



Process Mapping to identify automation opportunities in pharmaceutical manufacturing



Dr Frank Thielmann

Head Lean – Global Operational Excellence
Takeda Pharmaceuticals International AG



PharmaCongress 2022

01.06.2022

Better Health, Brighter Future

Disclaimer

This presentation is based on publicly available information; These slides are intended for educational purposes only and for the personal use of the audience. These slides are not intended for wider distribution outside the intended purpose without presenter approval;

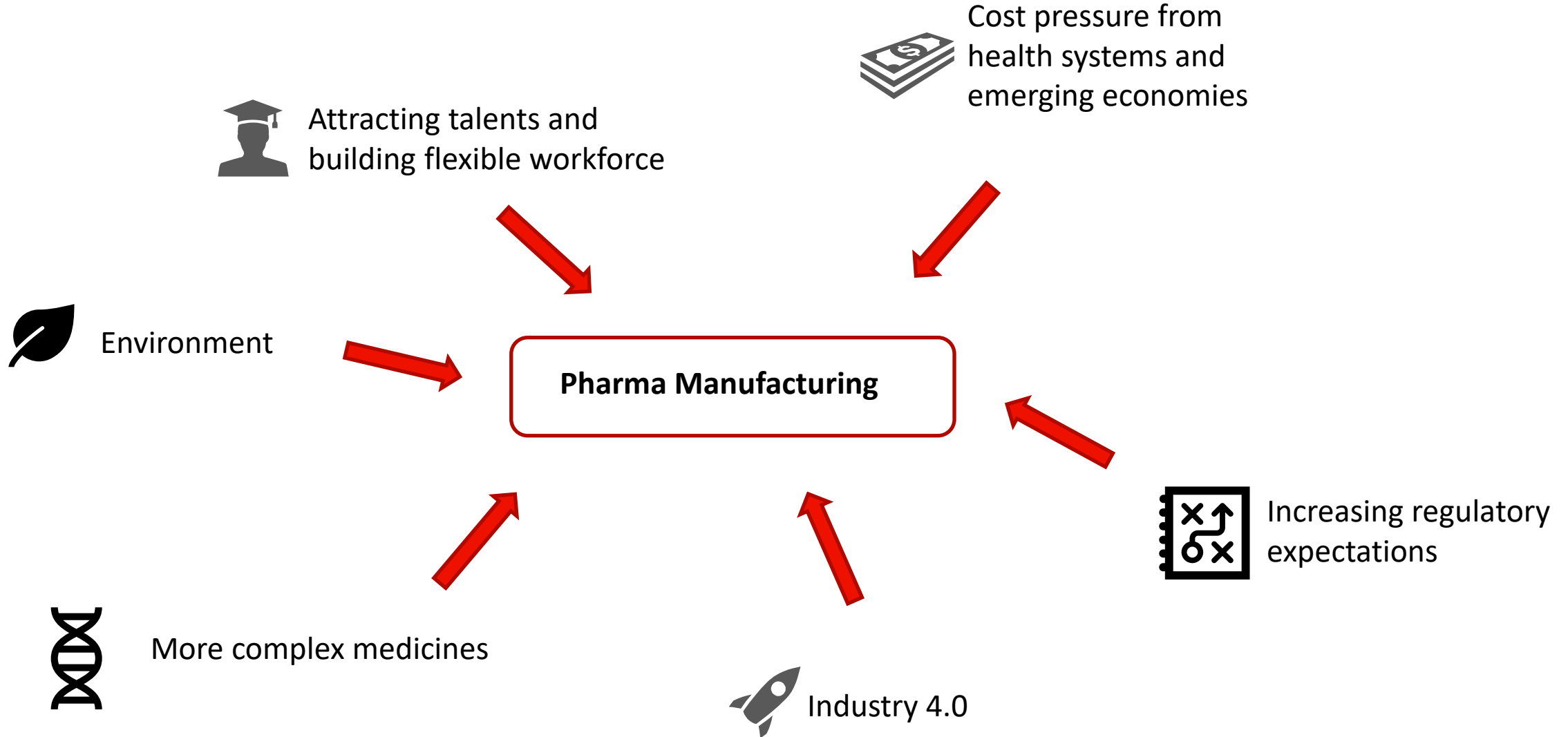
The content of this slide deck is accurate to the best of the presenter's knowledge at the time of production.

The views and opinions expressed in this presentation are those of the author and might not reflect the official policy or position of Takeda or any of its officers.

Overview

- **Case for change in pharmaceutical manufacturing**
- **Automation trends – Status in the pharmaceutical industry**
- **Process mapping for automation**
- **Conclusions**

Need for change and challenges



Current State of Pharmaceutical Manufacturing

- Not state-of-art compared to other industries
- Achieve reasonable quality – but at great effort and cost
- High amount of waste
- Manufacturing costs make high contribution to product unit cost
- Some issues to predict scale-up effects

