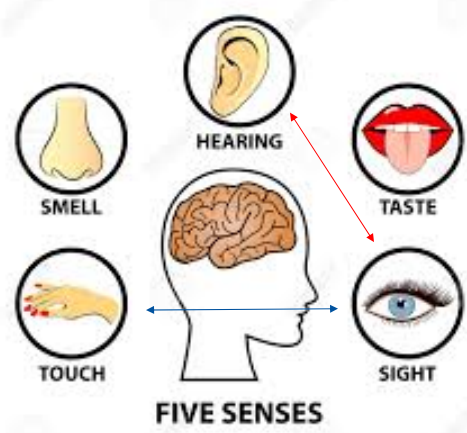


REMOTE SOLUTIONS FOR:

- 1) Training
- 2) Factory Acceptance Testing (FAT)
- 3) Auditing



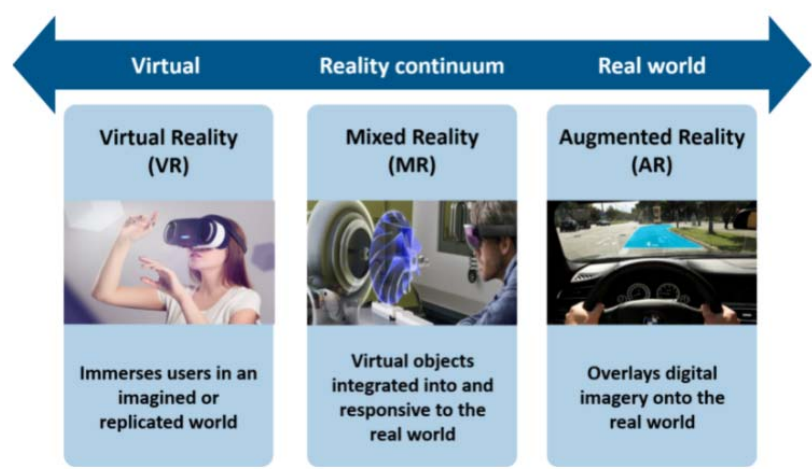
Five Senses of Communication:



- 2-Dimension to 3-Dimension



VR / MR / AR:



SOURCE: THE DELTA PERSPECTIVE, JANUARY 2018



Virtualization Tools:

	VR	AR/MR
PC	 VIVE	 CINOPTICS
Standalone	 oculus	 magic leap
Smartphone	 SAMSUNG Gear VR	 IKEA

Source: IDTechEx Research, "Augmented, Mixed and Virtual Reality 2020-2030: Forecasts, Markets and Technologies". For more information please visit www.IDTechEx.com/ARVR (PRNewstfoto/IDTechEx)




INTERACTIVE REMOTE SOLUTIONS FOR SKILLS TRAINING

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PRESIDENT, ADVANCED TOOLS
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ISPE Boston Chapter
June 23, 2021



PROS	CONS
<ul style="list-style-type: none"> • Can be used for new hires, annual training, cross-training etc. • Safe and controlled experiential learning environment • Learning-by-doing through authentic workplace activities • Safe troubleshooting skills training and learning from mistakes • Wide range of training and educational applications • High ROI due to scalability, adaptivity and reusability • Instant feedback/performance support • Scheduling flexibility • No need for expensive equipment and materials (can act as training sandbox) • No cost for travel/accommodations • Multilingual support 	<ul style="list-style-type: none"> • High Up-Front Cost • Lack of the real-time in-person interaction and teamwork spirit • Not always possible to completely emulate real-life situations. • Time and effort needed for preparing instructors to efficiently use training software and hardware • Not very useful for soft skills training. Some topics are open to interpretation • May require expensive AR smart glasses or VR headsets, as well as regular technical updates to keep pace with newest technologies • Possible physical side effects when using VR




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Process Flow Simulation

Virtual Labs allow learners to conduct authentic experiments and workplace tasks online, using highly accurate simulations (*digital twins*) of actual laboratory and industrial scale equipment.

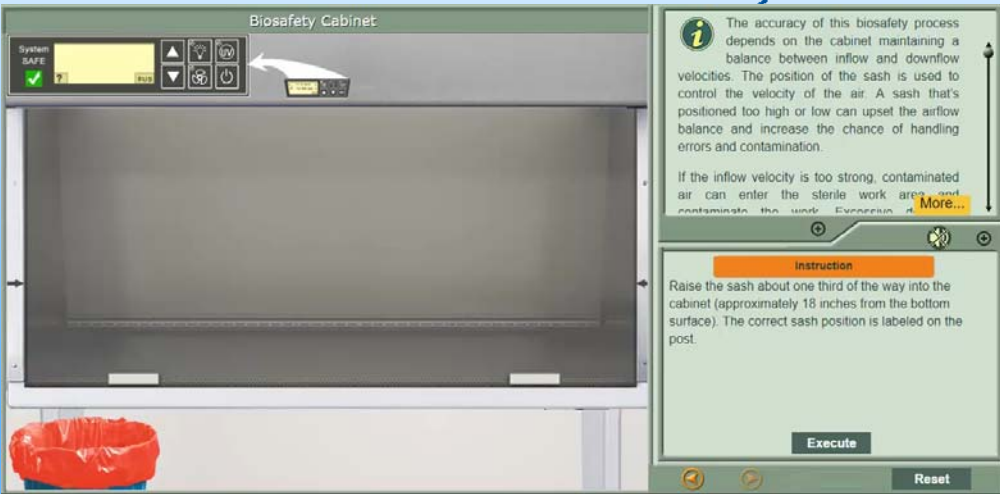
Self-guided online assignments facilitate skill development and knowledge acquisition by providing "just-in-time" contextual learning opportunities.



