



Augmented reality in Process Execution

Opportunities and challenges of digitization in everyday working life



GOODLY INNOVATIONS: WHERE LEAN MEETS PHARMA 4.0

We enable next level lean improvements to boost productivity and quality of Pharma manufacturing and packaging processes and beyond.

We transform manufacturing workflows with smart digital solutions.

TRUSTED PARTNER TO THE PHARMA INDUSTRY FOR NEXT LEVEL DIGITAL LEAN



We believe in augmented reality and its power to **drive efficiency** and **productivity**. We enable **next level Lean** improvements to pharma manufacturing by providing a system that **amplifies a team's potential**.



Focused on Life Sciences Industries

Founded 2017 by industry experts with a pharma purpose
Co-founded by former AstraZeneca VP Lean, Global Operations



Partnering with 6 of the top 20 Pharma

Installed in 7 countries world-wide



Award Winning Technology

Pharma 4.0 MES Innovation Award 2019
Top 10 Pharma Industry Trends 2021 by StartUS

GxP is our DNA

#1

FOCUS ON
PHARMA &
COMPLIANCE

#2

MULTI-USER &
MULTI-DEVICE
SOLUTION

#3

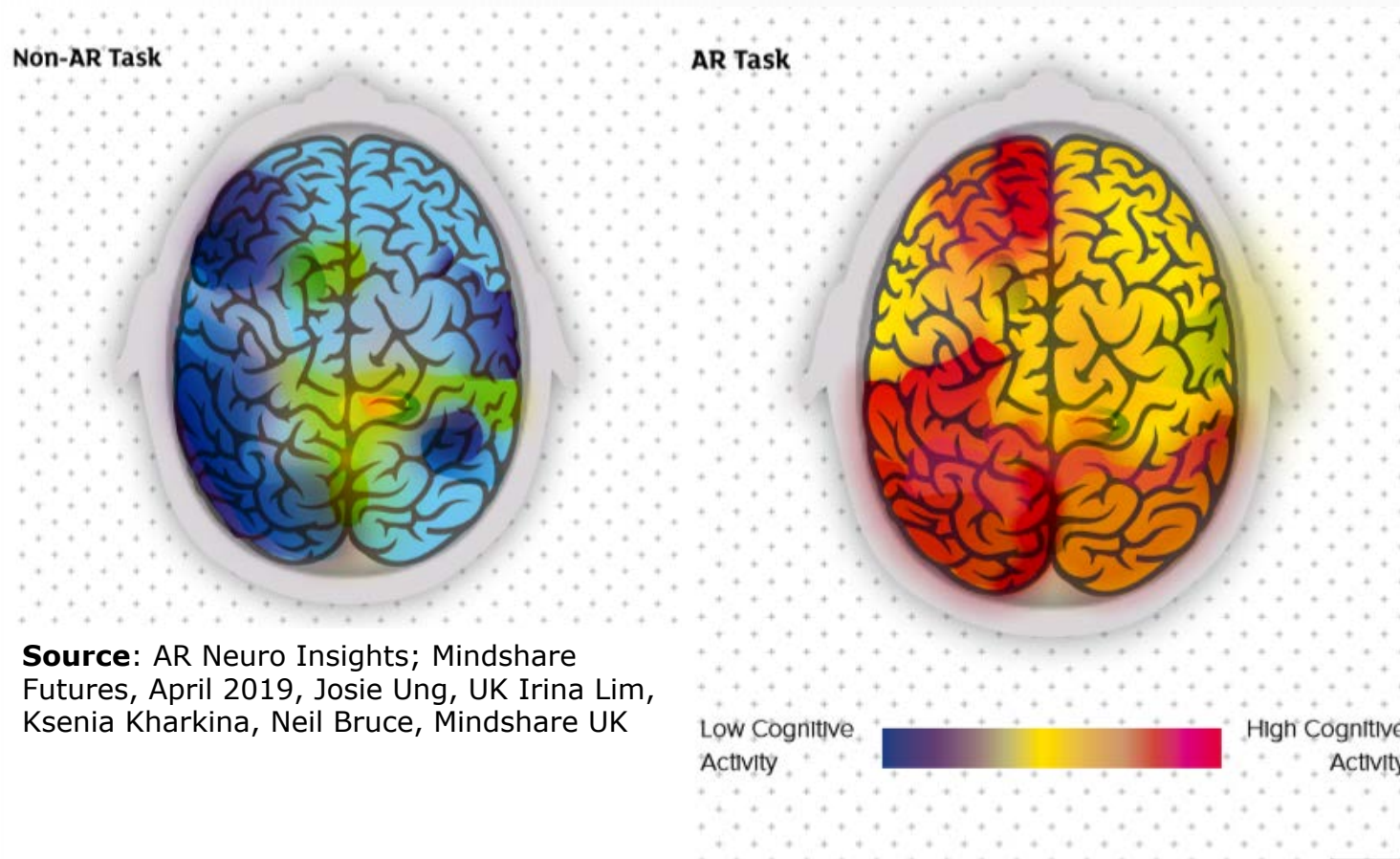
Examples







WHY AR? THE COGNITIVE BENEFITS



Source: AR Neuro Insights; Mindshare Futures, April 2019, Josie Ung, UK Irina Lim, Ksenia Kharkina, Neil Bruce, Mindshare UK

