Agenda

1. **Introduction - Trends in market and need for application**

2. **Explanation of process**

3. **Evaluation of application**

    a. Attractivity

    b. Cost Effectiveness / ROI

    c. Area of Application, flexibility and easyness to integrate

4. **Final Message - Highlights**

1. Introduction – Trends in the market

Requirements for glove minimization

Changing regulatory environment

Annex 1

Use of digital engineering

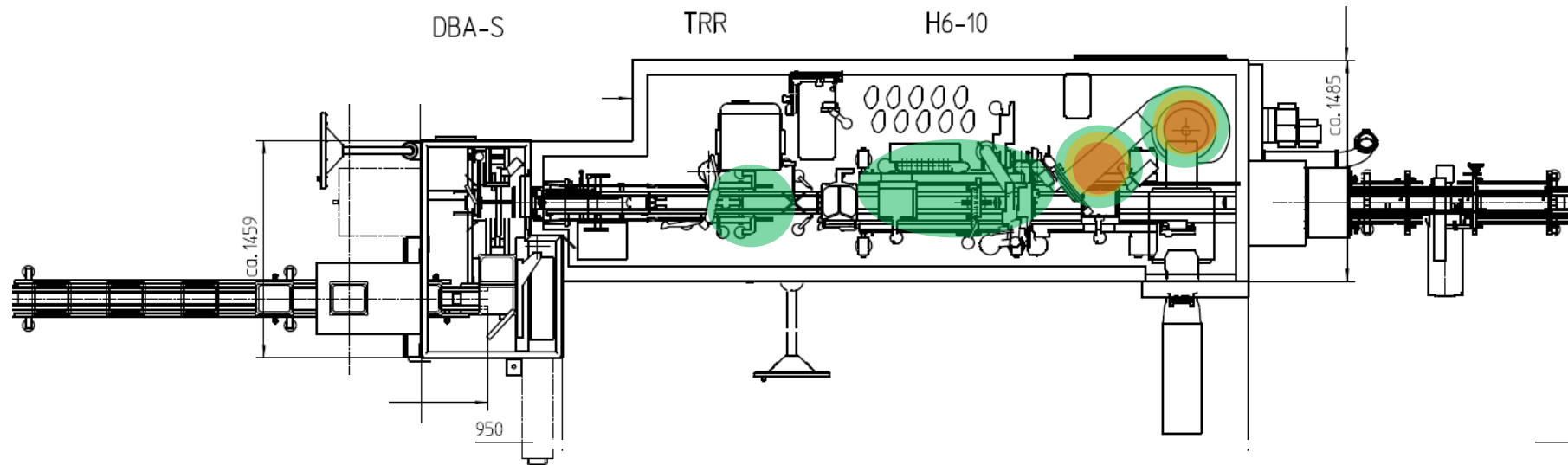for minimizing risks before design start (digital twin, simulations)

Glove minimization

Glove often seen as root cause for failure

1. Introduction – Need for application

Greatest potential for improvement after evaluation process from customer studies

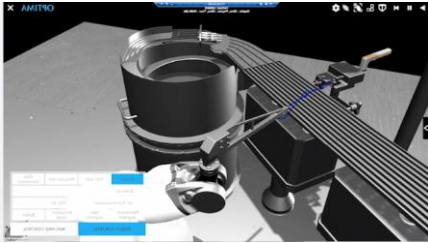**Heat map for typical syringe line for nested syringes**

► >90% of all interventions happen during the **stopper sorting/ intervention**

2. Application – Process description

Gloveless intervention on stopper sorting - Robot autonomously driven by AI

▶ Video

1	**2**	**3**	**4**	**5**
o Camera detects the **incorrectly sorted stopper and it's individual position** by using AI in the short linear track	o If the stopper is sorted incorrectly, **the short linear track and sorting bowl stops.** o The camera using AI **take a photo again (by rest)** and **transfer the coordinates of the incorrectly sorted stopper to the robot**	o **Autonomous path planning based on digital twin**. o Autonomous path planning considers pharma-compliant and best efficient execution.	o **Robot picks up incorrectly oriented stopper** with needle gripper. o **New picture is taken** before the sorting technology starts again as a cross check	o The **stopper will be removed**, and the robot returns to the rest position. Short linear track and sorting bowl start operation again. o The removement of stopper is checked by a cross check