Training simulation

V-Labs include an intelligent tutoring mechanism that monitor learner performance and keep them on the right track.

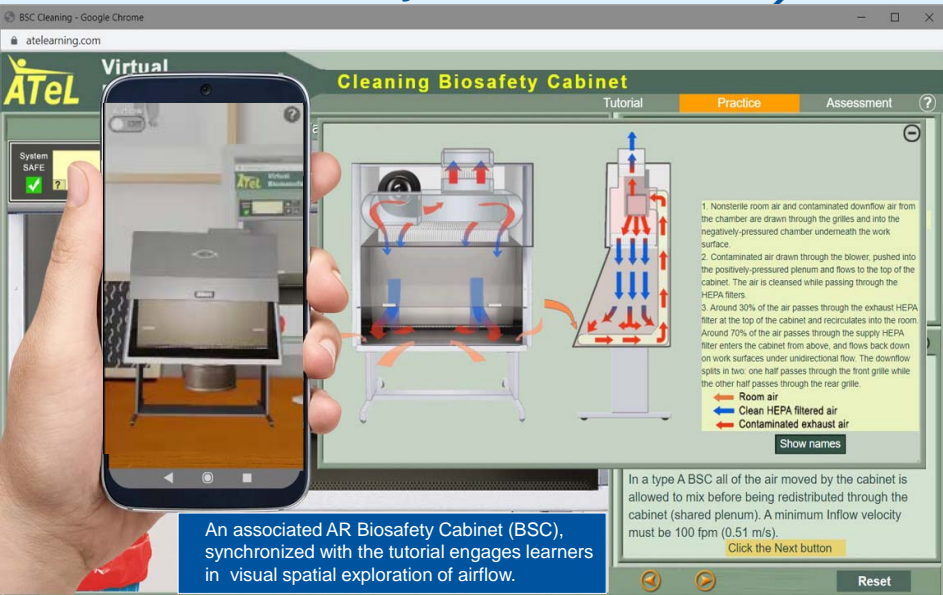
A smart instructor avatar provides instant feedback and helpful tips, when necessary.



AR embedded into a virtual laboratory

Interactive Mixed Reality (Virtual Labs + Augmented Reality (AR) and Virtual Reality (VR) is an engaging and motivational educational tool for today's Digital Natives.

AR visualizes processes and objects enabling a user to better understand operational principles of systems and devices.



An associated AR Biosafety Cabinet (BSC), synchronized with the tutorial engages learners in visual spatial exploration of airflow.

AR Connections and Synchronization with Digital and Physical Equipment

Processes simulated and executed in virtual labs can be connected and synchronization with AR objects running on smartphones or tablets of local and remote participants.



AR and Digital Equipment for pre-Training and Troubleshooting

Instant micro-practicing:

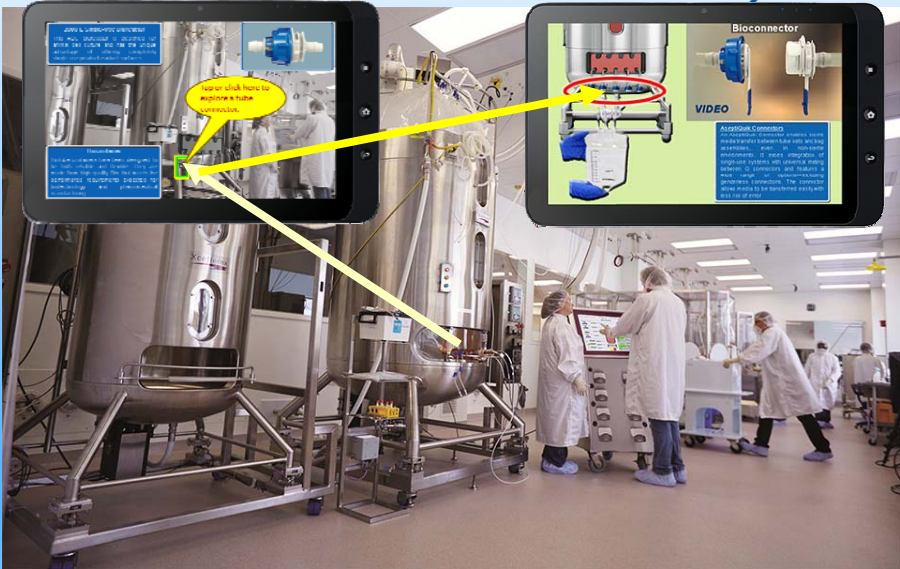
Mastering performing particular procedures **prior** to executing them during an actual workplace task.