Adapted from Janet Woodcock, FDA, February 2007

Purpose of Automation in the Pharma Industry

Increase productivity and reduce waste

Improve unit costs

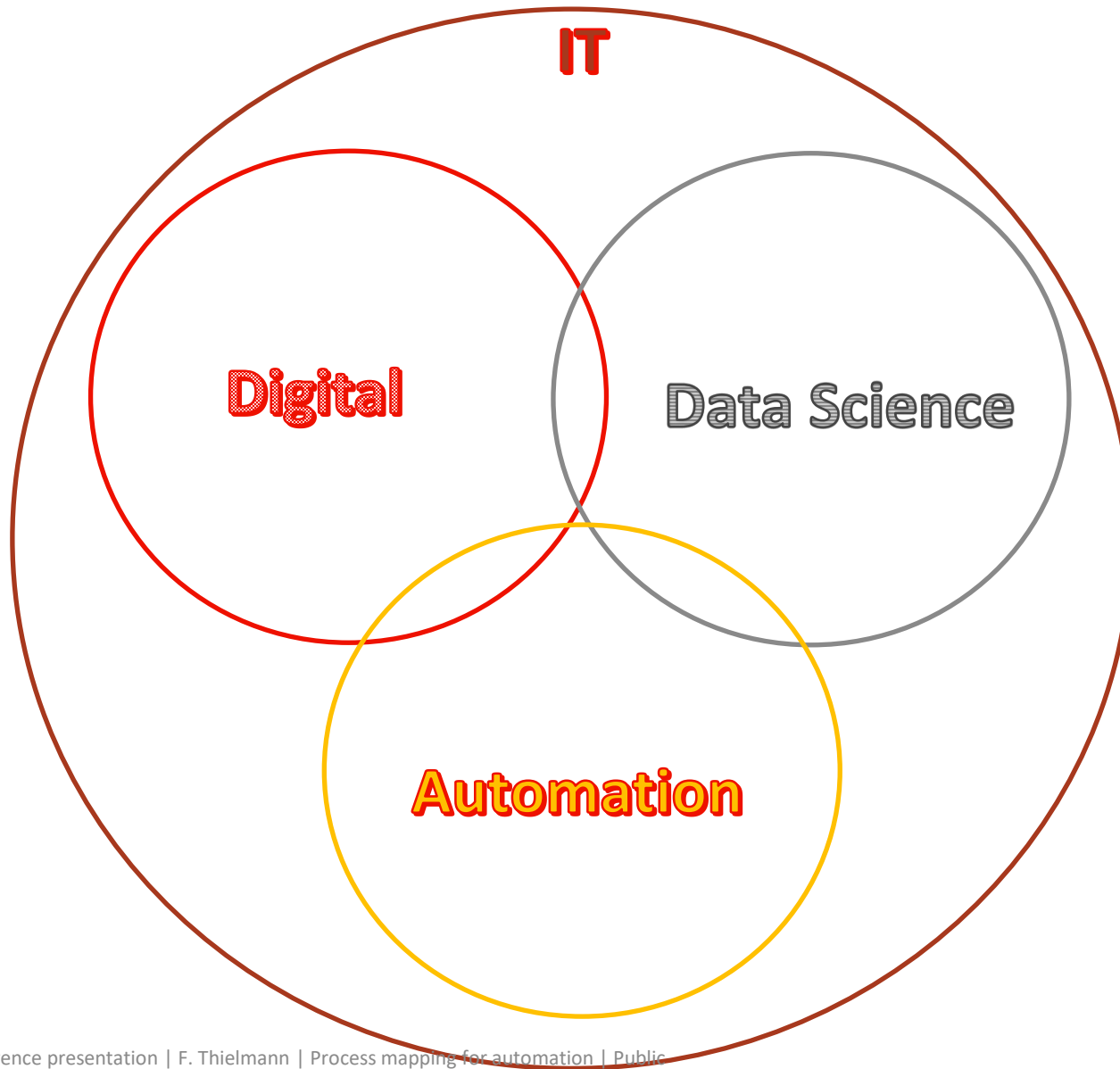
Reduce human errors

Improve quality

Better ergonomics (e.g heavy lifting)

Safety (handling of hazards)

Automation in Industry 4.0



What is different with respect to “classical” automation?

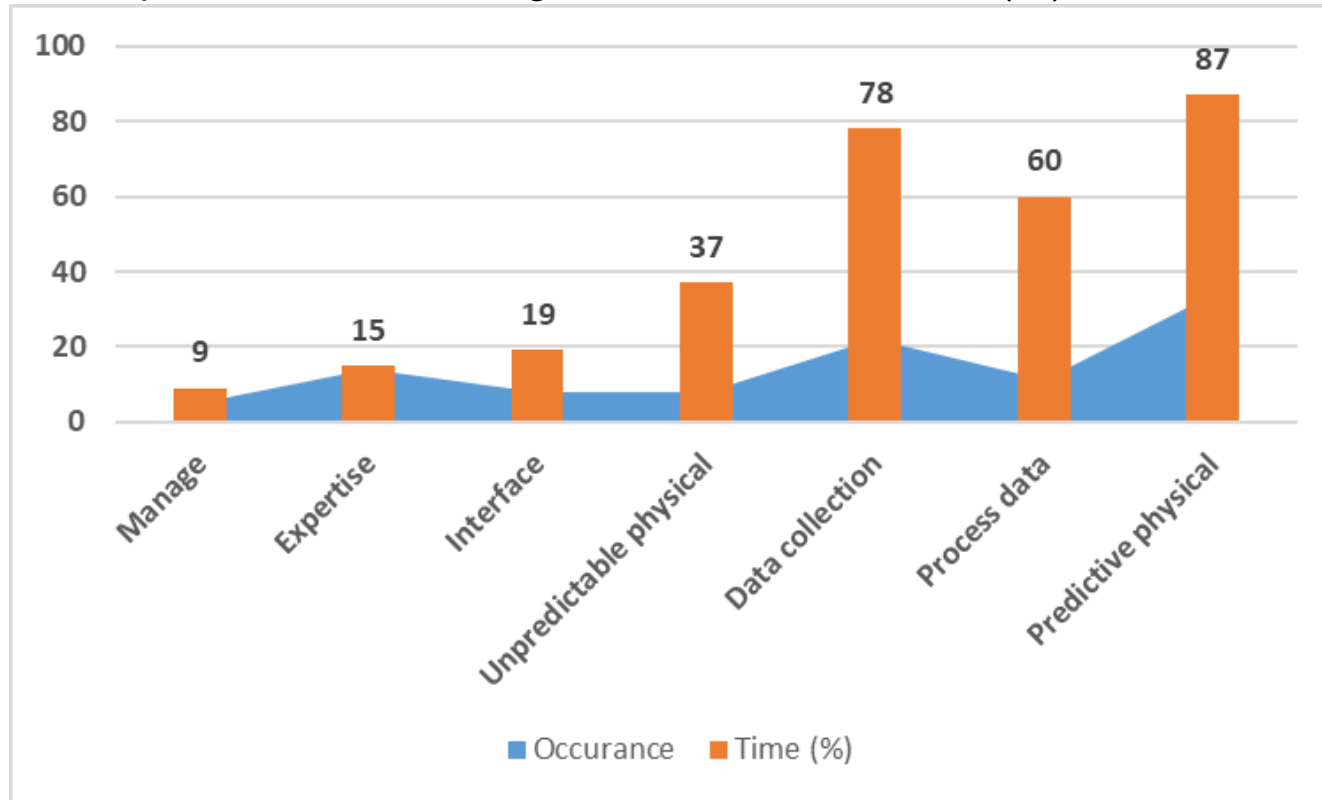
- Integrated solutions as part of Digitalization
- Better sensors, e.g. image recognition, touch sensors
- Collaboration with less space requirements (Cobots)
- More flexibility, e.g. based on AI/ML
- Simpler maintenance, programming etc

Overview

- **Case for change in pharmaceutical manufacturing**
- **Automation trends – Status in the pharmaceutical industry**
- **Process mapping for automation**
- **Conclusions**

Opportunities for automation

Time spent in manufacturing that can be automated (%)