Neuro-Insight, an international neuroanalytics company's study researched brain response to many different media, and the study has shown that AR delivers exceptionally high attention levels of cognitive activity: 45% higher than the average media. (e.g. online reading or watching Video tutorials)

PRODUCTIVITY CHALLENGES

- Complex manual processes
- Decreasing batch sizes
- Paper-based documentation efforts
- Extensive Operator training & qualification
- Workforce mobility & turnover

XR SOLUTIONS

- Augmented Reality Work Instructions
- Automated documentation in EBRs
- Remote Assistance
- Virtual Reality Training



CHANGEOVER & LINE CLEARANCE



Increased Productivity

Multiple manufacturers report significant reduction in change-over times with values between 27% and 45%



Higher Training Effectivity

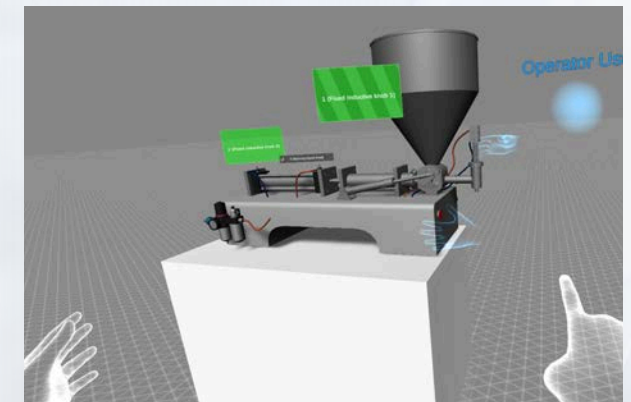
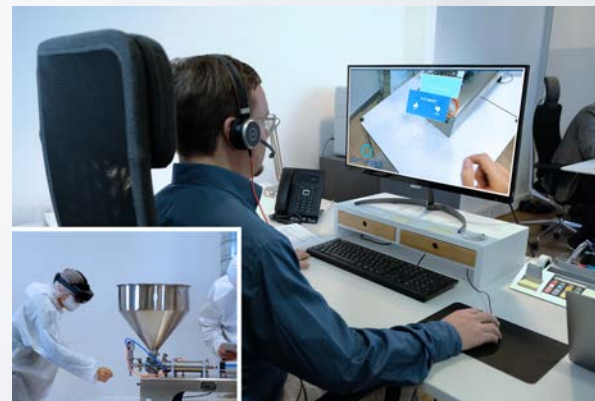
Multiple companies experience benefits for new employees with regards to accuracy (increased right-first-time) and performance (execution time)

