

A View Into Pharma 4.0

Modernizing Manufacturing in Regulated Industries to Support the Connected Worker

Presented by

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Thank you for joining!

Use the Q&A button on the bottom of your screen to submit questions

Speakers



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Webinar Objectives

1 Human-centric Digital Manufacturing

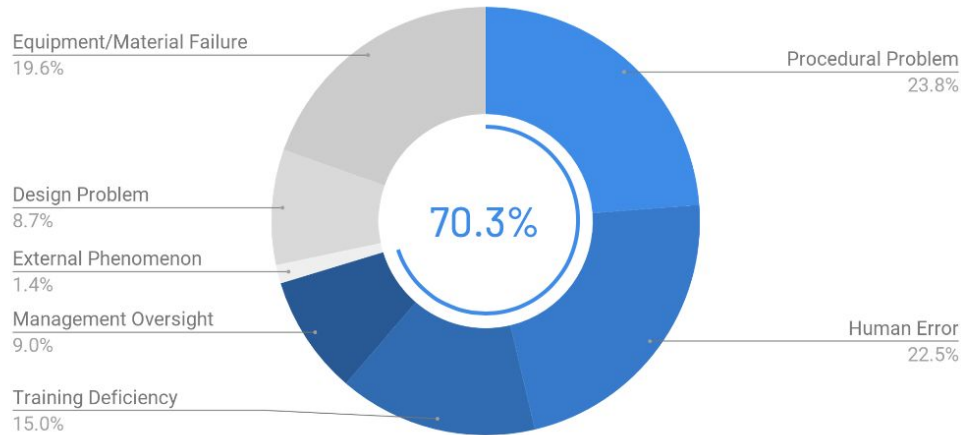
- Why people matter
- The augmented and connected worker
- What is digital manufacturing

2 Digital pharma manufacturing in practice

- Exemplifying digital manufacturing at Vertex
- Benefits of connecting & augmenting workers

Automation is not the solution

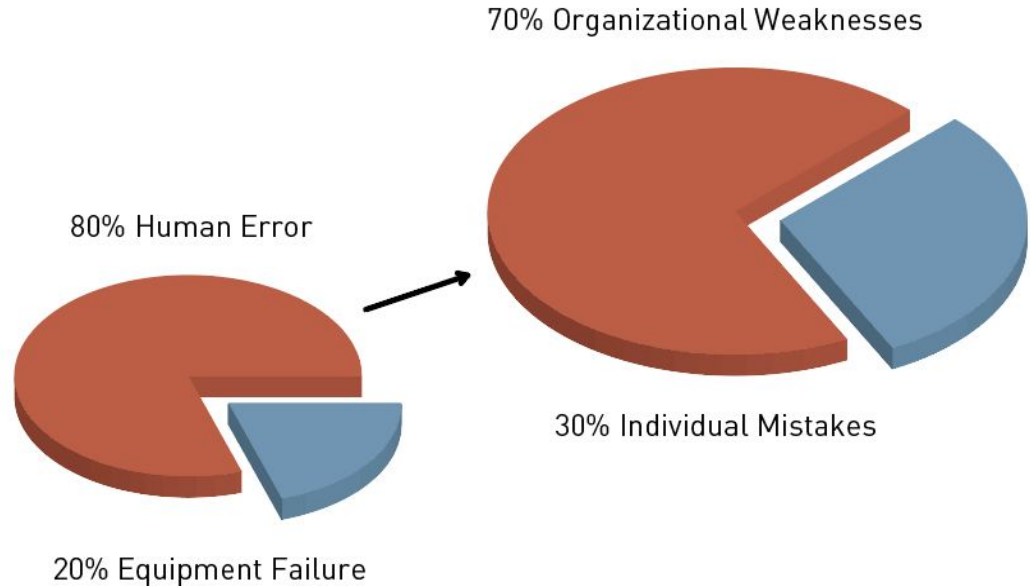
Manufacturers spending \$2T/year on automation, but **it's not solving their biggest problems**



Source: IHS Markit, DOE "Human Performance Improvement Handbook"; Noria research

70-80% of factory failures are caused by **human-centric processes**

These “human problems” are symptoms of other failures



Augmentation scales human capabilities

Humans are magnificent machines.

Excellent visual context analysis.



Real Intelligence.