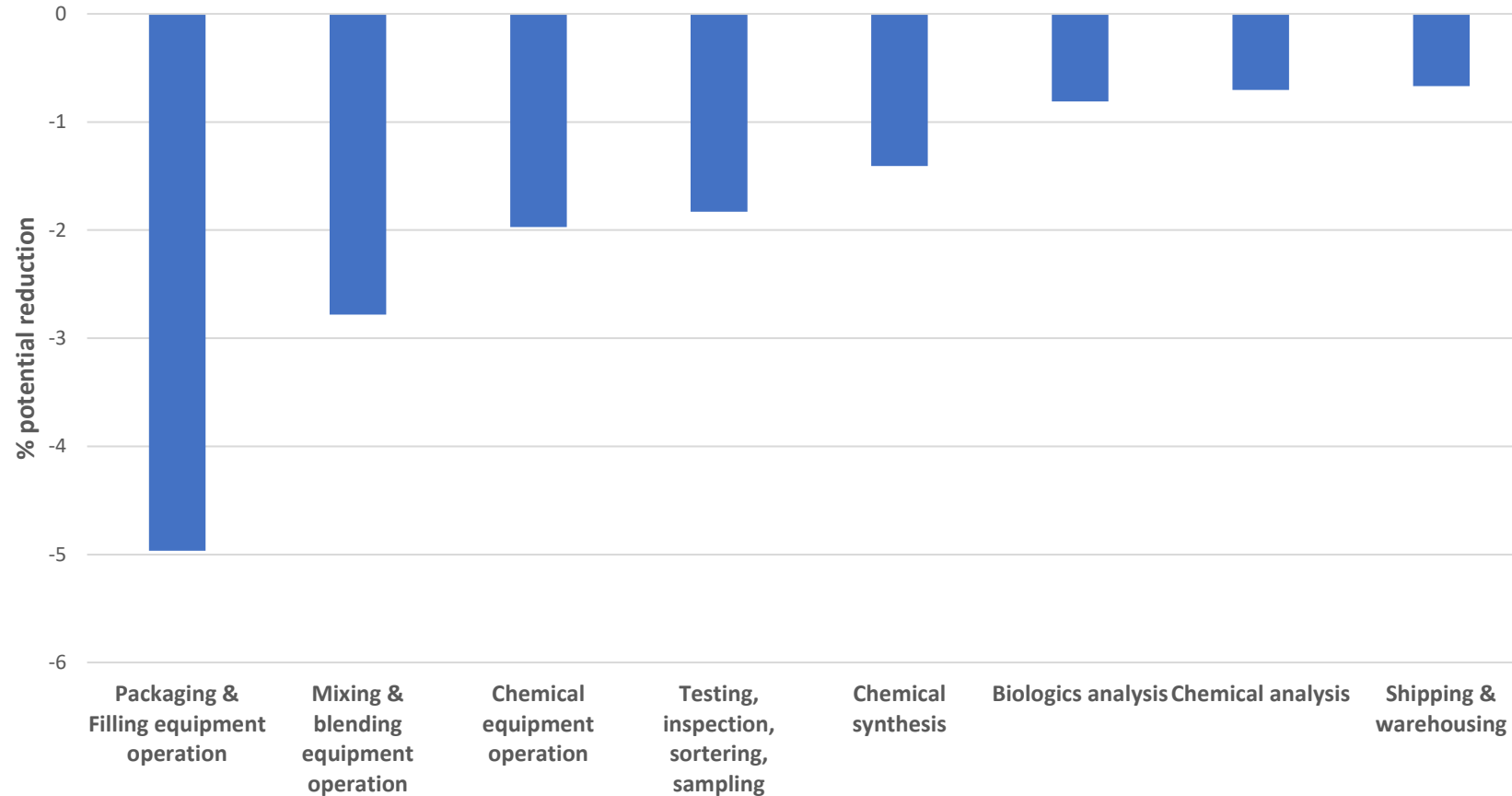


60% of manufacturing tasks can be automated, only 3% are!