ASEPTIC FILLING

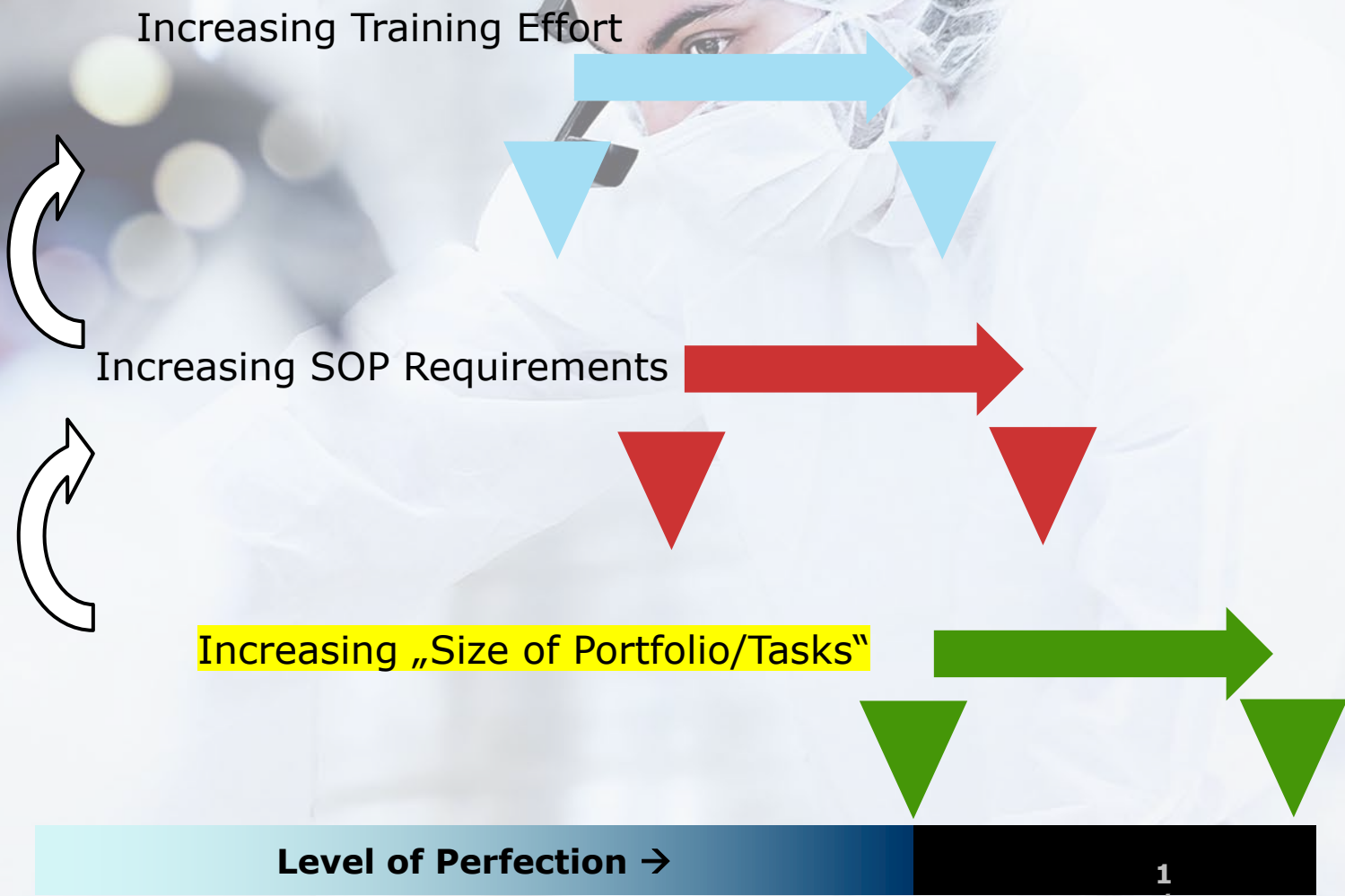


Increased Process Quality

A manufacturer reports significant reductions of deviations leading to savings in decontamination efforts