Troubleshooting:

Playing various troubleshooting scenarios in a virtual environment allows personnel to choose the best solution to be implemented.

AR Remote Assistance

allows experts and instructors to provide real-time remote assistance via voice and video.



Connections and Synchronization Digital and Physical Equipment

Connected and synchronized digital and physical equipment help users become comfortable with system controls and operation.

Virtual Dashboard can link with and control the digital Production Line

Processes occurring within the bioreactor can be simulated and visualized for exploration and analysis.

REMOTE SOLUTIONS FOR FACTORY ACCEPTANCE TESTING (FAT)

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ISPE BOSTON CHAPTER
JUNE 23, 2021



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Pros

- No quarantining / travel restrictions
- No close contact between FAT team members from different organizations
- Cost savings on travel



Cons

- Safety considerations
- Additional operator to film testing
- Typically done in shops and may be hard to hear
- Time zones can cause schedule challenges
- Often need to involve IT to ensure viable connection and no unwanted feedback
- Hardware / software needed to show multiple web cam, video, IP camera, and streaming video feeds.



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Considerations

- Documentation practices
- QA buy-in if using results for qualification (understanding of client CQV approach)
- Data Integrity



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Virtual tools to optimize success:

- Noise cancelling Bluetooth headsets for mobility and sound quality
- Execute in 2 parts: Installation verification activities and functional testing
- Remote 3 screen setup: feeds from machine, HMI, and test case being executed.
- Factory site: One operator with mobile video to show test case being performed, stationary video of HMI, and one operator for execution

Collaboration tools:

- MS Teams
- Dropbox / Box / OneDrive
- WhatsApp, Facetime, Teams Video, GoTo Meeting, private YouTube channels, GoPro, Zoom



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Lessons Learned

- Safety – activities being directed remotely, executed locally
- Setting up roles, responsibilities, and schedule ahead of time avoids confusion and frustration during FAT & minimizes wait time
- Pre-FAT is critical. Ensure everyone can login/log on and all video and audio systems are working
- Other critical prep work: share manual, screen shots, schematics, I/O checks, safeties (use collaborative platform)
- Some typical FAT requirements are more appropriate in SAT (seal integrity testing, cosmetic appearance)
- Remote FAT typically takes more time than an in-person FAT, and requires more people



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REMOTE SOLUTIONS FOR AUDITING

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Remote Audit

- Virtual Audits for thirds party are viable alternatives- Specifically for raw materials vendors and second time Audit visits. A Risk based approach tools would be beneficial.
- IT support and technology challenges exists.
- It is not recommended for first time CMOs and CROs.
- Allow auditors to get use to the new platform
- Third party template can be utilized as a checklist to stay organized



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Pros of Remote Audits

- Requested documentation can be viewed any time for the duration of the Audit, even after audit hours- Allow to inspector to work on their own time
- Availability of site being audited can be quicker due to remote access, Availability of SME from Multiple sites
- Sites may be willing to allow additional personnel during the Audit
- Decrease Travel Time
- Enables business continuity during challenging times
- Option for Non-consecutive inspection days- If sites agree



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Cons of Remote Audits

- Slower Paced than onsite inspection.
- Can not see Body language;
- Virtual Tour is not allowed, or it's censored. Sites can control the narrative of the audits, facility presentation and on the floor staff conversations/Interactions
- In some cases, Daily list of question are provided to the site- Time consuming and lack spontaneity.
- Time zone differences for different counties and language barriers.
- Not Ideal for complex Validation and equipment audits documentations, unless the validation utilizes an electronic protocols
- Duration of document availability varies.
- Operator Fatigue should be considered due to using a monitor for prolong amount of time.



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Common tools utilized during an Audit:

- Emails
- Checklist
- Zoom meetings
- Smart Glasses
- SharePoint to upload needed documents
- Spreadsheet to communicate request and capture responses



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Smart Glasses

- Meets Annex 1 requirement to allow auditors to observe the facility without viewing windows
- Perform Gemba in the event of incidents
- Vendor Troubleshooting
- Future electronic batch records, Video SOPs and Augmented Reality for training
- Access information quicker
- Allow SMEs and Manager to oversee multiple facilities



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PANEL DISCUSSION &
QUESTIONS



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Vs NEW YORK RED BULLS
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PRIDE NIGHT

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game over at the stadium!

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