**No machine stop/ production stop during the intervention**

3. Evaluation of the application

a) Attractiveness – Addressing critical point in fill & finish line (>90%)

Glove interventions are minimized through automatic fault elimination

❯ Improved process quality and efficiency

- **Annex 1 conform**: Autoclaved robot stopper handling tool

- **Glove minimization**: No manual intervention

- **Increased OEE**: No machine stop due to robotic intervention

- **Implementation in every fill & finish machine of the complete portfolio possible**: No machine-specific feature
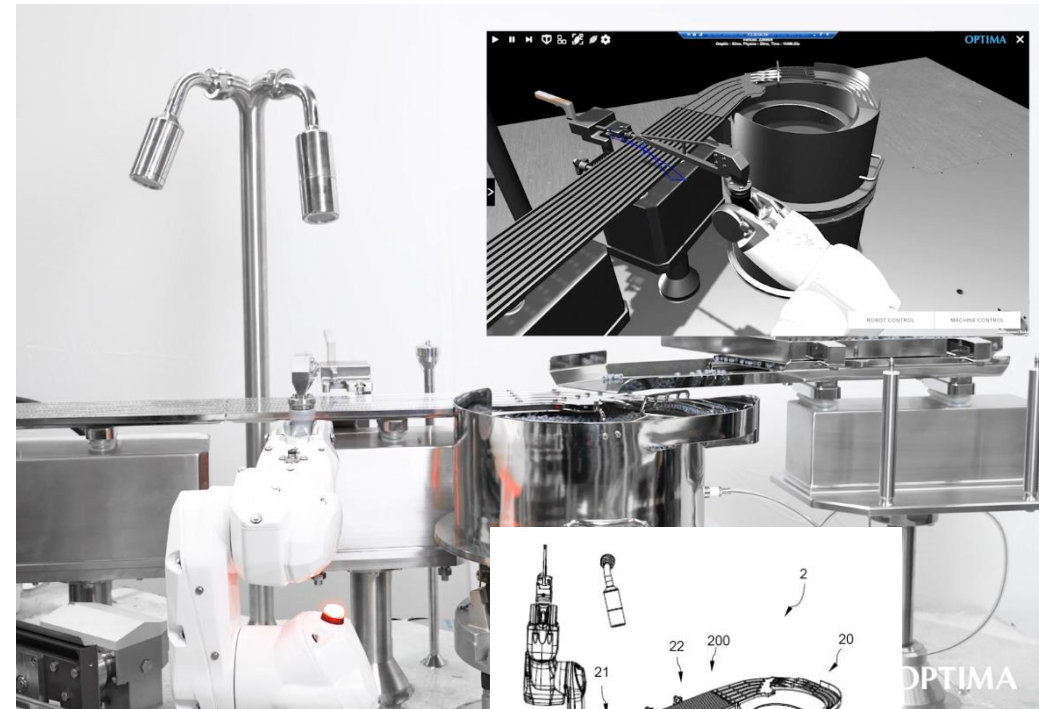
3. Evaluation of the application

b) Cost effectiveness – High economic potential

High economic potential, as it affects a very common fault in the system

❯ Estimated Return-on-Invest: approx. 1 year

- **Fewer personnel resources** required →**no manual intervention** needed for this activity

- **Less manual documentation** effort during production by operator

- **Reduced risk for contamination** →**no glove intervention**

- **Improvement of OEE** →**autonomous process during production**

3. Evaluation of the application

c) Area of application and flexibility

Area of application:

Every fill and finish machine for pharma/ biotech

Benefit: not machine-specific!

High flexibility of the application and easy integration in every fill & finish machine

> Needle gripper for:
> - **all stoppers**
> - **almost all defects**

> Flexibility of robot:
> - **fault can be removed along the entire stopper feeding path**
> - **Easily integration** into any application and portfolio
> - **Autonomous path planning** considers pharma-compliant and best efficient execution **for every fill & finish machine**

4. Final message - Highlights

Robotic intervention for glove minimization by using AI

Attracting all fill & finish systems in the pharma / biotech industry

- ✓ Addressing the most critical point in fill & finish line (>90%)

- ✓ Reduction of pharmaceutical risk as no manual intervention

- ✓ Increase of efficiency / OEE

- ✓ No intervention in fill & finish process during stopper feeding (gloveless)

- ✓ Patented technologies

- ✓ Technology already integrated at almost on 20 machines