Perfection: Moving Target



Perfection – what happens if it is not fulfilled



Augmented Reality and Training – a good combination



AR-System



Training



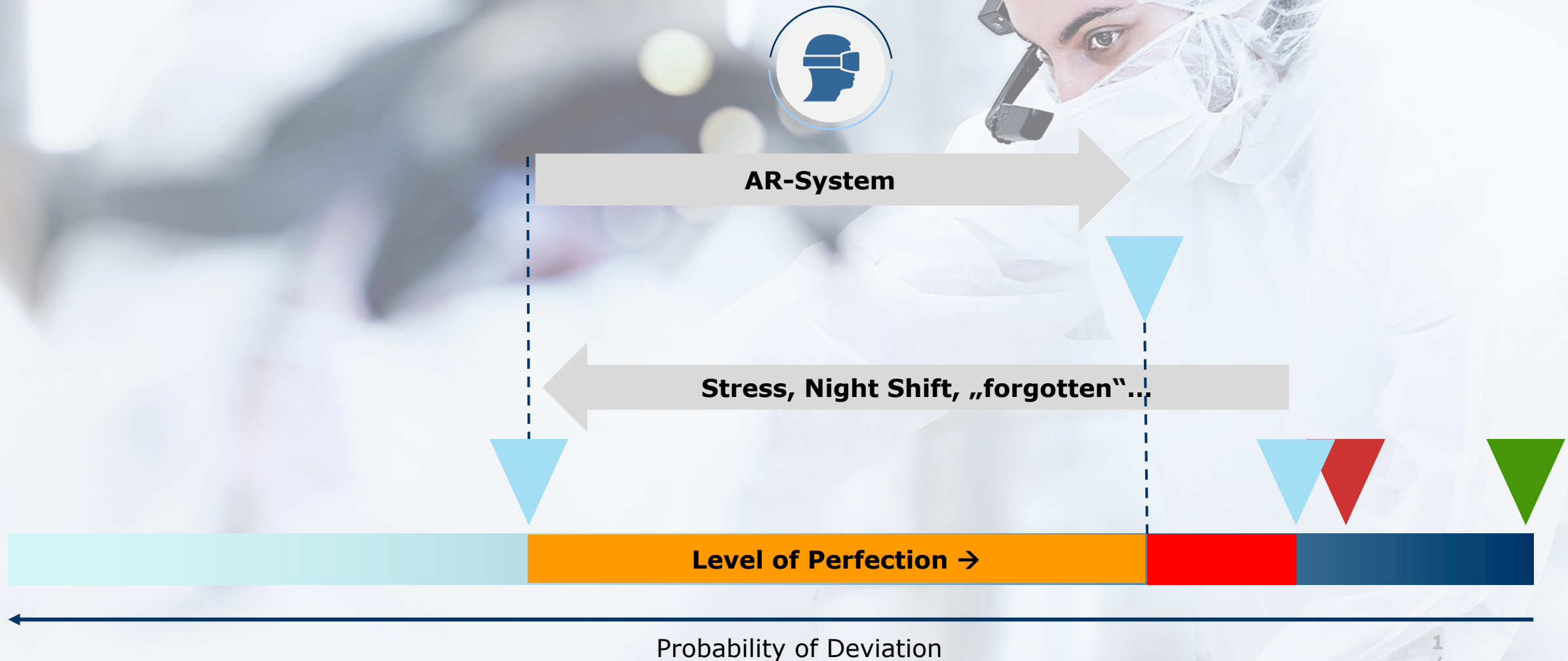
SOP

**Absolute
Perfection**

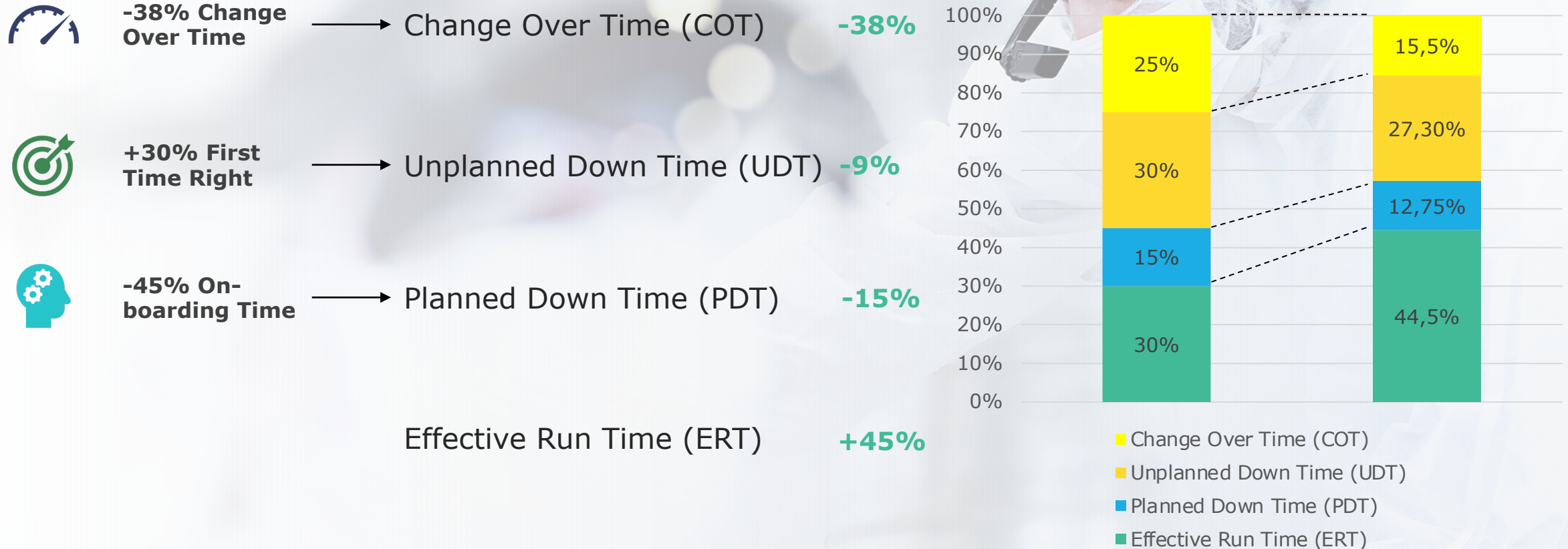
Employee
Know-How and
Behaviour

Level of Perfection →

Augmented Reality – keeps your Level of Perfection



QUANTIFYING THE ECONOMIC IMPACT OF XR WORKER GUIDANCE



Assumptions:

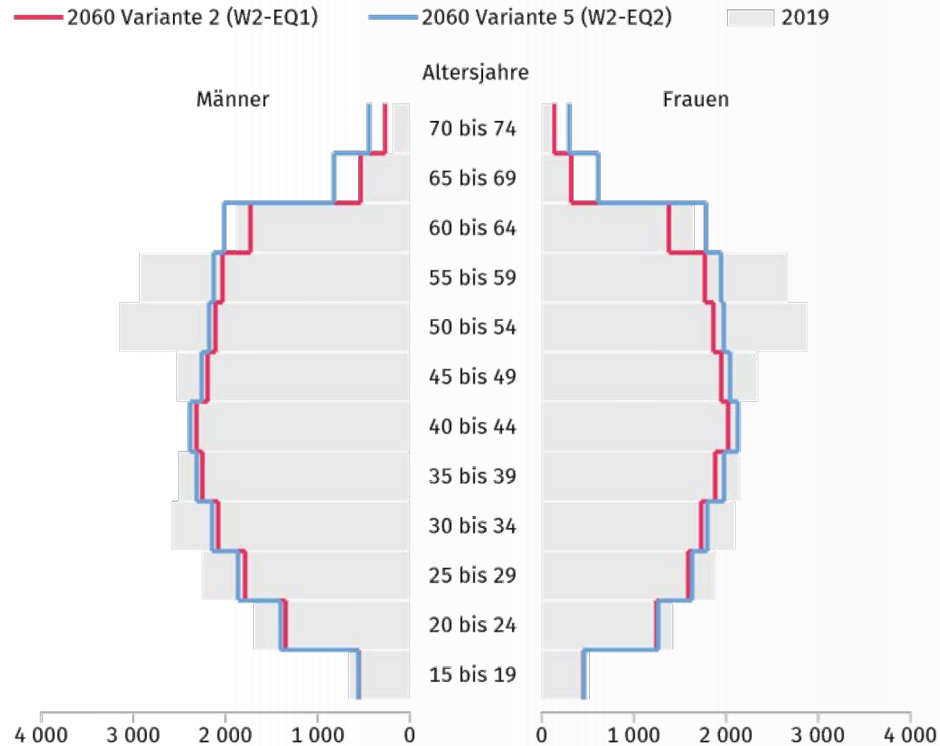
- 30% of UDT are related to change-over errors
- 1/3 of PDT are for Operator Training

*Pharmaceutical Packaging Productivity: Industry benchmarks and a proven process to deliver TOPtier Performance by Stephen Watt (Author, Illustrator), Tim Mantle (Author)

HOW TO HANDLE KNOWLEDGE TRANSFER – FROM A WHOLE GENERATION – IN 15 YEARS

Altersaufbau der Erwerbspersonen 2019 und 2060

Tausend Personen



Erwerbspersonen in Privathaushalten.

2019: Ergebnisse des Mikrozensus.

2060: Ergebnisse der Erwerbspersonenvorausberechnung.

