



LIVEWORX

A NEW ERA IN PRODUCT LIFECYCLE INNOVATION

SESSION ID: AR1545B

Improve Pharmaceutical Manufacturing Quality with Augmented Reality

SPEAKER(s): Rene Zoelfl

Global Advisor Life Science, PTC

David Blewitt

VP of Cloud Compliance, USDM Life Sciences

May 17, 2023

LIVEWORX.COM | #LIVEWORX



Macro Forces Impacting the Pharma Industry

Complexity & Regulatory Burdens



Average of 1250 cGMP required SOPs and average maintenance burden of 15,000 hrs./ firm.



Skilled Worker Shortage



Skilled worker shortage and pressure to keep current workers' skills up to become more flexible and competitive.



Cost and Risk



Stringent sterile environments makes production extremely susceptible to human error and contamination.



Sustainability



91+ pharmaceutical, biotech and Life Science companies, committed to zero carbon dioxide emissions by 2050.



The **Business Impact** of Errors is Significant



of *product yield is scrapped* due to inefficiencies and errors during line clearance



loss in revenue from shutting down operations due to batch contamination

Current Training Leads to Execution Issues

“

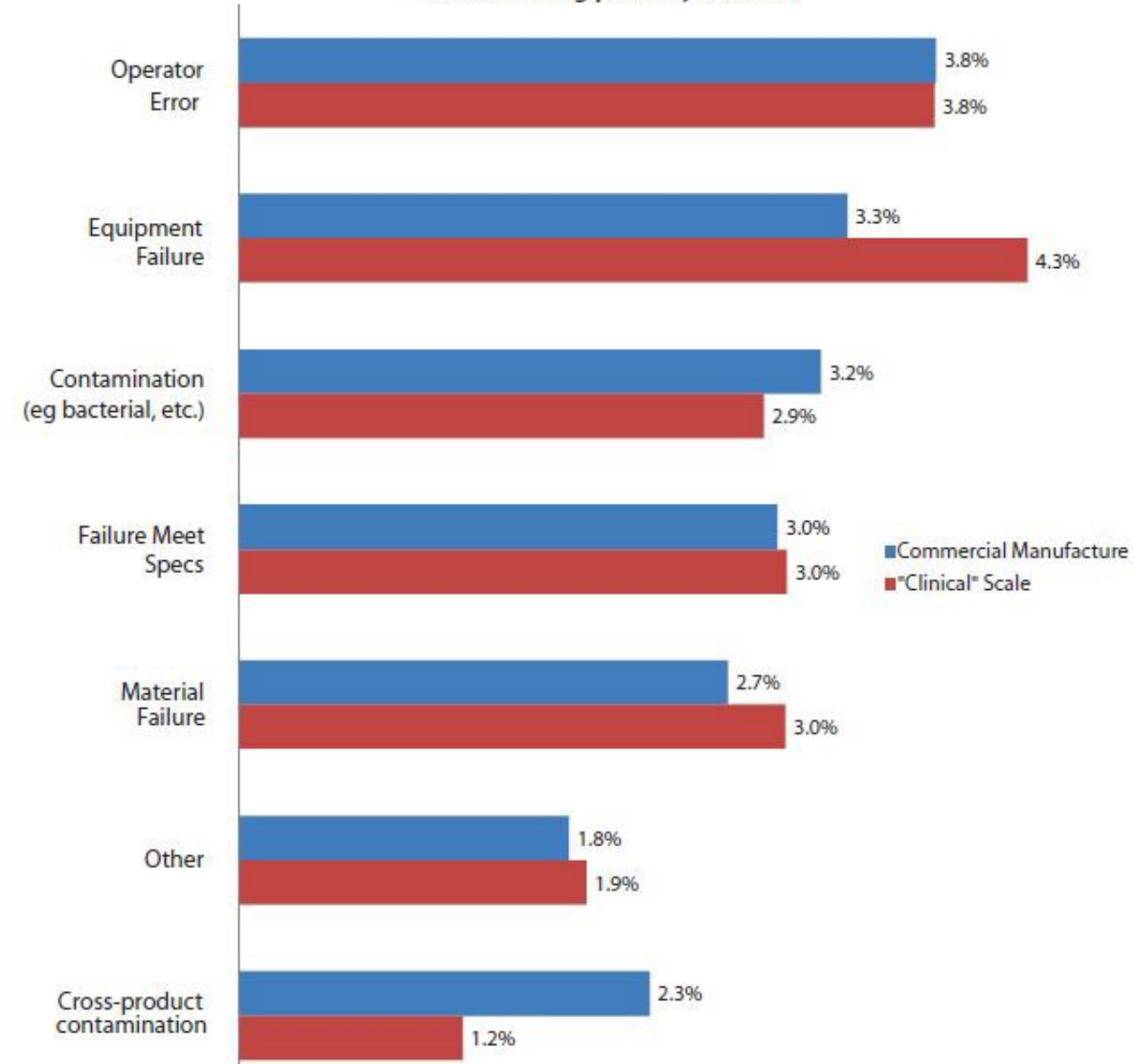
How do we reduce human error, human variability, and human ability to do complex tasks in complex environments in a much more efficient way?”

