

# Streamlining Aseptic Operator Training Success Stories of VR Training Implementations

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**PDA Aseptic Processing of Biopharmaceuticals Conference 2024**

# Background



## Sebastian Scheler

Master of Science Psychology

Clinical Psychology & Training Science

PDA Trainer for Aseptic Processing



## Official Partner for PDA

Global Training Course

Design and Delivery

# Streamlining Aseptic Operator Training

## Agenda

- 1 Pitfalls for effective Aseptic Operator Training
- 2 Overcoming pitfalls through technology
- 3 Case-Study 1: From FDA Warning Letter to Success (Bora Pharmaceuticals)
- 4 Case-Study 2: VR and advanced blended learning (Moderna, Kindeva)
- 5 Learnings and recommendations

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# Decision-making process in training



## **WHAT to train**

Definition of  
**Training CONTENT**

## **HOW to train**

Definition of  
**Training METHOD**

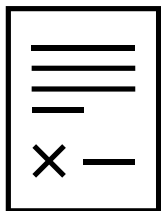
# WHAT to train – Pitfalls

	Tasks
Preparation activities	89
Filling Line SETUP	160
Filling Line OPERATIONS	72
Filling Line INTERVENTIONS	108
Formulation MIXING	112
Formulation FILTRATION	88
Total	<b>629</b>



Cleanroom staff need to be able to do **many different things.**

# WHAT to train – Pitfalls



- 1 Omission of essential training content
- 2 Wrong training focus
- 3 Misalignment of training, SOPs and oversight

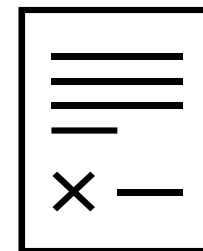


# WHAT to train – Pitfalls

## Training Content Definition

## Training Content Justification

	Principle-based	Process-related
Knowledge	Fundamental knowledge on aseptic processing	Process- / Equipment-specific knowledge
Behavior	Cleanroom behavior & Aseptic techniques	Specific process handling
Risk Awareness	General risk awareness	Specific risk awareness



## HOW to train – Pitfalls



- 1 VR realism is not strong enough
- 2 Feedback in VR is inaccurate
- 3 VR modules are not configurable

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Training-design is  
**resource-  
intensive, time-  
consuming and  
error-prone.**

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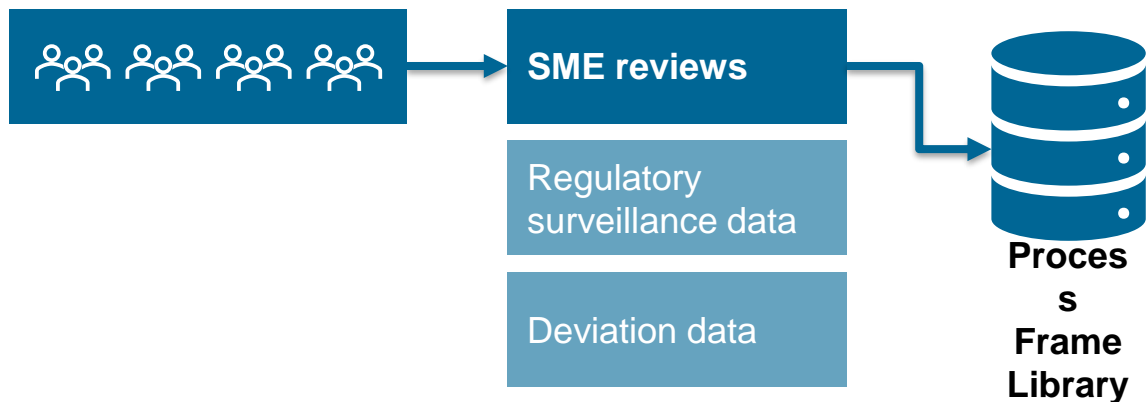
# WHAT to train

Definition of  
Training **CONTENT**

**Towards a more  
data-driven  
approach**

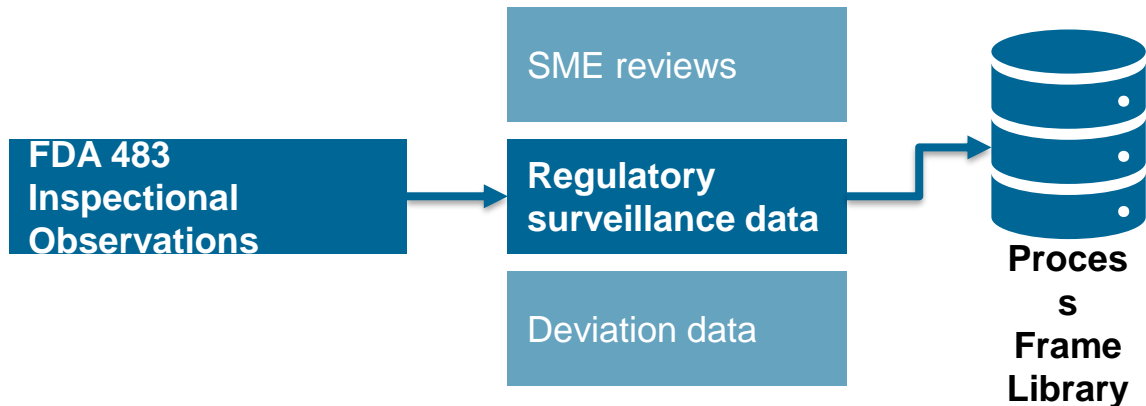
# WHAT to train: Frame-by-Frame Approach

## Standardized Data-Collection



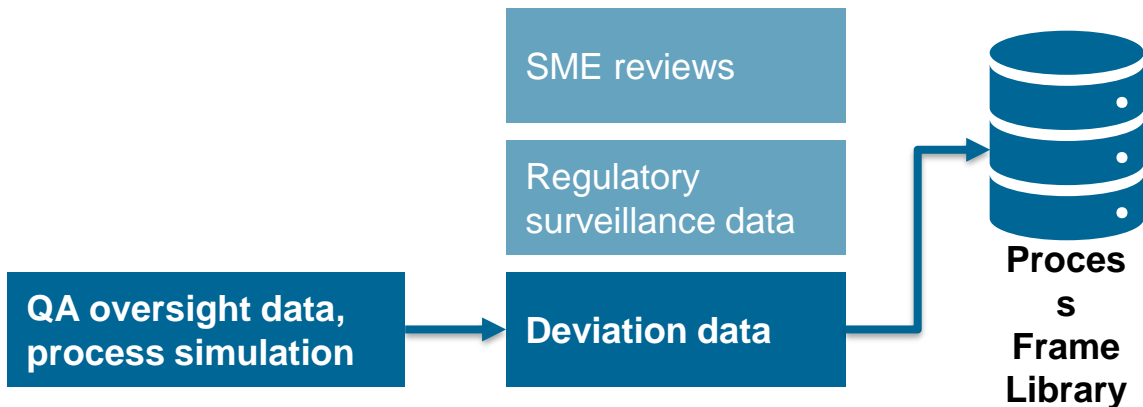
# WHAT to train: Frame-by-Frame Approach

## Standardized Data-Collection



# WHAT to train: Frame-by-Frame Approach

## Standardized Data-Collection





# “Process Frames” = micro steps in manufacturing



Frame-Nr.	1025
Description	Insert filling needle in empty vial
Frame-ID	F-FL23-FN-VI-3



Frame-Nr.	0150
Description	Insert right gloved hand in isolator glove
Frame-ID	F-INS-GL-IL-32



Frame-Nr.	1850
Description	Make sterile connection
Frame-ID	F-SC3-FN-VI-3

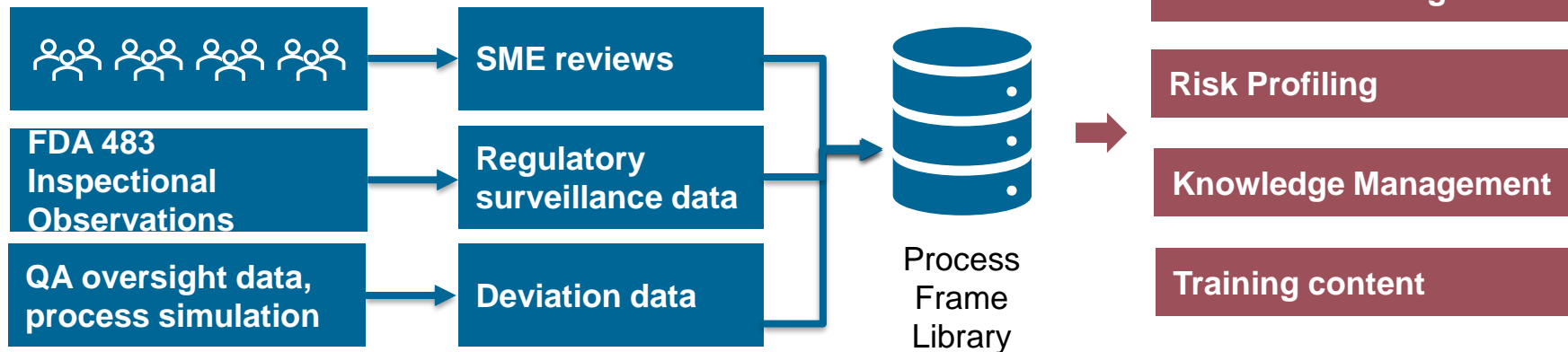


Frame-Nr.	2759
Description	Place covered filling needle in filling needle holder
Frame-ID	F-FL23-PL-VI-NH-1