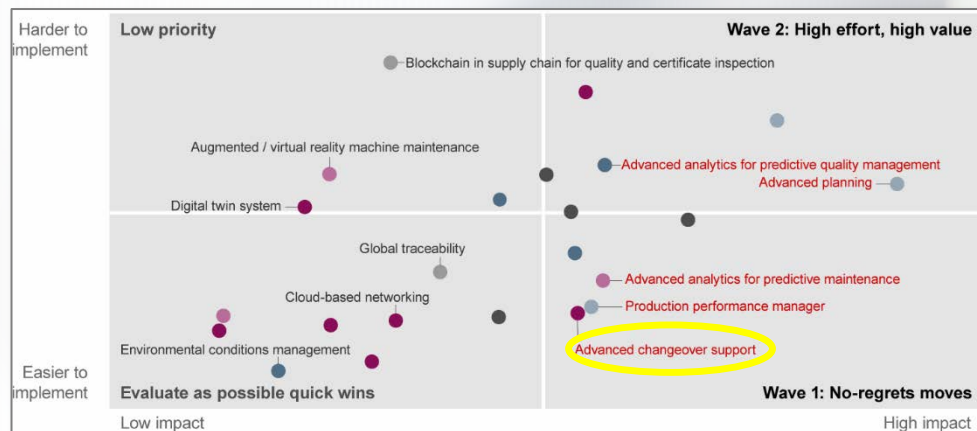
Variante 2: Moderate Wanderung bei konstanten Erwerbsquoten.

Variante 5: Moderate Wanderung bei steigenden Erwerbsquoten.

© Statistisches Bundesamt (Destatis), 2020

- By 2030 the “Baby Boomers” will retire from the workforce
- Major trends like remote work even reduce the human resources for lab- & operations staff
- Millennials and following generations have a very different perception on life, work and technology

FOR ENTERPRISE USE CASES – THE RAPID TIME TO VALUE MAKES AR A “NO-REGRETS”



“When teams on the shop floor reconfigure machinery to produce different products, they need to move rapidly to reduce manufacturing downtime. Advanced changeover support guides workers during that process. **Augmented Reality glasses [...] help operators follow a defined procedure to make changes as quickly as possible.**”

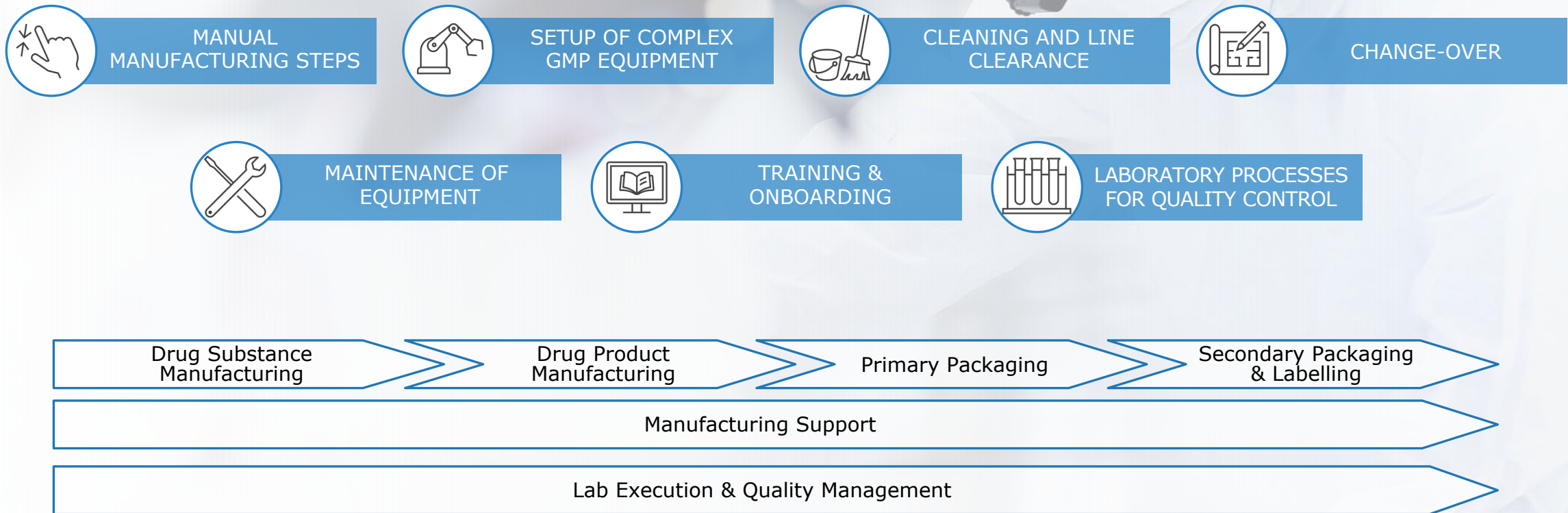
Source: Bain & Company Pharma 4.0 Survey 2020



“Accelerated adoption for quick-win solutions that help companies respond and adapt to the new norms—such as tracking employee health, enforcing safe distancing on the shop floor, and supporting remote collaboration. **Digital work instructions, augmented reality-based operator assistance**, and use-cases relying on simple, inexpensive retrofit automation may also **become more widespread regardless of companies’ existing technology infrastructure.**”

Source: McKinsey Industry 4.0: Reimagining manufacturing operations after COVID 19, 2020

AR PROCESS GUIDANCE USE CASES ALONG THE PHARMA VALUE CHAIN



AR PROCESS GUIDANCE USE CASES ALONG THE PHARMA VALUE CHAIN



CLEANING AND LINE CLEARANCE

Receive spatial guidance to hot-spots that need to be checked during line clearance. Thereby not missing out. Document clearance hands-free & mobile with AR. Work together with a colleague flexibly to have 4-eye confirmation and get automatic documentation in EBR.