MFG Innovation Leader,
Global Pharmaceutical Company

Source: <https://www.bioprocessonline.com/doc/bioprocessing-sees-continued-improvements-in-batch-failure-reductions-in-0001>

**Batch Loss Primary Causes
by Scale of Manufacture, 2022**

"About what percentage of batches at your facility are lost annually to each of the following primary causes:"



Vuforia AR Helps Address these Challenges

- On-demand, visual AR guidance enables operators to **execute work properly the first time.**
- Interactive AR training **boosts knowledge retention & speeds time to productivity.**
- Streamlined knowledge capture & SOP creation helps **retain valuable tacit knowledge.**
- Standardized AR instructions **reduce complexity to improve safety and compliance.**



Delivering Business Value for Pharma

Efficiency – Effectiveness - Compliance

Right -First Time Quality Improvement

 **90%**

- Minimize human errors
- Decrease scrap and rework
- Reduce complexity of standard operating procedures

Production Processes Optimization

 **30%**

- Increase workforce efficiency and reduce costs
- Accelerate time-to-market
- Improve compliance and continuous improvement

Time and Cost to Competency Reduced

 **50%**

- Improve knowledge capture & transfer
- Increase engagement and knowledge retention
- Reduce time to productivity

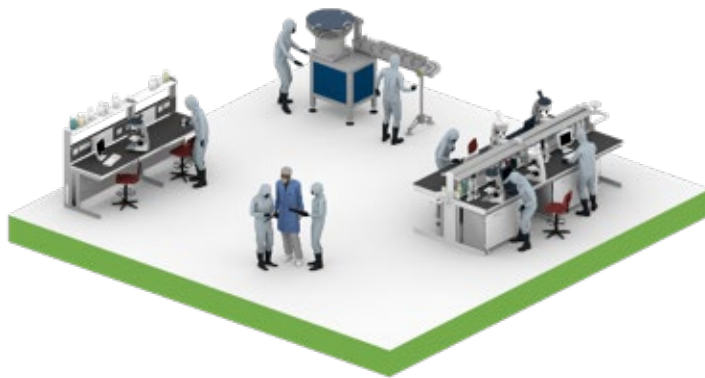
AR Enables Key Use Cases Along The Pharma Lifecycle

Discovery

Commercialization

Scaled Operations

Laboratory Execution



- Laboratory Testing
- Instructions for Complex Operations

Manufacturing Efficiency

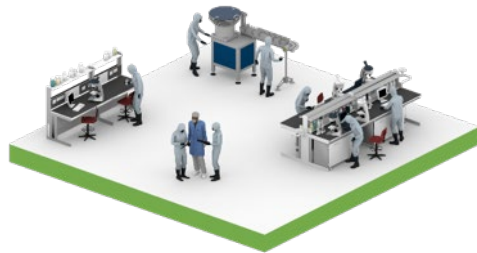


- Training and Onboarding
- Line Clearance Instructions
- Complex Equipment Set-up & Installation
- Change-Over Instructions
- Operator Instructions
- Maintenance Operations / Instructions

AR Supports Key Pharma Value Drivers

Eliminate Errors

Commercialization



Each time an operation occurs, contamination risk and single-use consumables have high cost of errors.

Expedite Standard Operations

Scaled Operations



Scaled, standardd work practices reduce downtime and scrap. Improve quality, throughput and drive revenue.

Accelerate Training

All stages



Training is time consuming. Company resources better utilized in full-impact, production work.