The Process Frame  
Library is a **central  
database** containing  
**detailed information**  
on **thousands of unit  
operations and  
process steps.**

# WHAT to train: Frame-by-Frame Approach

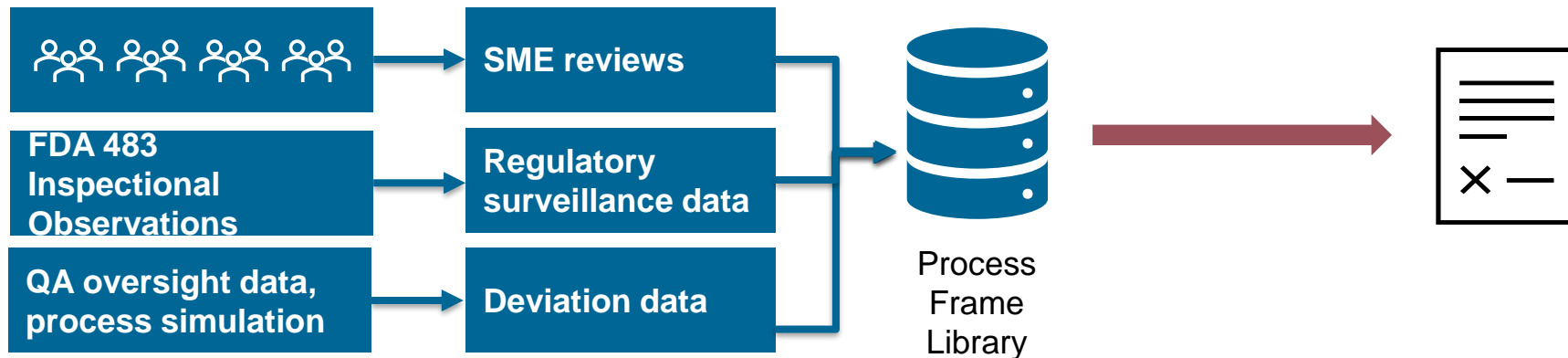
## Standardized Data-Collection



# WHAT to train: Frame-by-Frame Approach

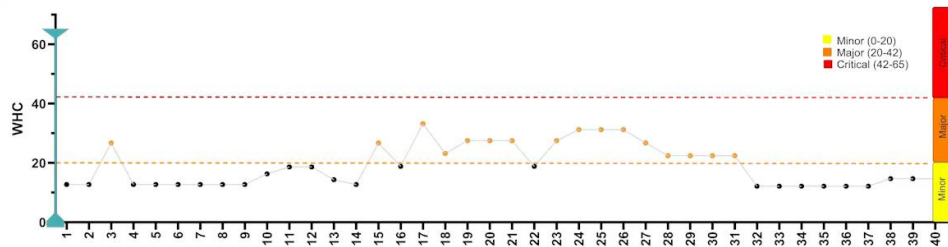
## Standardized Data-Collection

## Definition of training content





Remove vial jam



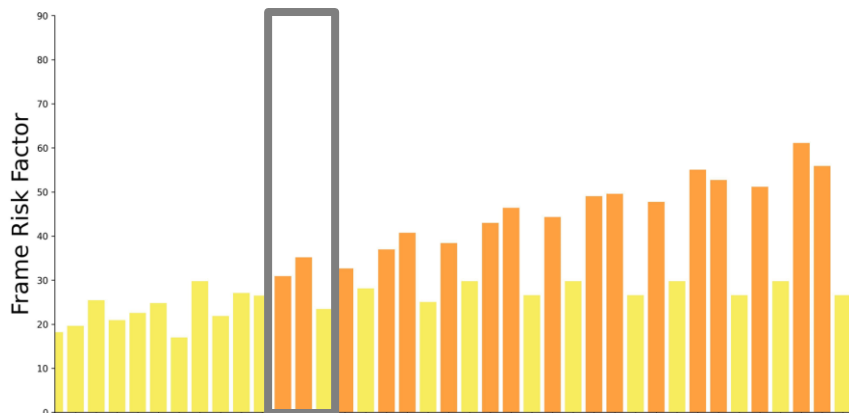
# WHAT to train: Frame-by-Frame Approach

Example: Insert gloved hands in isolator gloves



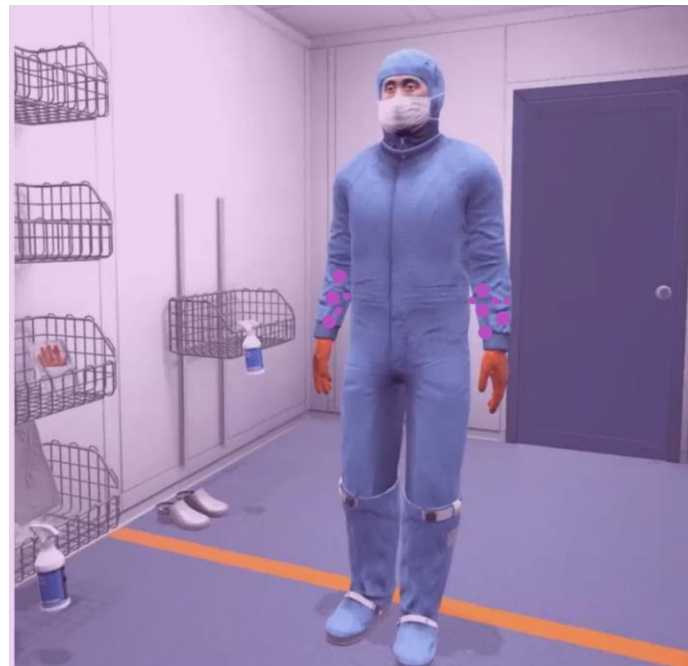
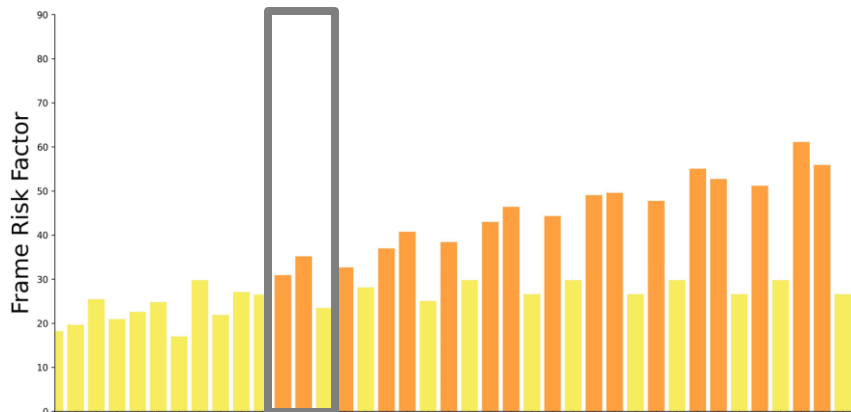
# WHAT to train: Frame-by-Frame Approach