- ✓ Faster process execution
- ✓ Less manual documentation effort
- ✓ Less typing / signing on EBR
- ✓ No spots missed

A German multinational pharma company uses OptiworX to support line clearance & cleaning procedures in an aseptic filling environment (isolator system). They report significant reduction of deviations.



Drug Substance
Manufacturing

Drug Product
Manufacturing

Primary Packaging

Secondary Packaging
& Labelling

Manufacturing Support

Lab Execution & Quality Management

AR PROCESS GUIDANCE USE CASES ALONG THE PHARMA VALUE CHAIN



CHANGE-OVER

Receive the step-by-step instruction when changing format, batch or product. Confirm completion of steps hands-free & mobile. Automatically receive the documentation of the process. Collaborate with as many colleagues as required during this change-over.

- ✓ Faster process execution
- ✓ Less deviations / re-work
- ✓ Less documentation effort

At Vifor SA, Villars sur Glane OptiworX Standalone has been in use for format changes since 2018. The total format change time went down from 360' to 260' (27%). The settings only from 195' to 106' (-45%).



Drug Substance
Manufacturing

Drug Product
Manufacturing

Primary Packaging

Secondary Packaging
& Labelling

Manufacturing Support

Lab Execution & Quality Management

AR PROCESS GUIDANCE USE CASES ALONG THE PHARMA VALUE CHAIN



MAINTENANCE OF EQUIPMENT

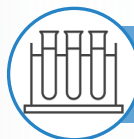
Get maintenance instructions for regular maintenance jobs in spatial context. No need to read through long manuals. In case: conveniently reach out to an expert for remote support with the AR glasses. Confirm maintenance completion hands-free and benefit of automated documentation.

- ✓ Faster process execution
- ✓ Less re-work
- ✓ Less documentation efforts

At a German pharma multinational OptiworX supports engineers in doing routine maintenance tasks and thereby reduce planned downtime of a critical mono-line in fill & finish.



AR PROCESS GUIDANCE USE CASES ALONG THE PHARMA VALUE CHAIN



LABORATORY PROCESSES FOR QUALITY CONTROL

Receive AR guidance for the use of sophisticated analytical equipment in the QC lab.
Easily confirm process step completion mobile & hands-free and benefit of automated documentation in LIMS.

- ✓ Less documentation effort
- ✓ Faster batch release
- ✓ Higher testing reliability

A swiss pharma company is implementing OptiworX to support QC lab technicians in setting up & operating complex analytical equipment to reduce procedure duration and increase batch release.



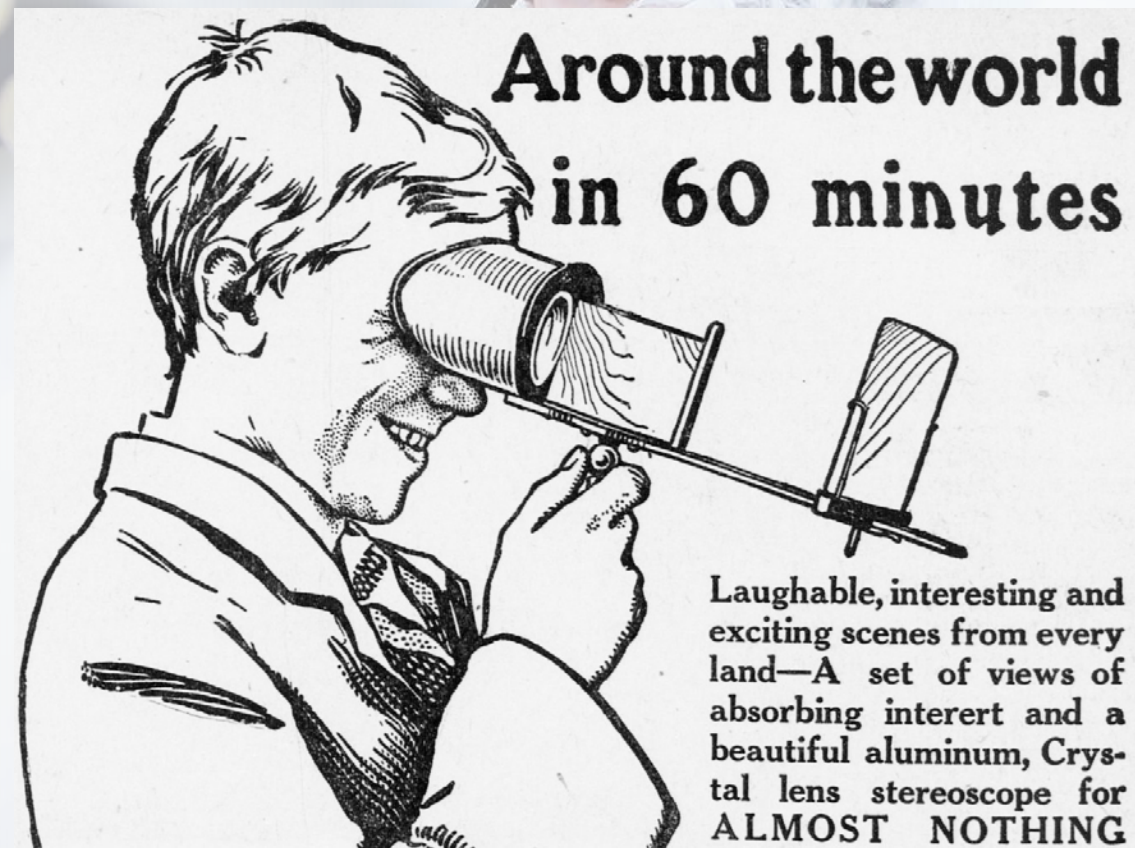
DEMO STREAMING DISCLAIMER

Parts of the demo contain stereoscopic 3D vision projected to a 2D screen, streamed to your display.