Adapted from Ulf Schrader, Quantum Black Consulting

Impact of automation

Reduction in required labor due to automation (%) in 2030

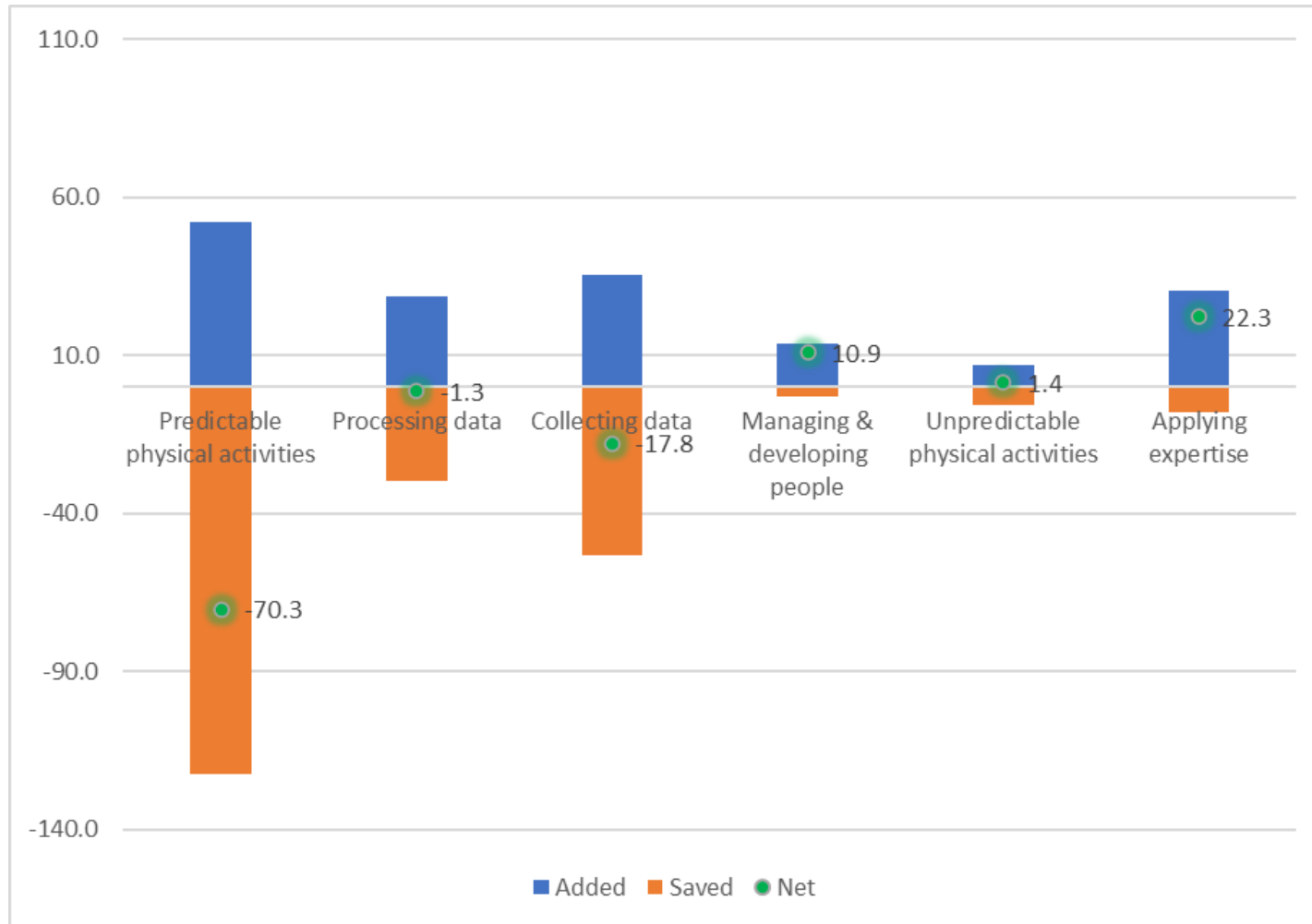


Opportunity to reassign workforce to more value-adding tasks!

Adapted from McKinsey Insights: Automation and the future of work in the US biopharma industry (2020)

Impact of automation

Percentage of working hours saved and added due to automation in 2030 in the pharma industry

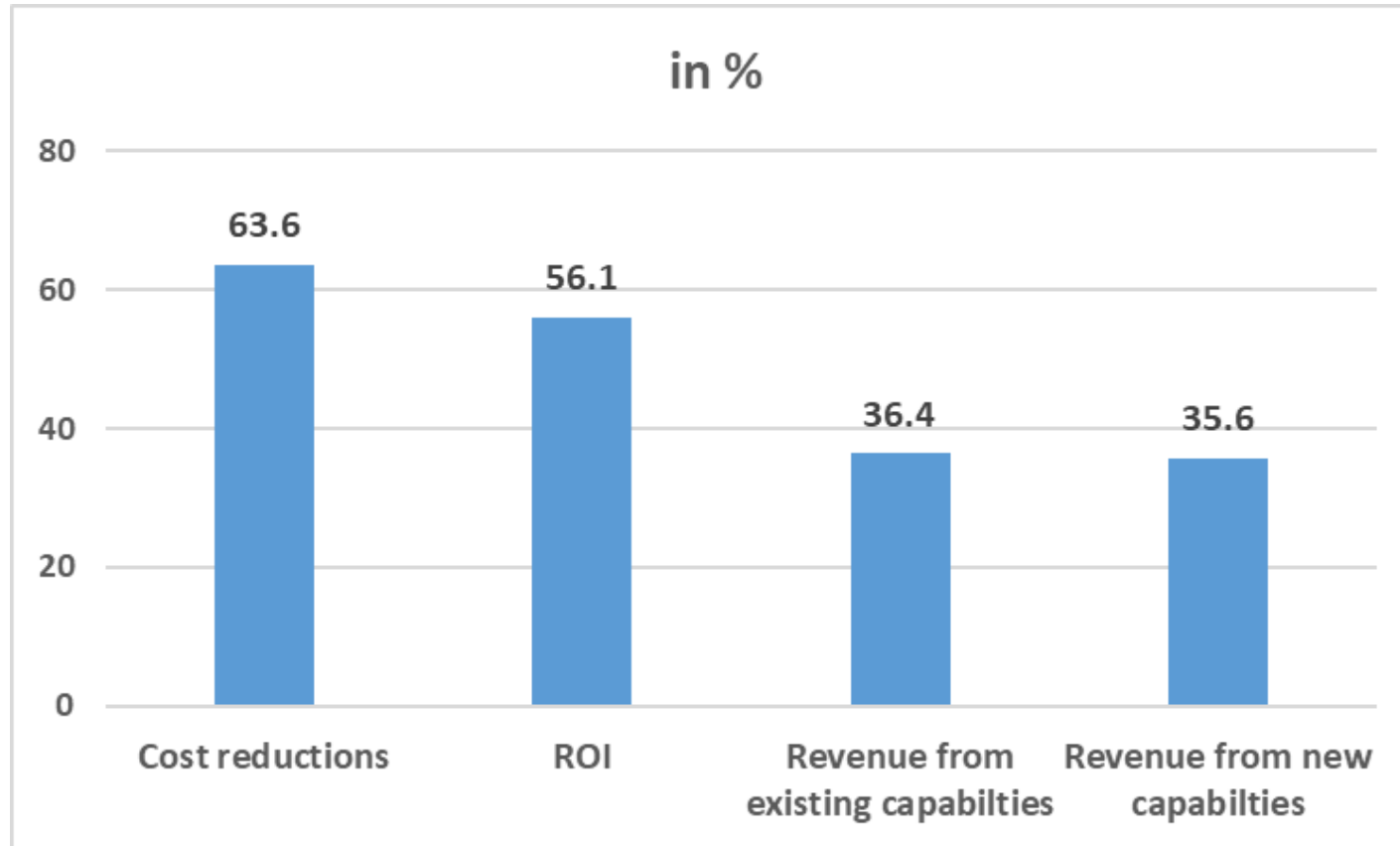


Opportunity to reassign workforce to more value-adding tasks!

Adapted from McKinsey Insights:
Automation and the future of work in the US biopharma industry (2020)

Measures of success in digital/ automation transformation

Financial Measures



Survey in different industries (including pharma)