2019/2020 without AR

2021 with AR

Total Experiments

84

100

% Errors due to Human Error

38%

0%

Hours Spent on Rework

~100 Hrs

0 Hrs

Cost of Failures and Rework

~\$200K

\$0K

Customer Story

Global Pharma
Company

Source: Customer proprietary data

Eliminate Errors

CHALLENGE:

- Operations are complex and difficult to get right.
- Contamination risk and single-use consumables make the cost of errors significant.
- Experts' time was being spent on training.

SOLUTION:

- Using **Vuforia Expert Capture** they recorded batch setups with step-by-step, first-person views, including narratives.
- Moved from typing and text to “make it look like this.”

RESULTS:

- Errors reduced to **zero**
- Their capacity to do experiments increased
- Critical resources were freed up to focus on high-value tasks



Customer Story

Global Pharma
Company

Source: Customer analysis data

Expedite Standard Operations

CHALLENGE:

- Line clearance can be long, complex, and difficult to complete – the biggest drag on scrap & compliance.
- Paper-based SOPs ended with scrapping **10%** of their product yield while executing slower and with room for improvement.

SOLUTION:

Using PTC's **Vuforia Expert Capture** AR solution to improve training and standardize the digitization of complex manual processes during line clearance.

RESULTS:

- Operating procedures at the right place, at the right time, on the right device
- Reduce errors and operating costs, and improve productivity
- The potential cost savings are estimated at \$27M per factory

Compliance Partnership



USDM Partnership

- Over a decade addressing GxP challenges together
- Assessment included design, development, testing, qualification, and maintenance
- Assessment based on USDM's Compliance Matrix that satisfies 34 global health authorities and 6,500+ regulatory requirements
- Results published in Vendor Assurance Report (VAR)



Vendor Certification

- Vuforia achieved its Cloud Assurance Certification
- Badge of trust for life sciences GxP use
- VAR utilized a true risk-based CSA methodology and minimizes validation burdens
- VAR is leverageable as objective regulatory evidence



Cloud Assurance

- Vuforia is bundled with USDM's Cloud Assurance managed service
- Reduces compliance risk by leveraging USDM domain experience, accelerators for Vuforia, and automated testing
- Delivers continuous compliance and offloads GxP qualification

Without AR you miss the **opportunity** of...

Reducing Operator Error



.damaging equipment and production resulting in high costs

Avoiding Contamination



.damaging production batches and risking patient safety

Attracting New People



.expecting modern technology at their workplace



QUESTIONS?

Thank you! You can find me at:



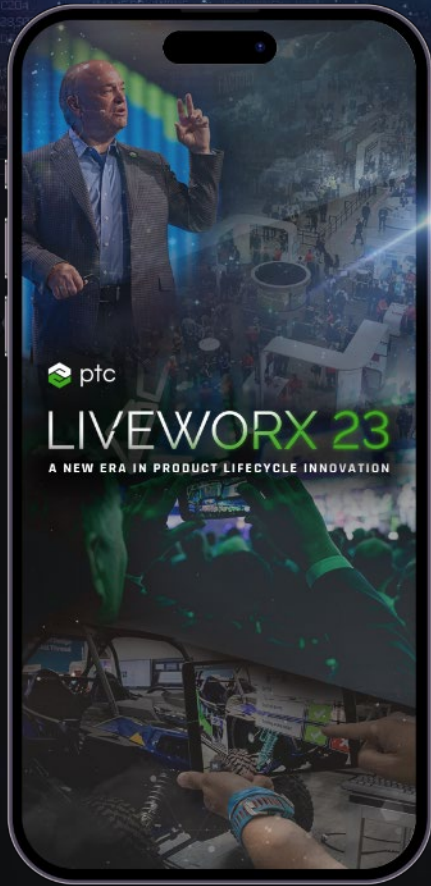
rzoe1fl@ptc.com



[@rzoe1fl](https://twitter.com/rzoe1fl)



<https://www.linkedin.com/in/renezoe1fl>



Please fill out the session survey.

Take your post-session survey(s) either in the event mobile app or via email post-event.

Your feedback provides us with valuable information on how to shape future content strategy for the event!

PROVIDE SESSION FEEDBACK



LIVEWORX

A NEW ERA IN PRODUCT LIFECYCLE INNOVATION

THANK YOU

LIVEWORX.COM | [#LIVEWORX](https://twitter.com/LIVEWORX)

ptc.com