Wearing a 3D AR headset, the human motion sense together with the stereoscopic input make the experience of holographic content extremely stable & natural.

This might not be for the experience you have when streaming the video feed of such a glass.

We would be very happy to allow you the full experience at an in-person demo as a follow-up activity to today's session.



OptiworX Live Demo

Create Process

Start Change-Over
Process

Execute Change-
Over Process

Start Line-
Clearance Process

Review Audit Trail



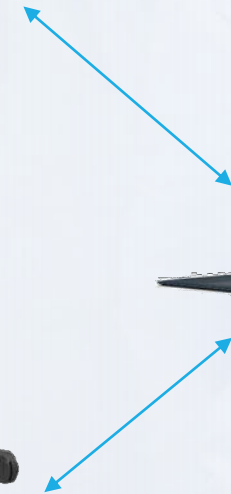
Process Owner



Shift Supervisor



Operator



Create Process

Start Change-Over
Process

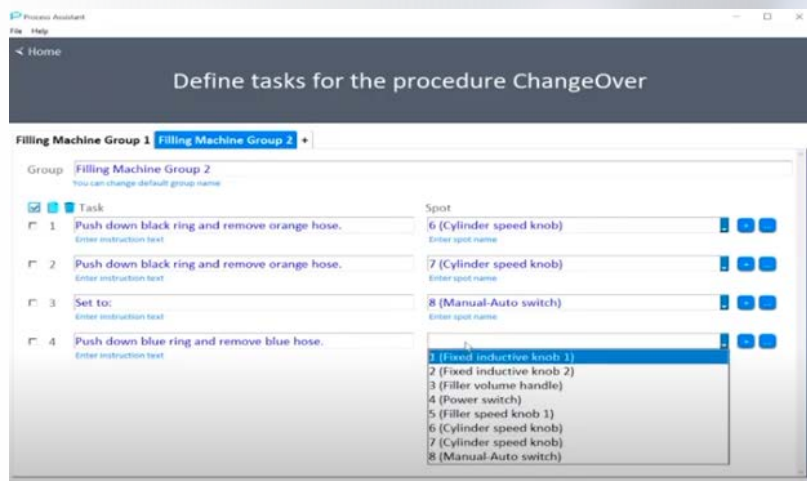
Execute Change-
Over Process

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AR Process Creation

1) Process Creation



On Desktop

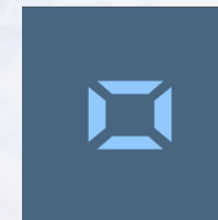


Process Assistant App

2) Spatial Placement



On Equipment using Hololens



Constructor App

Create Process

Start Change-Over
Process

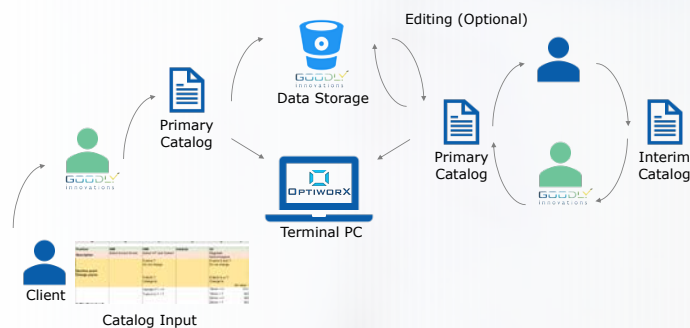
Execute Change-
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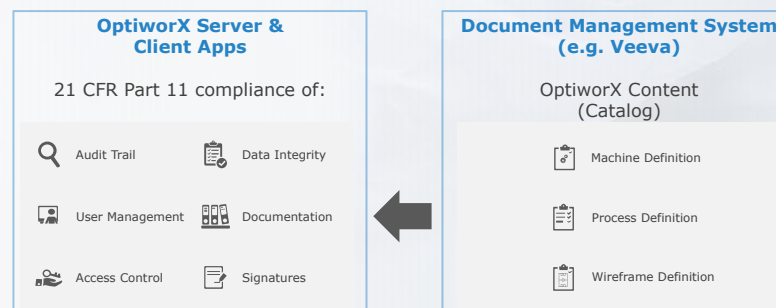
Review Audit Trail