Example: Gowning for grade B



# WHAT to train: Frame-by-Frame Approach

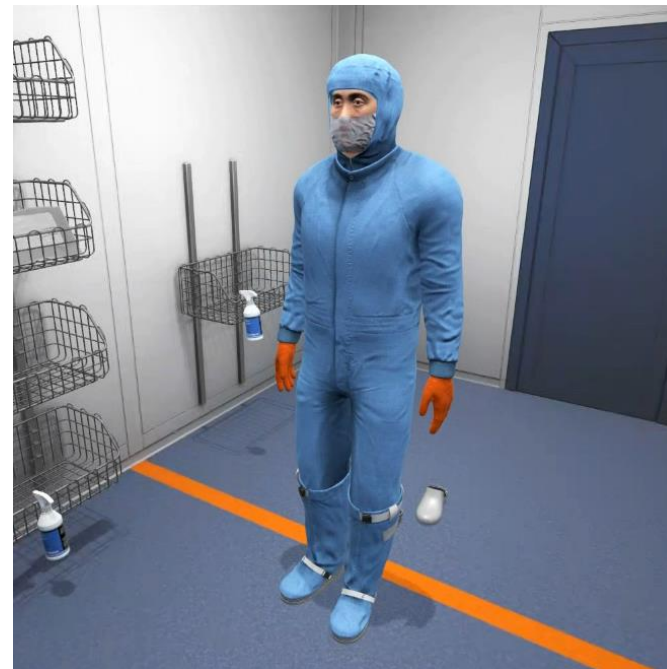
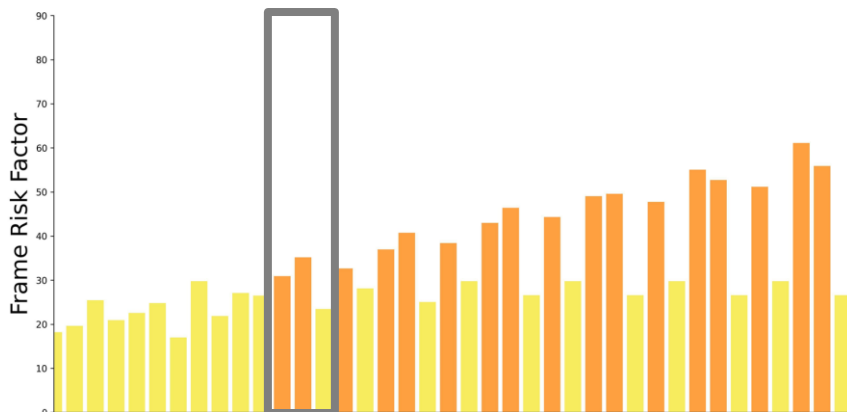
Example: Gowning for grade B





# WHAT to train: Frame-by-Frame Approach

Example: Gowning for grade B






# **HOW to train**

Definition of  
**Training CONTENT**

**Using more  
advanced  
technologies**

# HOW to train Using more advanced technologies

<p><b>IMMERSION</b> Technical capabilities &amp; physics of the VR system</p>	<p><b>PRESENCE</b> Illusion of “being there”</p>	<p><b>ECOLOGICAL VALIDITY</b> Realism of user response/behavior in VR</p>
		
<p>Field-of-view, graphical resolution, degrees of freedom, latency of head tracking</p>	<p>Depth of “Place Illusion” and “Plausibility Illusion” in VR</p>	<p>Simulation quality of environment &amp; processes, physics, microbiology, scenarios</p>
<p>Mainly depended on <b>VR Hardware capabilities</b></p>	<p>Mainly depended on <b>Overall VR software quality</b></p>	<p>Mainly depended on <b>VR Simulator components</b></p>
<p>Slater (2003) Slater &amp; Sanchez-Vives (2016)</p>	<p>Slater (2009) Diemer et al. (2015)</p>	<p>Paljic (2017)</p>

# HOW to train - Using more advanced technologies

## Increased immersion through better hardware

<p><b>IMMERSION</b> Technical capabilities &amp; physics of the VR system</p>
<p>Field-of-view, graphical resolution, degrees of freedom, latency of head tracking</p>
<p>Mainly depended on <b>VR Hardware capabilities</b></p>
<p>Slater (2003) Slater &amp; Sanchez-Vives (2016)</p>



First VR headset by Ivan Sutherland (1969)



VR Project by NASA (1989)