Adapted from APQC Digital Transformation Survey

Overview

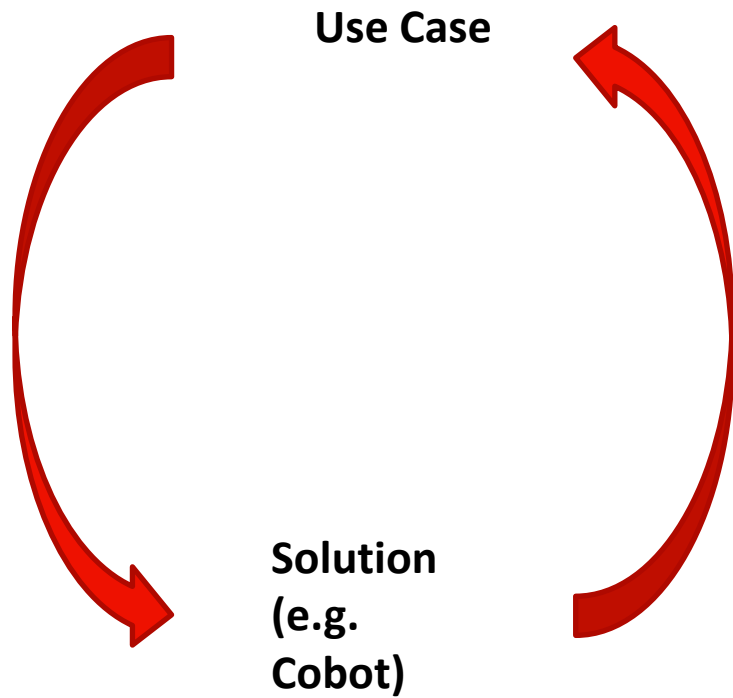
- **Case for change in pharmaceutical manufacturing**
- **Automation trends – Status in the pharmaceutical industry**
- **Process mapping for automation**
- **Conclusions**

Challenges for Automation in the Pharma Industry



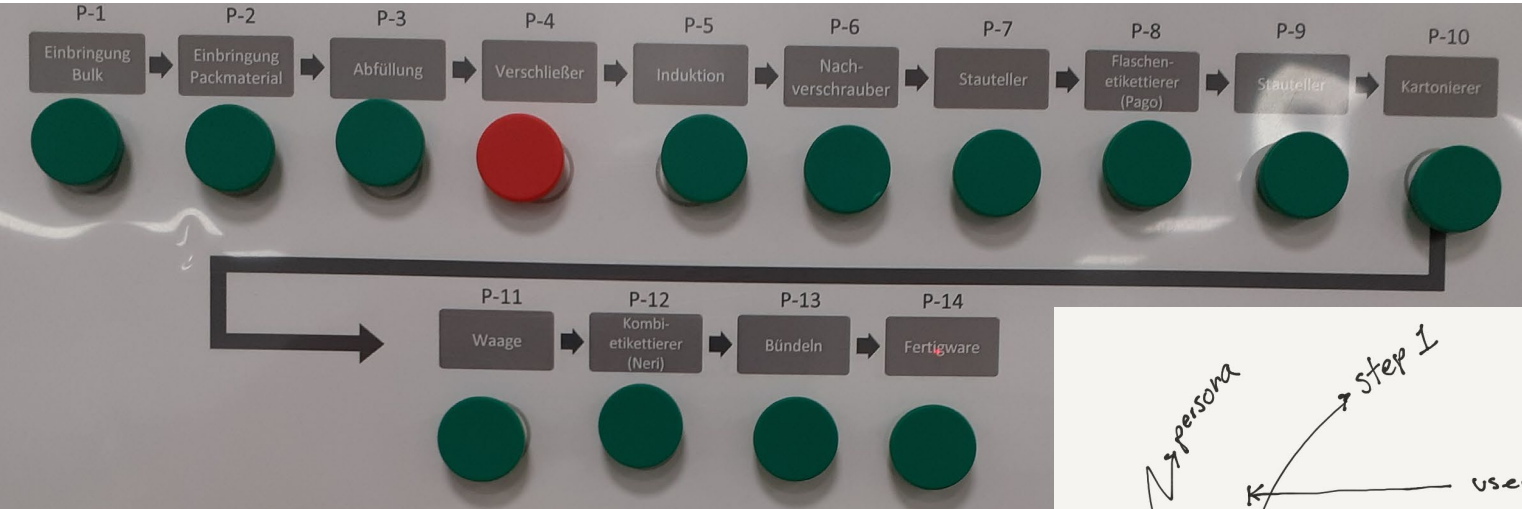
Need for tailored solutions

How and where to automate?