Releasing Process Descriptions

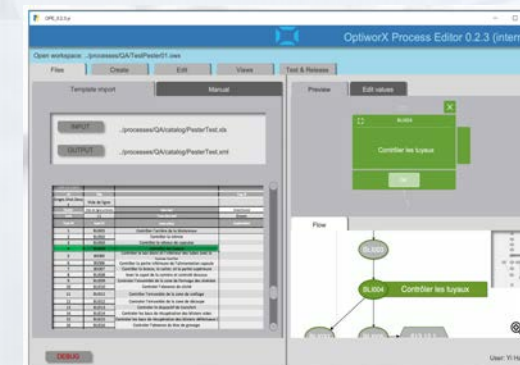
1) Data Management as a Service



2) File-Based in DMS



3) Process Editor Workflows



OptiworX Live Demo



③ Back Changeover (Custom)

Summary

1 Dosage Product A 50 mL

2 Set filling mode

Set filling mode

☐ Automatic

☐ Manual

☐ Bypass

Previous Next

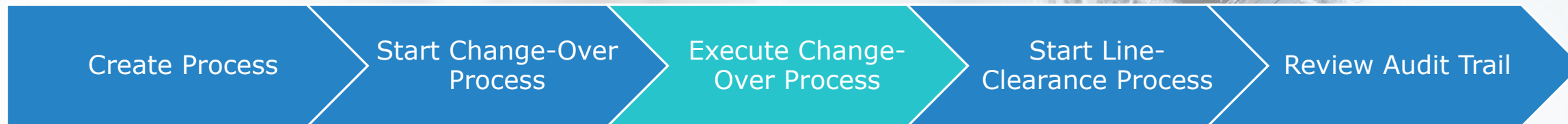
Highlights:

- ✓ CFR 21 Part 11 compliant user- & access management
- ✓ Process configuration based on input parameters for increased efficiency & scalability
- ✓ Secure pairing of device & user credentials
- ✓ Can be triggered through MES

Video procedure selection:

<https://youtu.be/YdmyiuXh3cw?t=38>

OptiworX Live Demo



Process Description:

Procedure:	CHANGE-OVER	Filling Mode:	Automatic	Manual	Bypass
		Dosage:	Product A 100mL	Product A 50 mL	Product A 15 mL
	Position on Machine (Spot)	Task			
Filling Machine Group 1	1 (Fixed inductive knob 1)	Push down blue ring and remove orange hose.			
	2 (Fixed inductive knob 2)	Push down blue ring and remove blue hose.			
	3 (Filler volume handle)	Adjust to:	12cm +2mm	10cm +1mm	8cm +1mm
	5 (Filling speed knob)	Push down black ring and remove orange hose.			
	4 (Power switch)	Turn on machine.			
Filling Machine Group 2	6 (Cylinder speed knob)	Push down black ring and remove orange hose.			
	7 (Cylinder speed knob)	Push down blue ring and remove blue hose.			
	8 (Manual-Auto switch)	Set to:	Automatic	Manual	
	9 (Conveying knob)	Push down blue ring and remove blue hose.			
	10 (Conveying knob)	Push down blue ring and remove orange hose.			
Conveyor Left	14	Untighten the screw			
Conveyor Right	15	Untighten the screw			

Highlights:

- ✓ AR Navigation
- ✓ AR Process Guidance
- ✓ Process Progression Feedback
- ✓ Multi User Collaboration
- ✓ Multiple Device Types Collaboration

Video Hololens:

<https://youtu.be/YdmyiuXh3cw?t=75>

Video RealWear:

<https://youtu.be/J9bQoUtB0sc>

OptiworX Live Demo

Create Process

Start Change-Over
Process

Execute Change-
Over Process

Start Line-
Clearance Process

Review Audit Trail

Example:

DateTime	2020-05-28T10:16:06 Europe/Berlin (+02)
Type	AuthenticationSucceeded
UserId	124bfd9f-5a95-49a9-9721-07e531215e6c
UserFullName	Stepan Stulov
DateTime	2020-05-28T10:16:09 Europe/Berlin (+02)
Type	ExecutionStarted
UserId	124bfd9f-5a95-49a9-9721-07e531215e6c
UserFullName	Stepan Stulov
ProcedureTitle(ProcedureId)	Procedure 02(P02)
DateTime	2020-05-28T10:16:14 Europe/Berlin (+02)
Type	AuthenticationSucceeded
UserId	124bfd9f-5a95-49a9-9721-07e531215e6c
UserFullName	Stepan Stulov
DateTime	2020-05-28T10:16:35 Europe/Berlin (+02)
Type	Joining
UserId	124bfd9f-5a95-49a9-9721-07e531215e6c
UserFullName	Stepan Stulov
UserDeviceKind	Tablet
DateTime	2020-05-28T10:16:35 Europe/Berlin (+02)
Type	PerformingStarted
UserId	124bfd9f-5a95-49a9-9721-07e531215e6c
UserFullName	Stepan Stulov
TaskId	P02.C1.L1 Task 1.1
TaskSummary	Push down blue ring and remove orange hose.
SpotId	MC01.S01
SpotTitle	Fixed_inductive_switch_1
DateTime	2020-05-28T10:17:05 Europe/Berlin (+02)
Type	AuthenticationSucceeded
UserId	ccf2e37c-f560-4a42-9663-f6abab15cf9b
UserFullName	Yi Han
DateTime	2020-05-28T10:17:21 Europe/Berlin (+02)
Type	Joining
UserId	ccf2e37c-f560-4a42-9663-f6abab15cf9b
UserFullName	Yi Han
UserDeviceKind	HoloLens

Highlights:

- ✓ Every action logged CFR 21 Part 11 compliant
- ✓ Human readable, non-editable PDF
- ✓ Machine readable format
- ✓ Can be integrated in EBR



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