HTC Vive Pro with lighthouse tracking

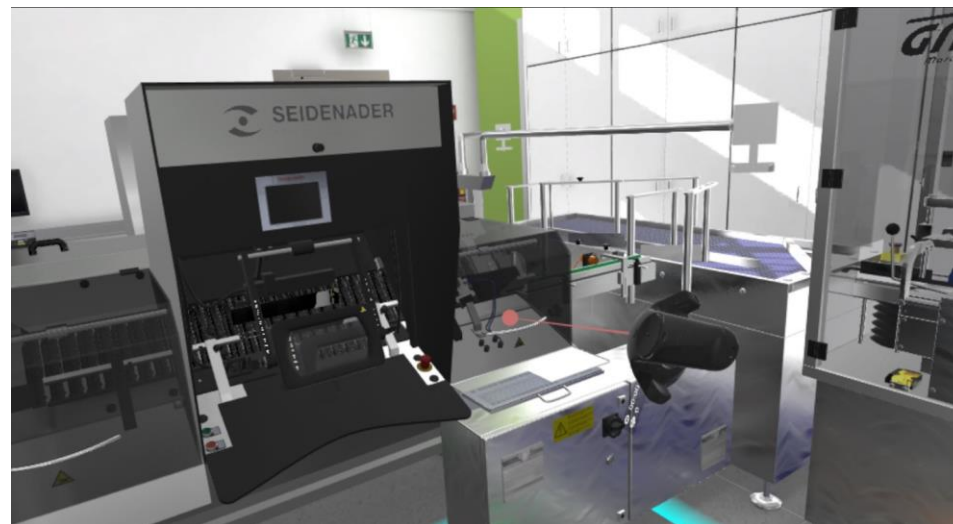


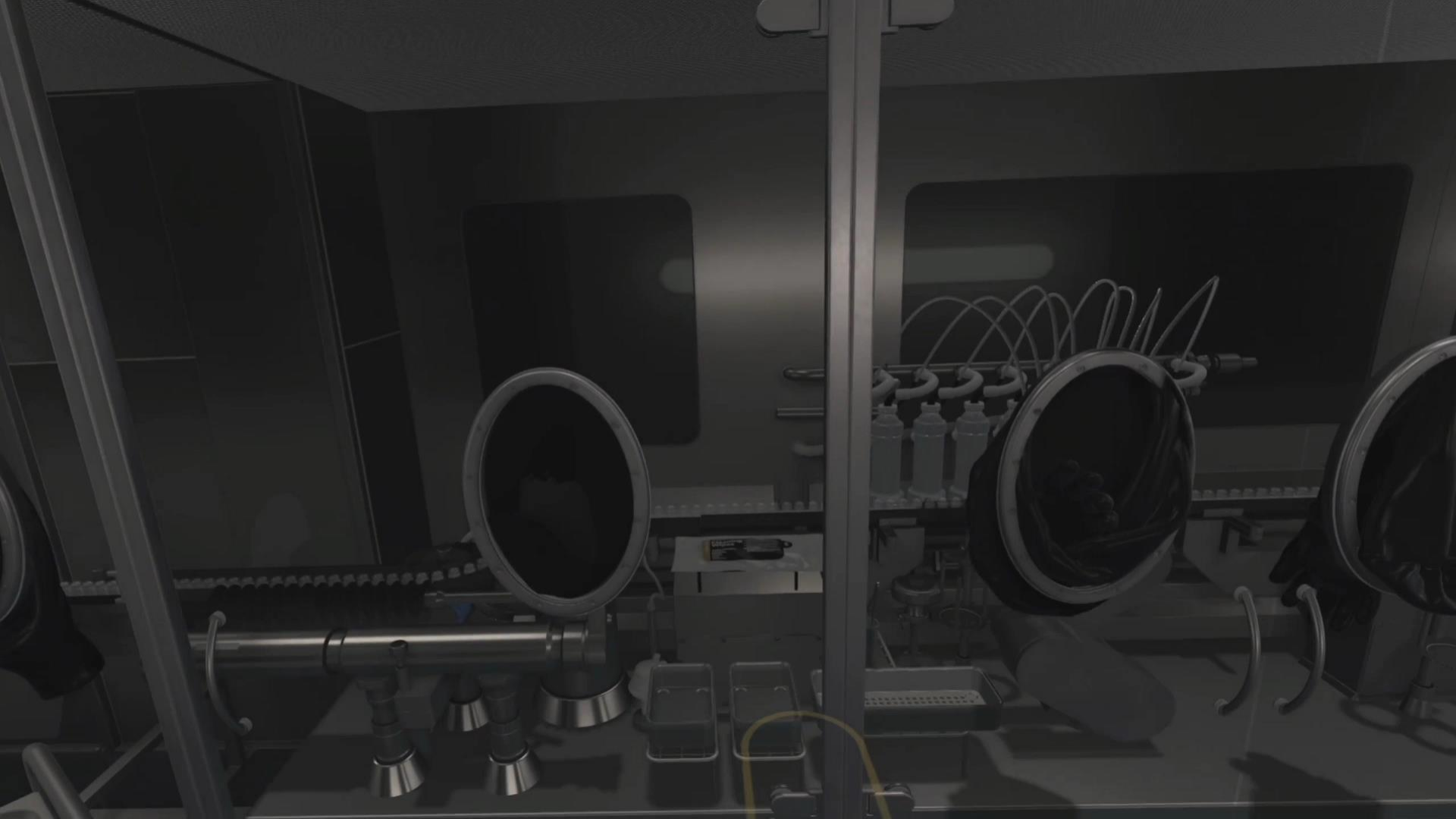
Meta Quest 3 with inside-out tracking

# HOW to train - Using more advanced technologies

## Increased presence and ecological validity

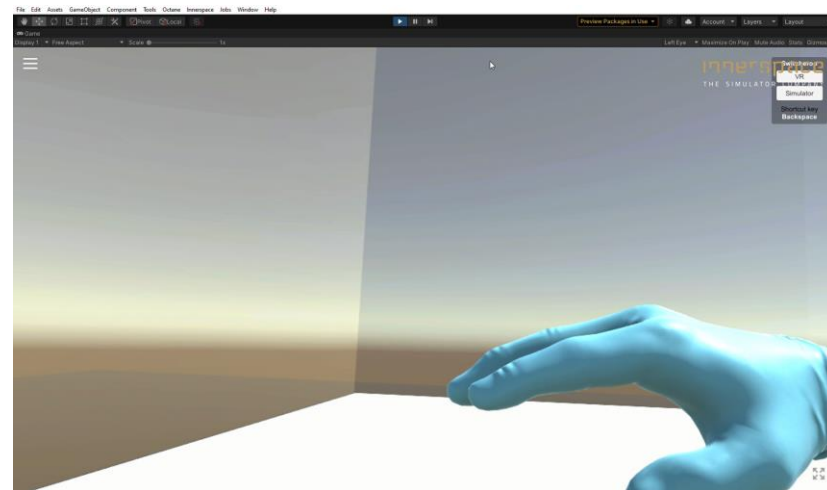
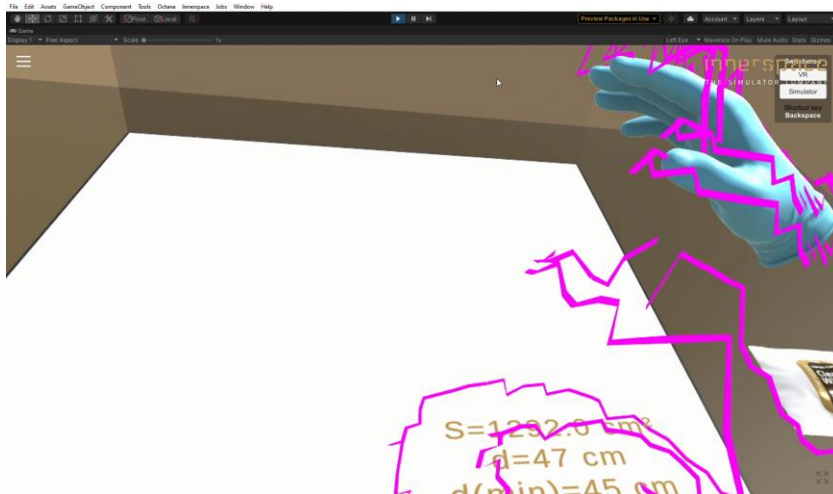
<p><b>PRESENCE</b> Illusion of "being there"</p>	<p><b>ECOLOGICAL VALIDITY</b> Realism of user response/behavior in VR</p>
	
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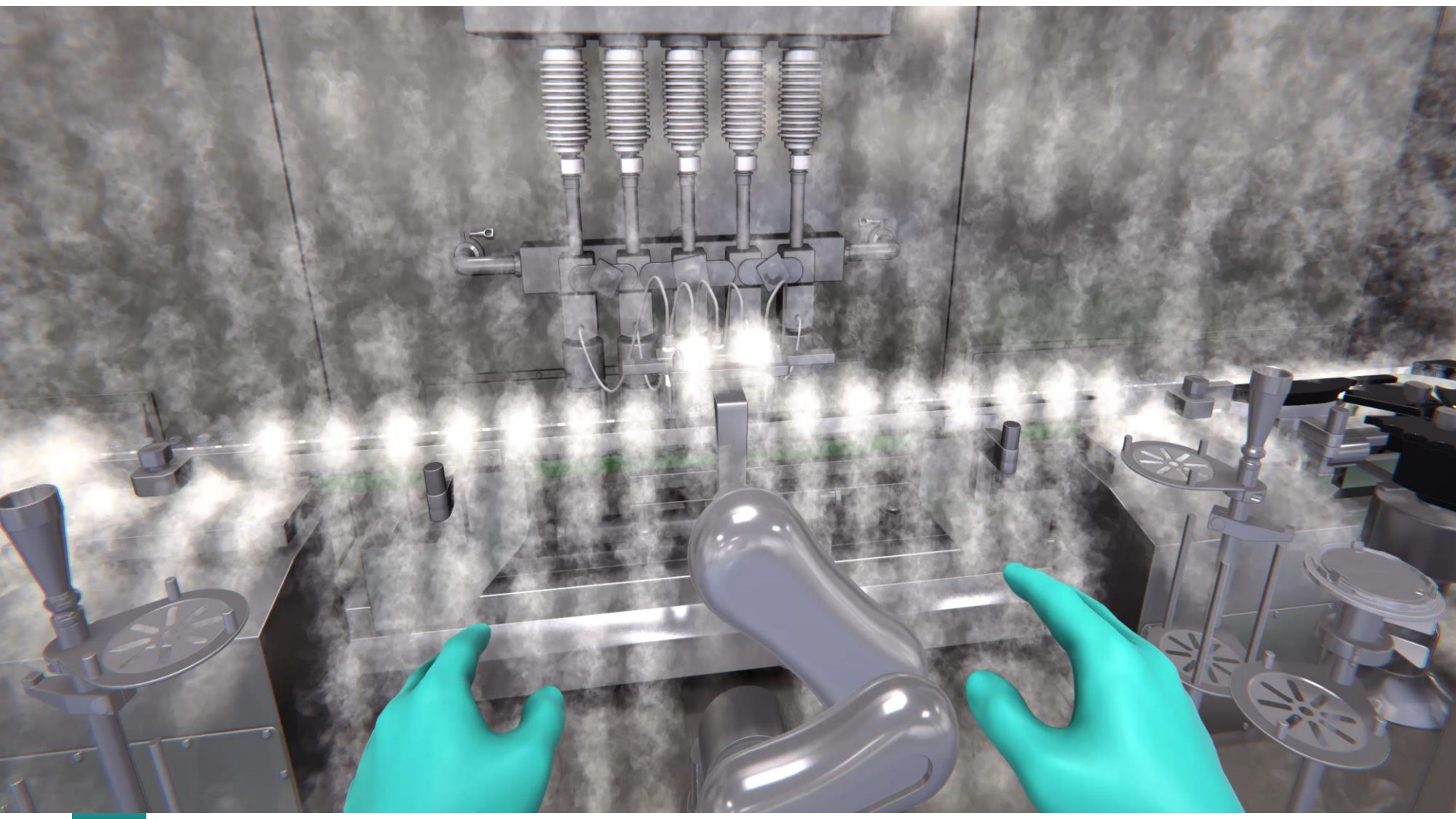




# HOW to train - Using more advanced technologies

## Advanced tracking for better feedback accuracy







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# Case-Study 1: From FDA Warning Letter to Success (Bora Pharmaceuticals)



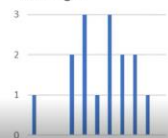
## Challenge(s)