Picture Source: adapted from Bing public domain images

Process Mapping to identify Use Cases



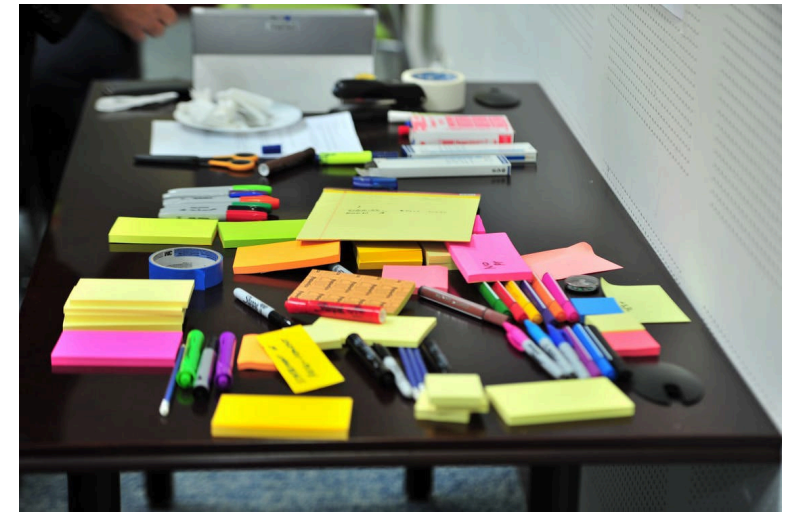
Picture Source: Takeda internal



Picture Source: adapted from Bing public domain images

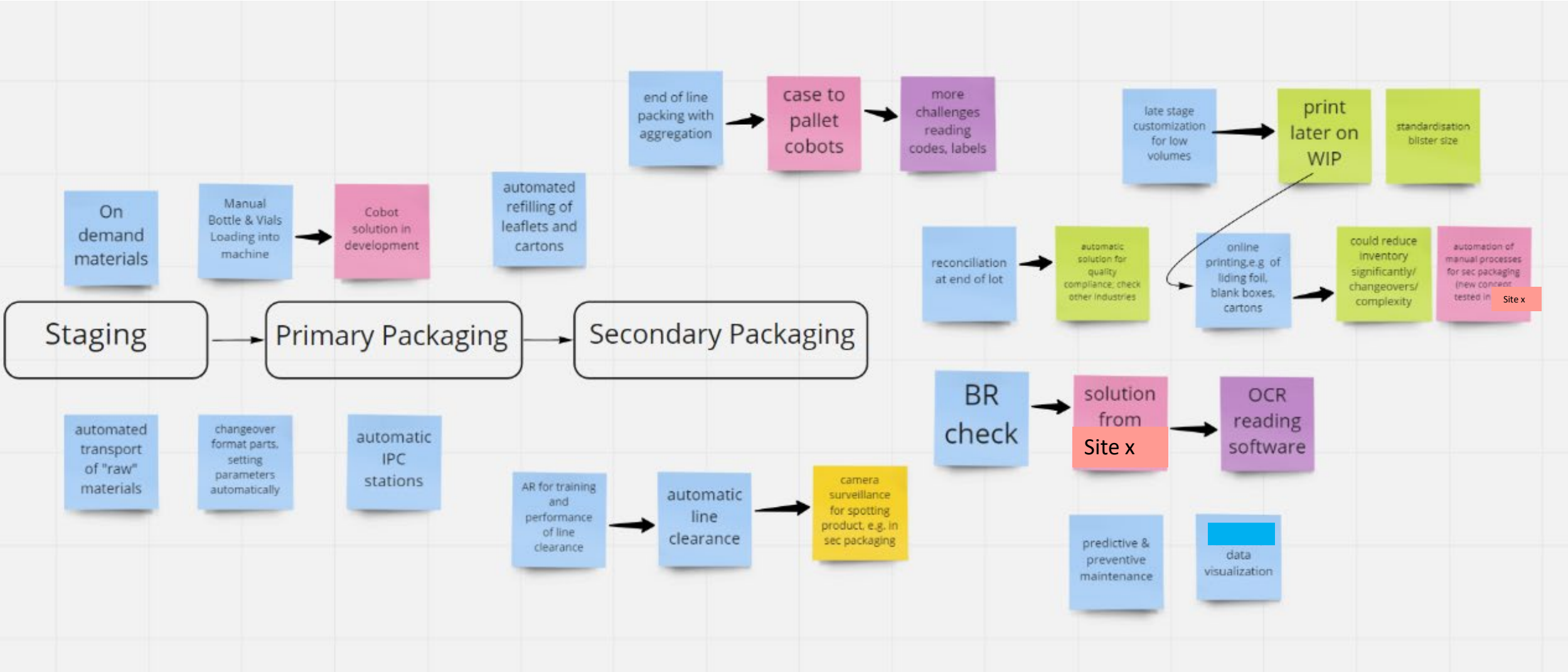
Process Mapping to identify Use Cases

1. Map key processes, i.e. OSD, F&F, QC, Packaging, logistics
2. Identify gaps where automation adds value (e.g. productivity, EHS, environment)
3. Identify appropriate automation solutions (internal and external)
4. Establish Roadmap for implementation and seek funding