### Challenges to the workforce

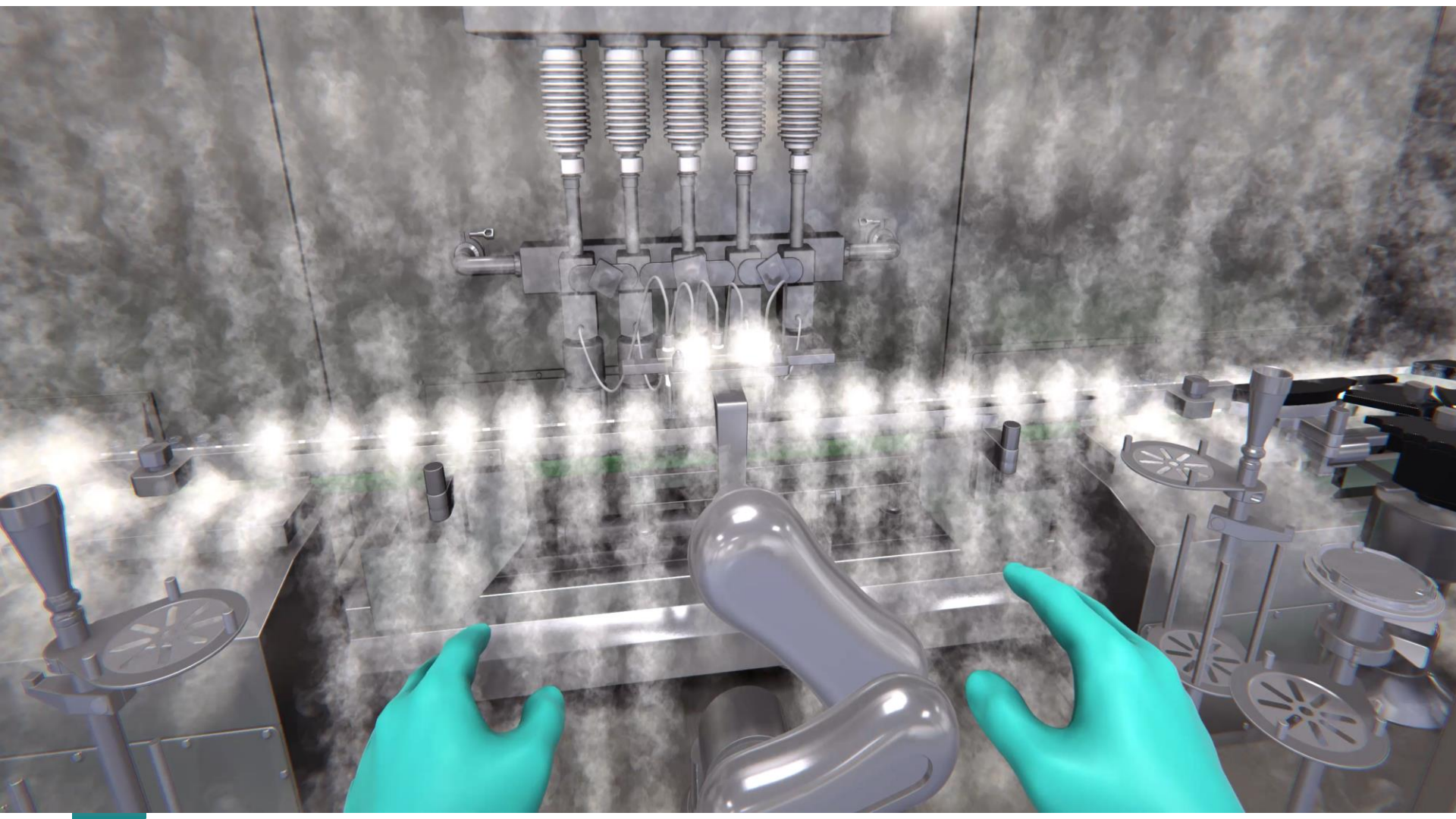
- Lack of access to aseptic training environments
- Task complexity
- Process changes
- New Equipment
- New and inexperienced workforce
- Trainer availability
- Time to be gown certified
- Changing old behaviors

### Challenges to the site and our customers

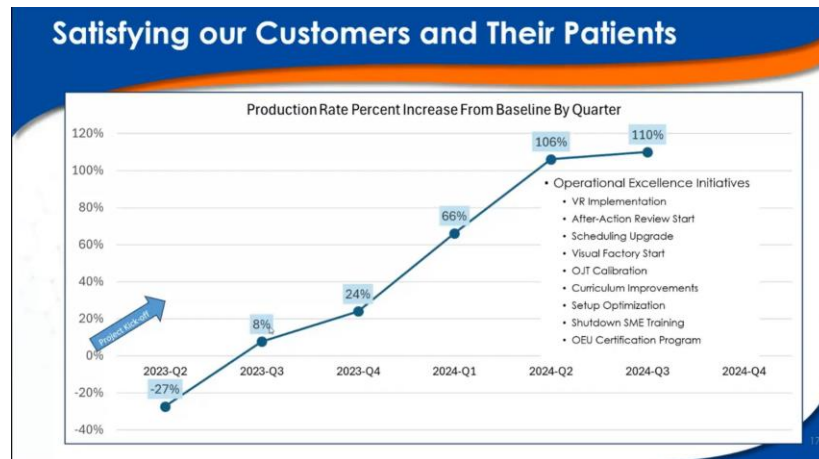
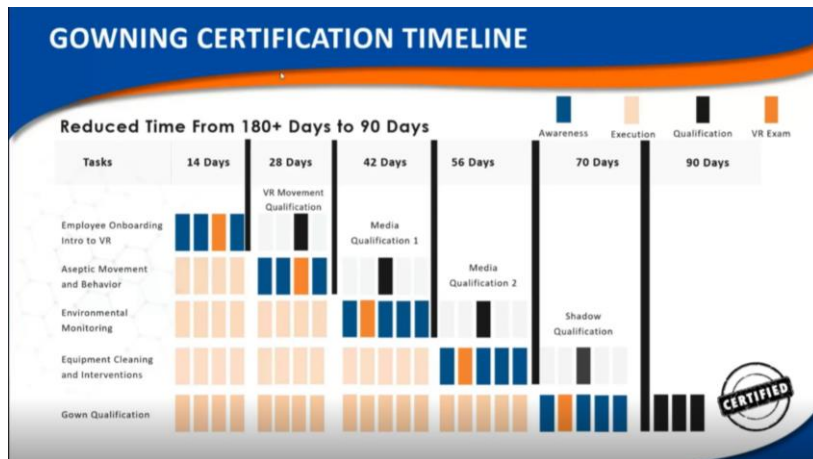
- Unknown capabilities
- Variable performance
- Managing high volumes of change



...Your procedures did not strictly instruct personnel to not disrupt the path of unidirectional air flow during sterile manufacturing



# Case-Study 1: From FDA Warning Letter to Success (Bora Pharmaceuticals)



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# Case-Study 2: Advanced blended learning (Moderna, Kindeva)



## Generic Training Content based on Virtual Reality

for effective Training/Assessment for fundamentals of aseptic manufacturing

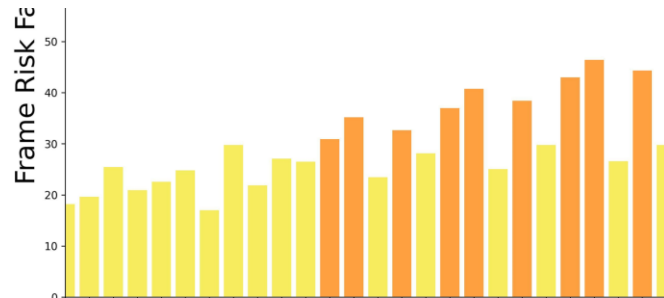


## Specific Training Content based on advanced Process Simulations

for effective Training for aseptic Interventions in fill-finish areas



# Case-Study 2: Advanced blended learning (Moderna, Kindeva)



**Principle-based Training**

**Process-specific Training**

# Crystal M1 Closed Vial Filling

## **Vial Filling and Sealing**

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Training Video

*Wrong / Right process execution*

**Moderna, Norwood Facility**

Based on Frame-by-Frame Risk Profiling



# Crystal M1 Closed Vial Filling

## **Vial Filling and Sealing**

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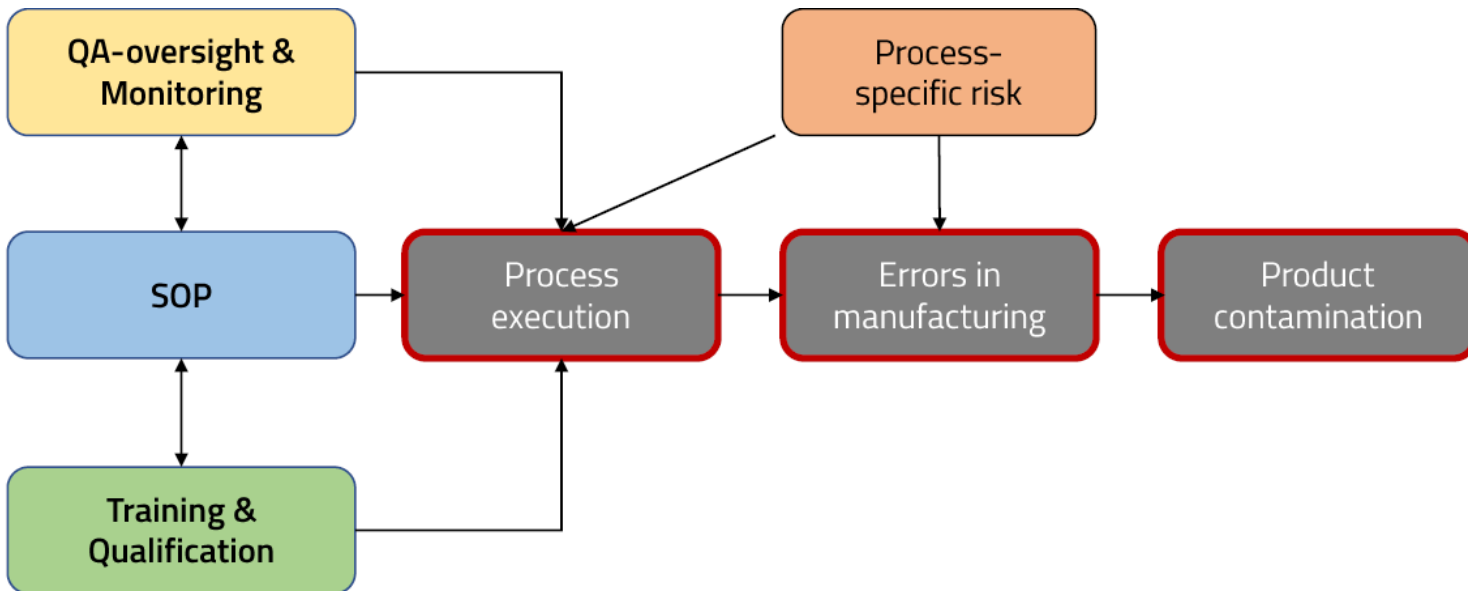
Training Video

*Wrong / Right process execution*

**Moderna, Norwood Facility**

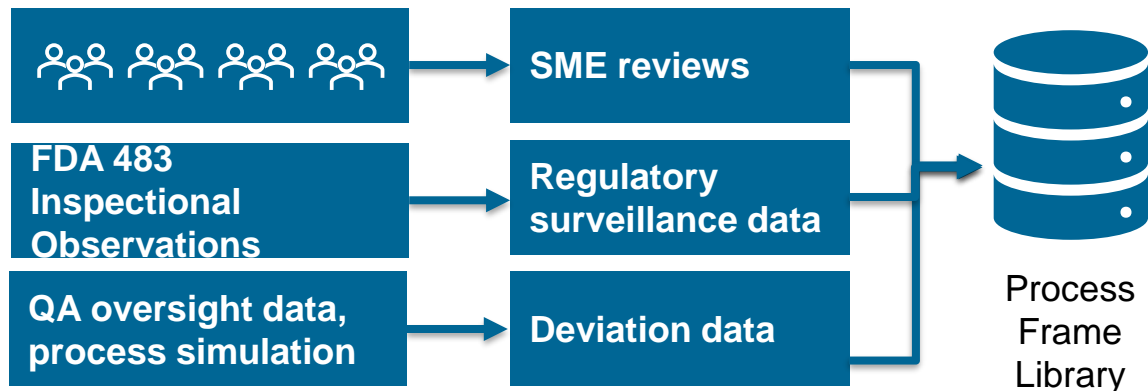
Based on Frame-by-Frame Risk Profiling

## Case-Study 2: Advanced blended learning (Moderna, Kindeva)

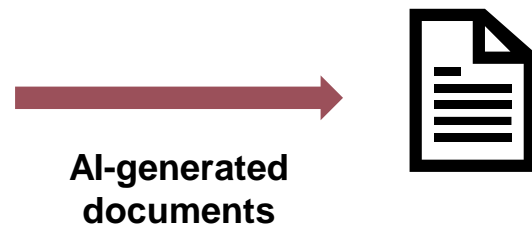


# Case-Study 2: Advanced blended learning (Moderna, Kindeva)

## Standardized Data-Collection



## Automation



# Auto-generated documents with Process Frame Library

Hazard scenarios
Grabbing the wrong needle protection
Touching tip of forceps with hand
Tip of forceps touching isolator
Touching tip of forceps with hand
Damaging tip of filling needle with forceps



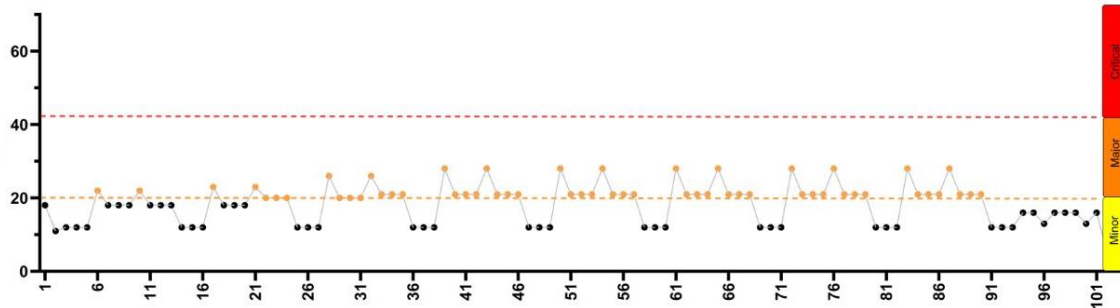
Frame	Work Instruction
7.2	<ul style="list-style-type: none"> <li>• Needle protections must be removed going from left (needle 8) to right (needle 1)</li> <li>• Keep left hand near glove port</li> <li>• Approach needle 8 with forceps in right hand from right side under needle holder</li> <li>• Grasp needle protection 8 with tip of forceps</li> <li>• Don't grasp tip of filling needle</li> </ul>

## 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

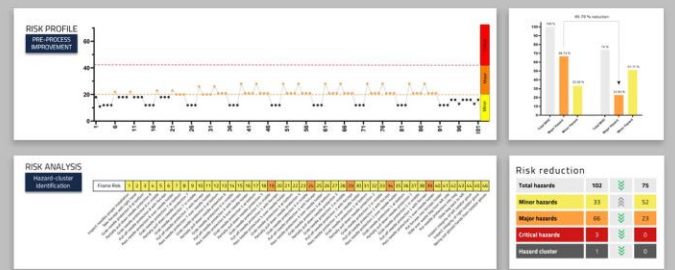
### 7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE 8

FRAME	VCC	WORK INSTRUCTION - PROCESS TASK (35/37)	OVERSIGHT GUIDELINE		
			EXECUTION	OBSERVATION	MITIGATION
1	Grasp bottom of needle protection 8 with forceps - Don't start with needle protection 1	<ul style="list-style-type: none"> <li>Needle protections must be removed from left (needle 8) to right (needle 1)</li> <li>Keep left hand near glove port</li> <li>Approach needle 8 with forceps in right hand from right side under needle holder</li> <li>Grasp needle protection 8 with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> <li>Grabbing the wrong needle protection</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Grab needle protection 8</li> </ul>
2	Partially pull-down needle protection with forceps - Don't fully remove protection	<ul style="list-style-type: none"> <li>Use forceps to pull needle protection halfway down going straight down</li> <li>Don't fully remove needle protection or needle might jump out</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Touching tip of forceps</li> <li>Filling needle jumping out</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Push back filling needle reach over from top and document observation</li> </ul>
3	Grasp middle of needle protection with forceps	<ul style="list-style-type: none"> <li>Grasp middle of needle protection with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> </ul>
4	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
5	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Place needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



## QRM Report – Dashboard

### Remove needle protection



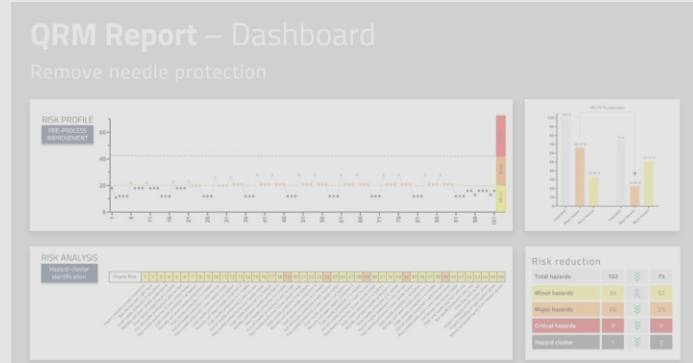
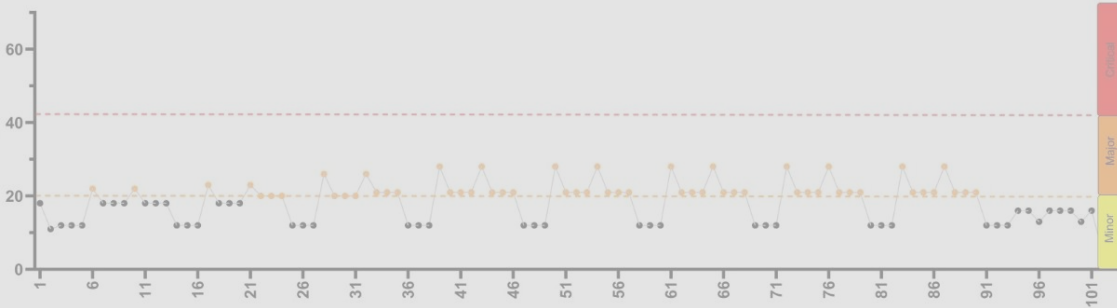
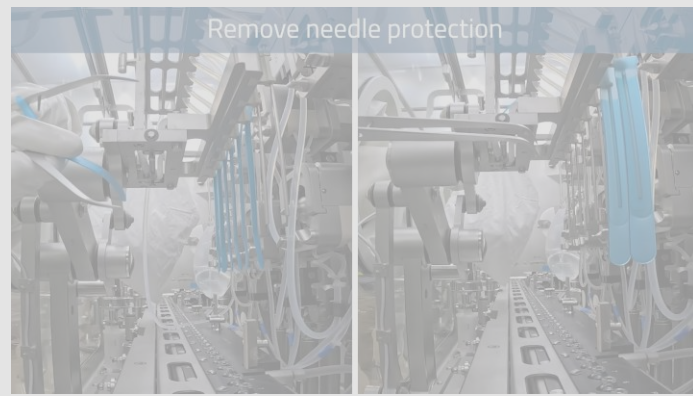
7.2

Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE 8

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3	Grasp middle of needle protection with forceps	<ul style="list-style-type: none"> <li>Grasp middle of needle protection with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> </ul>
4	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
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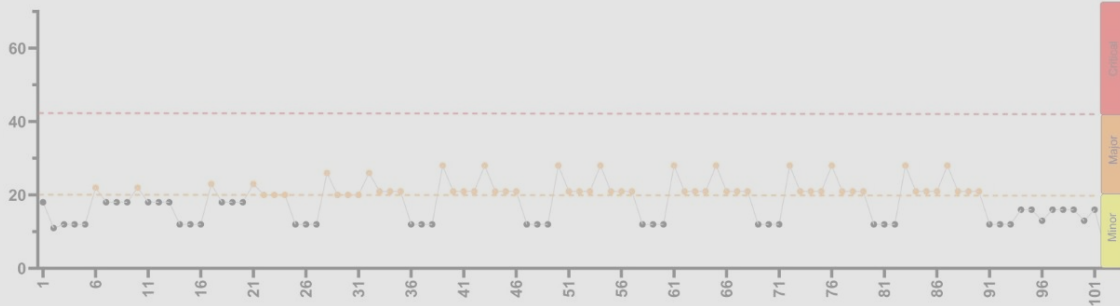
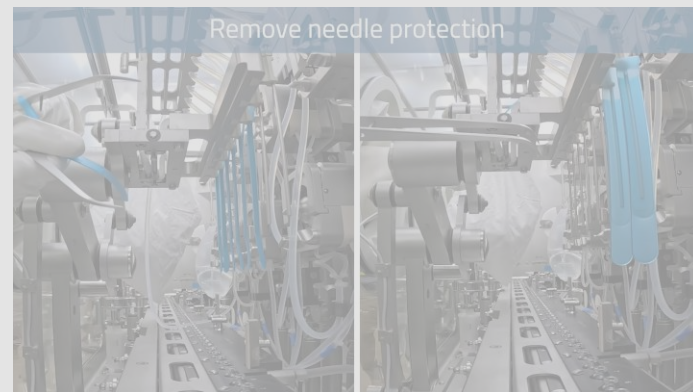


### 7.2 Operator A: Remove needle protection from needle 8

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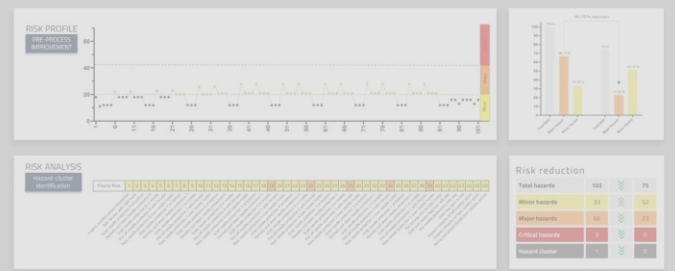
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3	Grasp middle of needle protection with forceps	<ul style="list-style-type: none"> <li>Grasp middle of needle protection with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> </ul>
4	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
5	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Place needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



### QRM Report – Dashboard

#### Remove needle protection

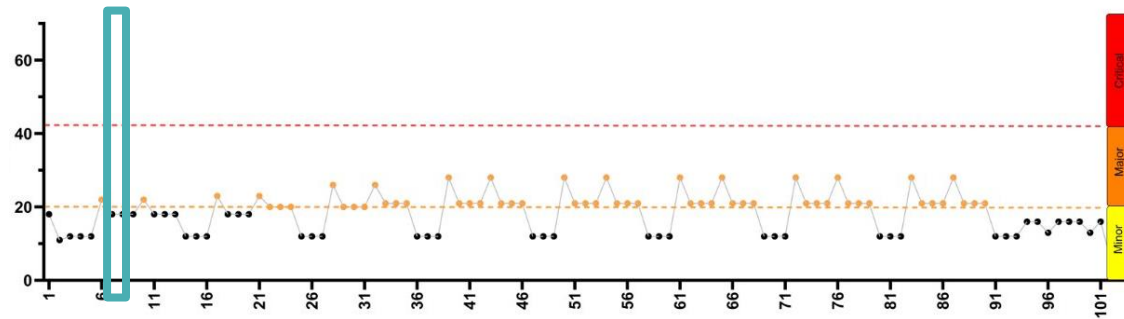
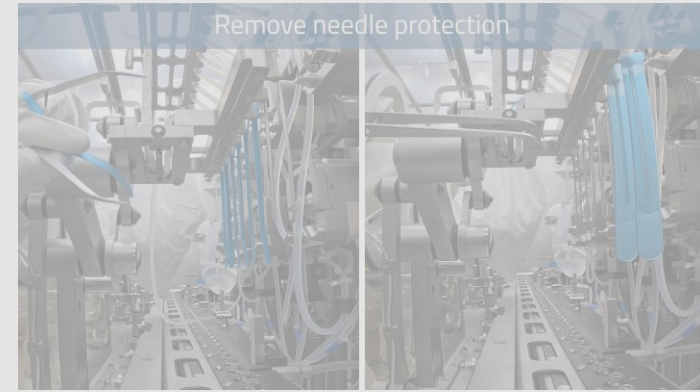


### 7.2 Operator A: Remove needle protection from needle B

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

#### 7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE B

FRAME	VCC	WORK INSTRUCTION - PROCESS TASK (35/37)	OVERSIGHT GUIDELINE		
			EXECUTION	OBSERVATION	MITIGATION
1	Grasp bottom of needle protection B with forceps - Don't start with needle protection 1	<ul style="list-style-type: none"> <li>Needle protections must be removed from left (needle B) to right (needle 1)</li> <li>Keep left hand near glove port</li> <li>Approach needle B with forceps in right hand from right side under needle holder</li> <li>Grasp needle protection B with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> <li>Grabbing the wrong needle protection</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Grab needle protection B</li> </ul>
2	Partially pull-down needle protection with forceps - Don't fully remove protection	<ul style="list-style-type: none"> <li>Use forceps to pull needle protection halfway down going straight down</li> <li>Don't fully remove needle protection or needle might jump out</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Touching tip of forceps</li> <li>Filling needle jumping out</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Push back filling needle reach over from top and document observation</li> </ul>
3	Grasp middle of needle protection with forceps	<ul style="list-style-type: none"> <li>Grasp middle of needle protection with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> </ul>
4	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle B</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
5	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Place needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



### QRM Report – Dashboard

Remove needle protection

**RISK PROFILE**  
PRE-PROCESS IMPLEMENTATION

**RISK ANALYSIS**  
NEEDLE GUARD IDENTIFICATION

**Risk reduction**

Total hazards	103	75
Minor hazards	75	52
Major hazards	16	23
Critical hazards	7	0
Unassessed	15	0

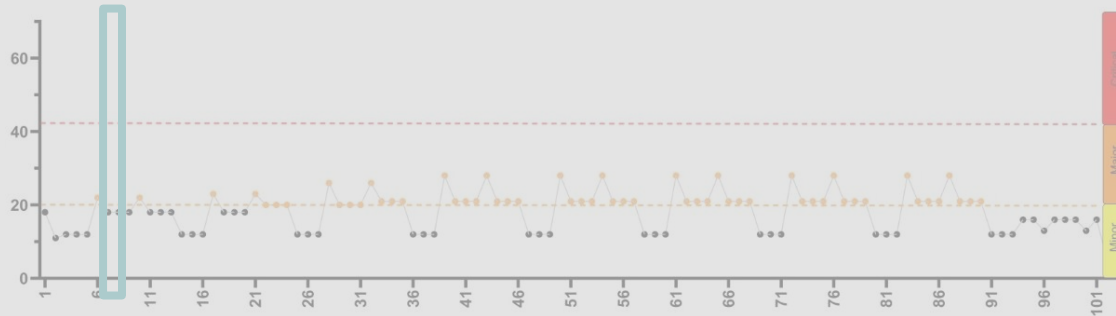
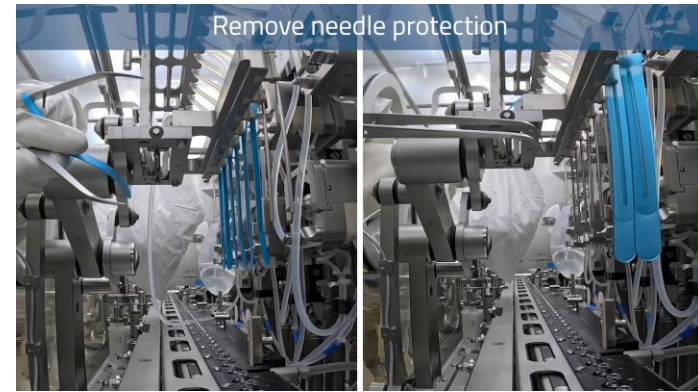