Picture Source: Bing public domain images

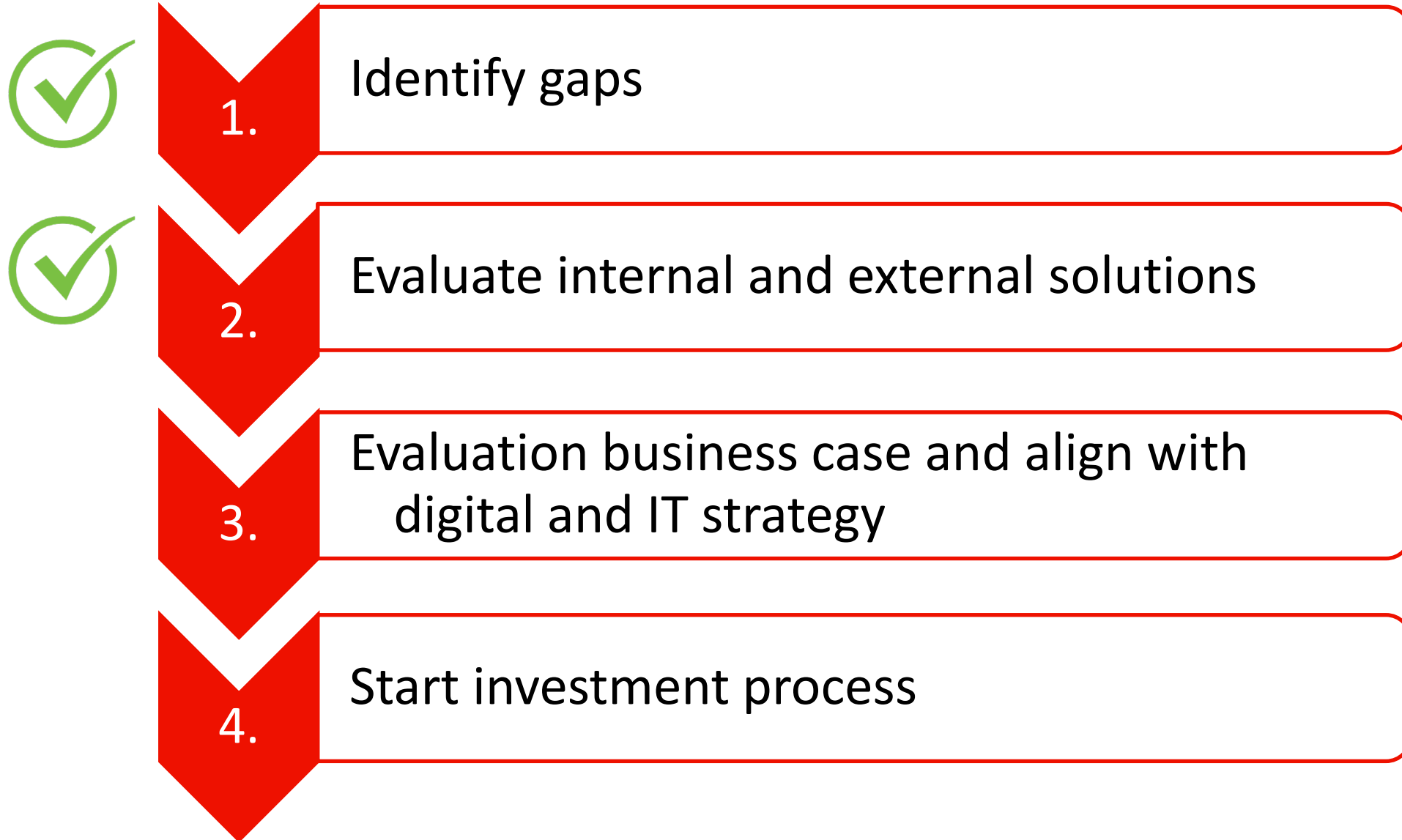
Process Mapping: Example Packaging



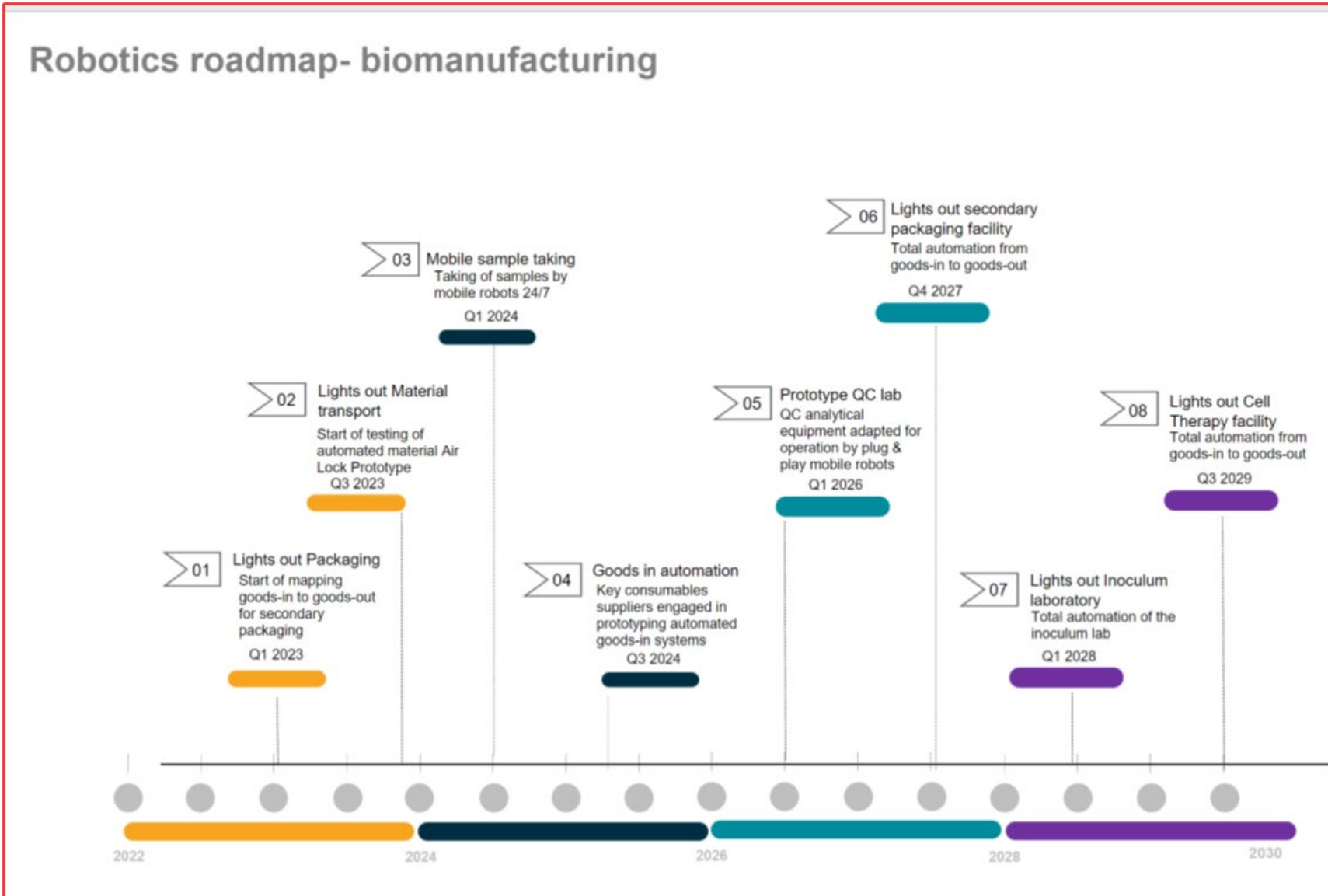
Process Mapping Packaging: what already exists

Process gaps	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7
Changeover	manual changeover, first discussions with suppliers about usage of AR, but nothing implemented yet	manual changeover, checklists available	AR / knowledge database assist for C/O processes (pilot) create21st century;	Manual Changeover	Manual Changeover	Manual Changeover	Manual changeover
Manual Bottle & Vials loading into machine	Operators open bags and puts PE-bottles into machine (bottle unscrambler)	yes, manual loading takes place		Not applicable	Operators open bags and puts bottles into machine	Operators open bags and puts bottles into machine	Operators open bags and puts bottles into machine
online printing, e.g. of lidding foil, blank boxes	1 blister machine with online lid foil printing capabilities but not in usage yet	online printing of variable data, but no blank boxes	analysed a couple of years ago due to very high investment costs	1 blisterline. Lidding foil is pre-printed. No online printing. Currently just 3 SKUs	1 blisterline equipped with online lid foil capability. Huge potential for reduction in inventory holding, changeover time etc. Should consider # colours on artwork	The blister module of the ampoule packaging line has a machine learning camera for detecting ampoule breakage on the drum. Now in the stage of collecting information for learning	
late stage customization for low volumes	currently not in place	currently not in place		Not in place. Only 3 SKUs in primary packaging. Multiple in secondary packaging	In place for 2 products (2 more in progress)		
line clearance	manual	manual	some mechanical improvements implemented; camera/ sensor system evaluated - negative cost/benefit ratio	Manual	Manual	Manually. As part of optimization projects, this procedure has been reduced and moved out of the flow of internal SMED operations	Manually