## 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

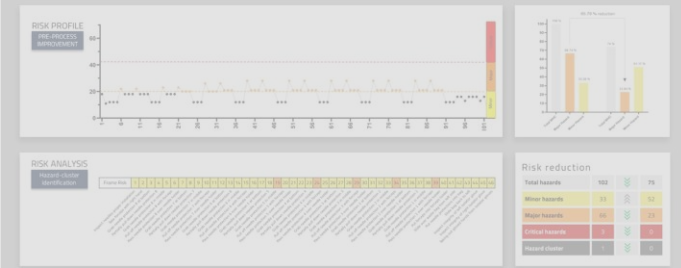
### 7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE 8

FRAME	VCC	WORK INSTRUCTION - PROCESS TASK (35/37)	OVERSIGHT GUIDELINE		
			EXECUTION	OBSERVATION	MITIGATION
1	Grasp bottom of needle protection 8 with forceps - Don't start with needle protection 1	<ul style="list-style-type: none"> <li>Needle protections must be removed from left (needle 8) to right (needle 1)</li> <li>Keep left hand near glove port</li> <li>Approach needle 8 with forceps in right hand from right side under needle holder</li> <li>Grasp needle protection 8 with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> <li>Grabbing the wrong needle protection</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Grab needle protection 8</li> </ul>
2	Partially pull-down needle protection with forceps - Don't fully remove protection	<ul style="list-style-type: none"> <li>Use forceps to pull needle protection halfway down going straight down</li> <li>Don't fully remove needle protection or needle might jump out</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Touching tip of forceps</li> <li>Filling needle jumping out</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Push back filling needle reach over from top and document observation</li> </ul>
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5	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Pass needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



## QRM Report – Dashboard

### Remove needle protection

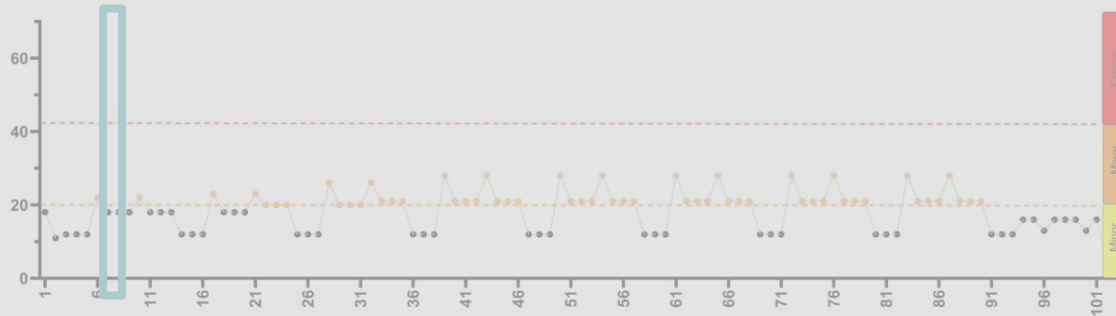
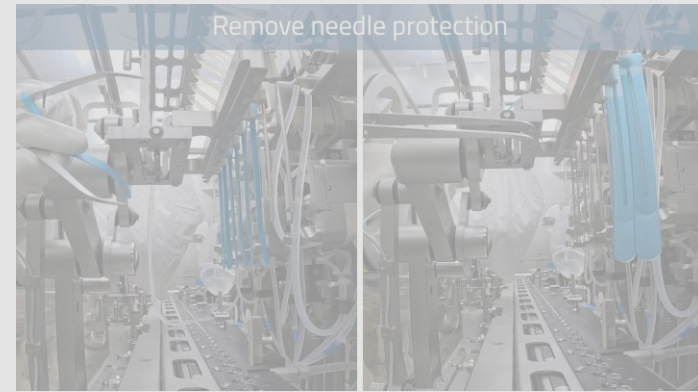


## 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

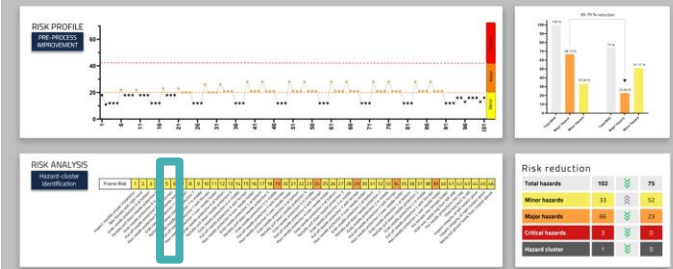
### 7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE 8

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## QRM Report – Dashboard

### Remove needle protection

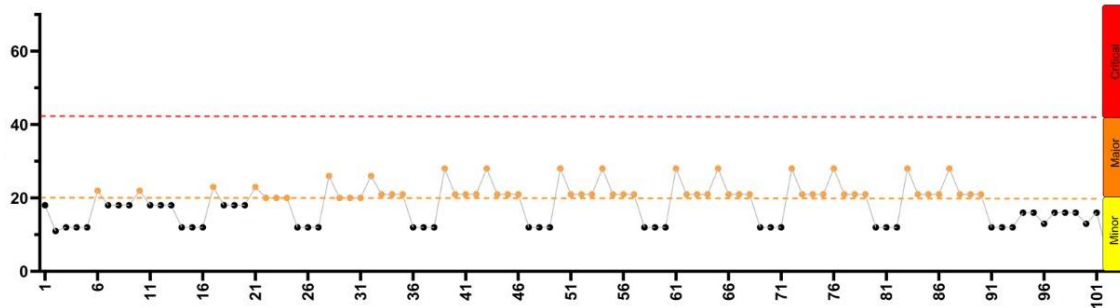


## 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

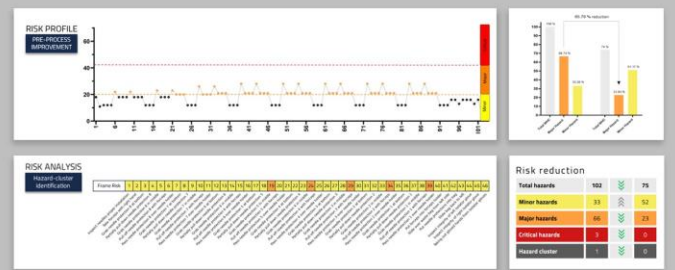
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## QRM Report – Dashboard

### Remove needle protection



# Streamlining Aseptic Operator Training

## Agenda

- 1 Pitfalls for effective Aseptic Operator Training
- 2 Overcoming pitfalls through technology
- 3 Case-Study 1: From FDA Warning Letter to Success (Bora Pharmaceuticals)
- 4 Case-Study 2: VR and advanced blended learning (Moderna, Kindeva)
- 5 Learnings and recommendations

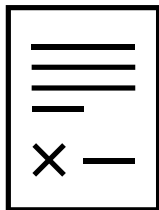
## Streamlining Aseptic Operator Training

# Learnings and recommendations

1

**Definition of Training Content: The more data-driven the justification of the training content, the less risk of pitfalls**

# WHAT to train – Avoid Pitfalls



1

Making sure that the essential training content is included

2

Right training focus for the right people

3

Full alignment of training, SOPs and oversight

## Streamlining Aseptic Operator Training

# **Learnings and recommendations**

1

Definition of Training Content: **The more data-driven the justification of the training content, the less risk of pitfalls**

2

Definition of Training Method: **The more targeted the training methods we use, the lower the risk of pitfalls.**

## HOW to train – Avoid Pitfalls



- 1 Strong VR realism as key effectiveness criteria
- 2 Measurable VR functionalities for accurate feedback
- 3 Configurable VR modules for adjusted training



## Streamlining Aseptic Operator Training

# Learnings and recommendations

1

Definition of Training Content: **The more data-driven the justification of the training content, the less risk of pitfalls**

2

Definition of Training Method: **The more targeted the training methods we use, the lower the risk of pitfalls.**

3

Effectiveness-Check: **Examine the quality of learning objectives**

## How to improve a training objectives?

### Example Environmental Monitoring

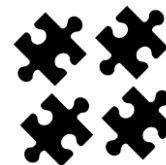
Learning objective example:

“Understand and being able to correctly execute personnel monitoring SOP/procedure.”



Learning objective example:

“Understand principles and **risks of personnel monitoring** and being able to correctly execute personnel monitoring SOP/procedure.”



## How to improve a training objectives?

### Example Environmental Monitoring

Learning objective example:

“Understand principles and the **five most important errors within our** personnel monitoring SOP/procedure and demonstrate how to execute it correctly.”

# How to improve a training objectives?

## Example Environmental Monitoring

Learning objectives:

- **Can explain** “why” personnel monitoring is important for protecting the product.
- **Can demonstrate** how to avoid the five most important errors while executing our personnel monitoring SOP.
- **Can identify** the five most important errors and where they can happen in our process.