Process Mapping for automation: next steps

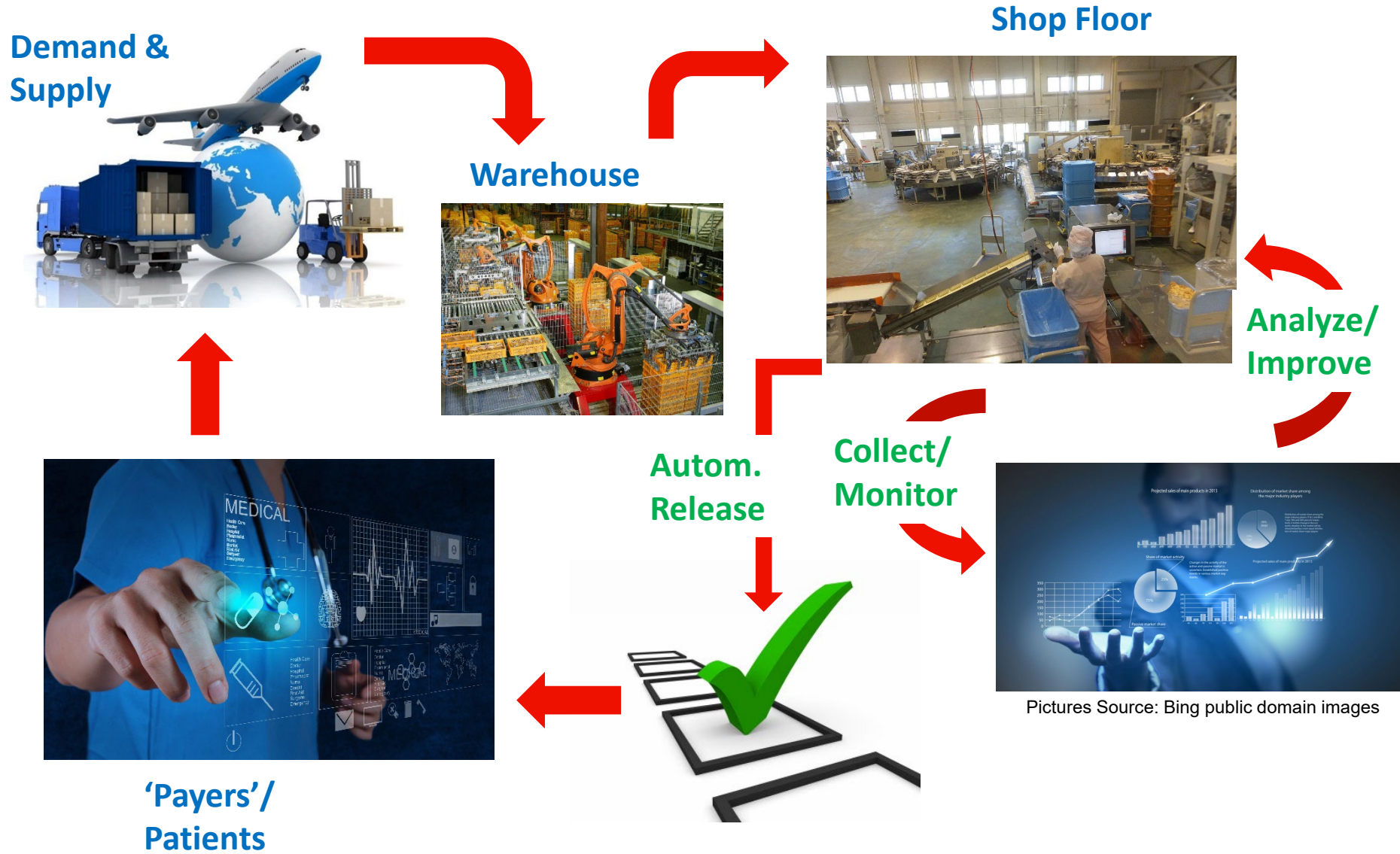


Generic roadmap to lights-off manufacturing for logistics to packaging



BPOG are looking of OE people to join the robotics technical road map team – if you are interested email graeme.moody@biophorum.com

Digital Future of Production



Overview

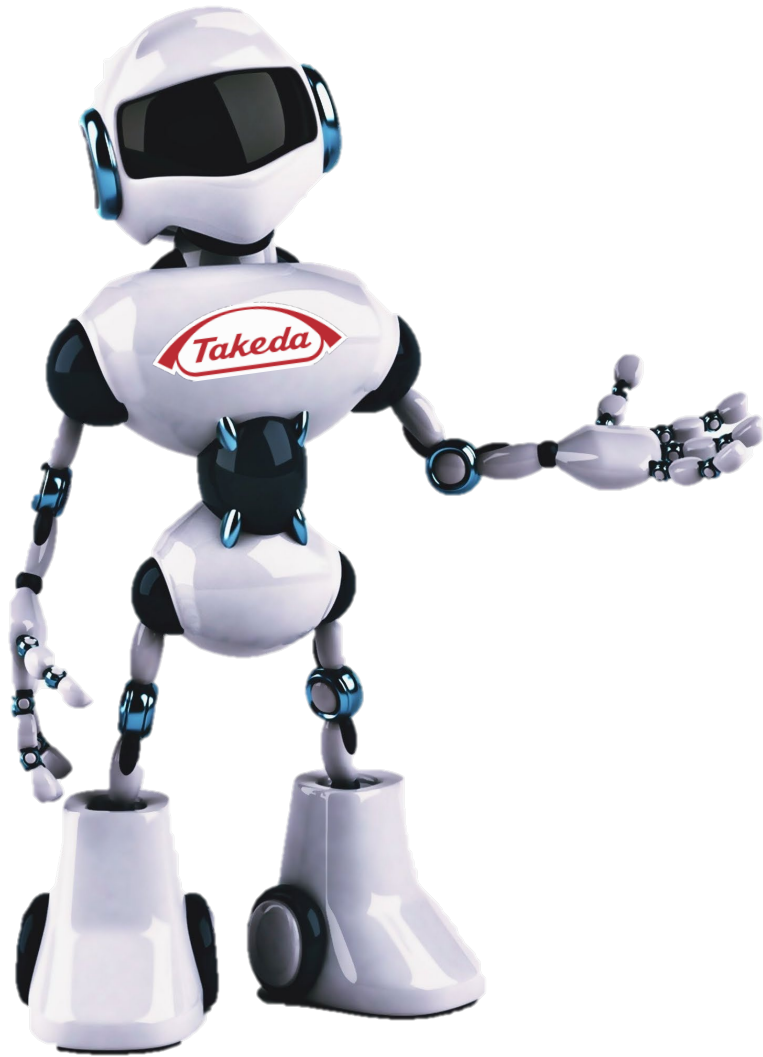
- **Case for change in pharmaceutical manufacturing**
- **Automation trends – Status in the pharmaceutical industry**
- **Process mapping for automation**
- **Conclusions**

Conclusions

- 1 Automation in combination with Digitalization is disruptive for the way the pharma industry is manufacturing products.
- 2 Automation solutions needs a careful selection to balance increased technical complexity with benefit.
- 3 Automation applications have enormous potential to improve quality, efficiency and decrease costs.
- 4 Automation and Digitalization is not just an opportunity for the core manufacturing process but also for the surrounding business processes.
- 5 Requires also a change in mindset: manufacturing operations must embrace innovation and continuous improvement culture more.

Acknowledgements

- **Takeda Global Engineering Process & Technology Team**
 - Julien Janda
 - David Wolton
 - Dominic Duda
- **Operational Excellence colleagues and many SMEs from various Takeda locations, especially**
 - Karoline Gundersen Botten
 - Bogdan Gandow
 - Deirdre Connaughton
 - Michael Huber
 - Maxim Petruchak



Thank You

Picture Source: adapted from Bing public domain images