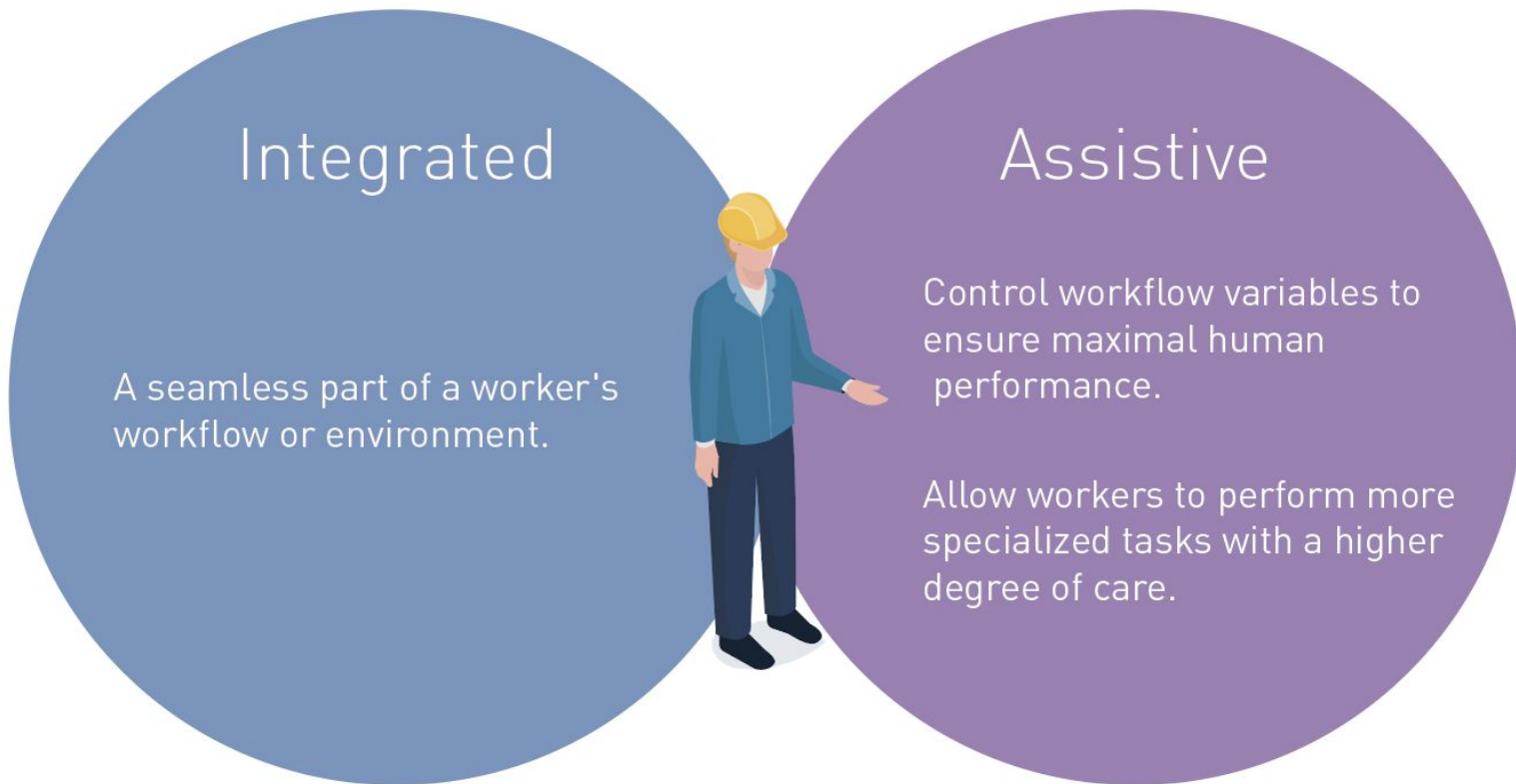


Mobile articulated grippers.



- + Digital technologies supplement hard skills - physical skills.
- + Digital technologies supplement uniquely human skills - people management, creativity, adaptability

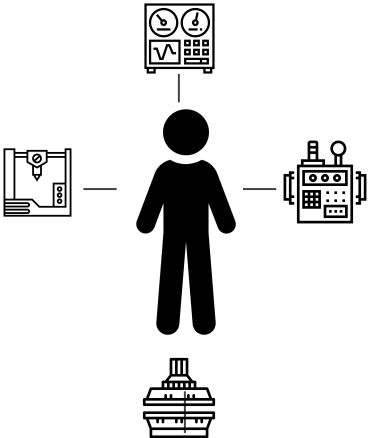
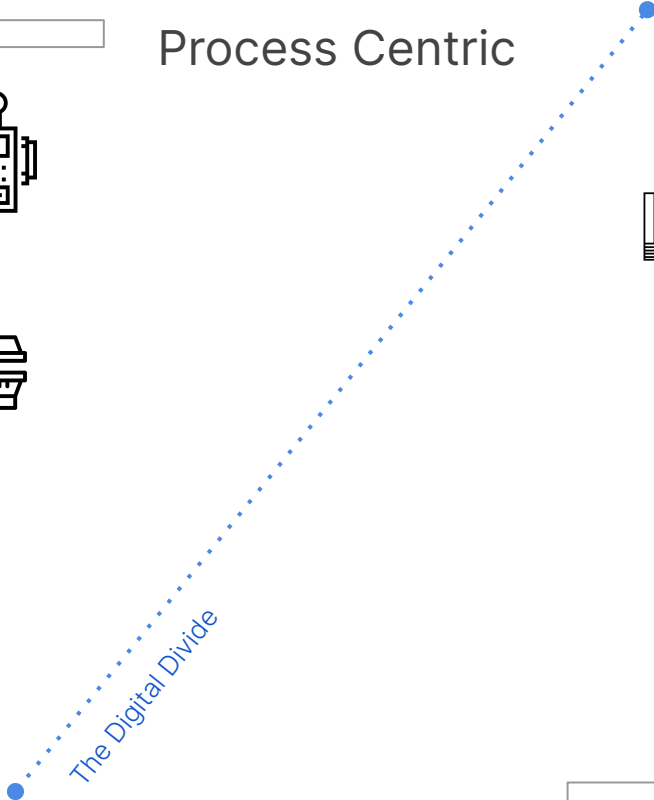
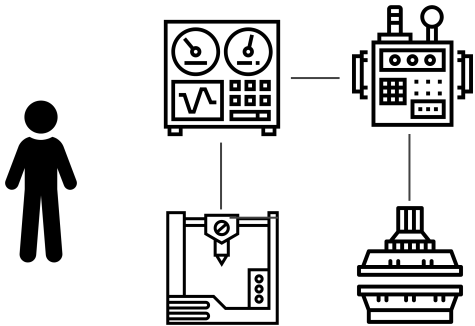
What makes technology human centric?



Digital manufacturing is human centric

3.0

Process Centric

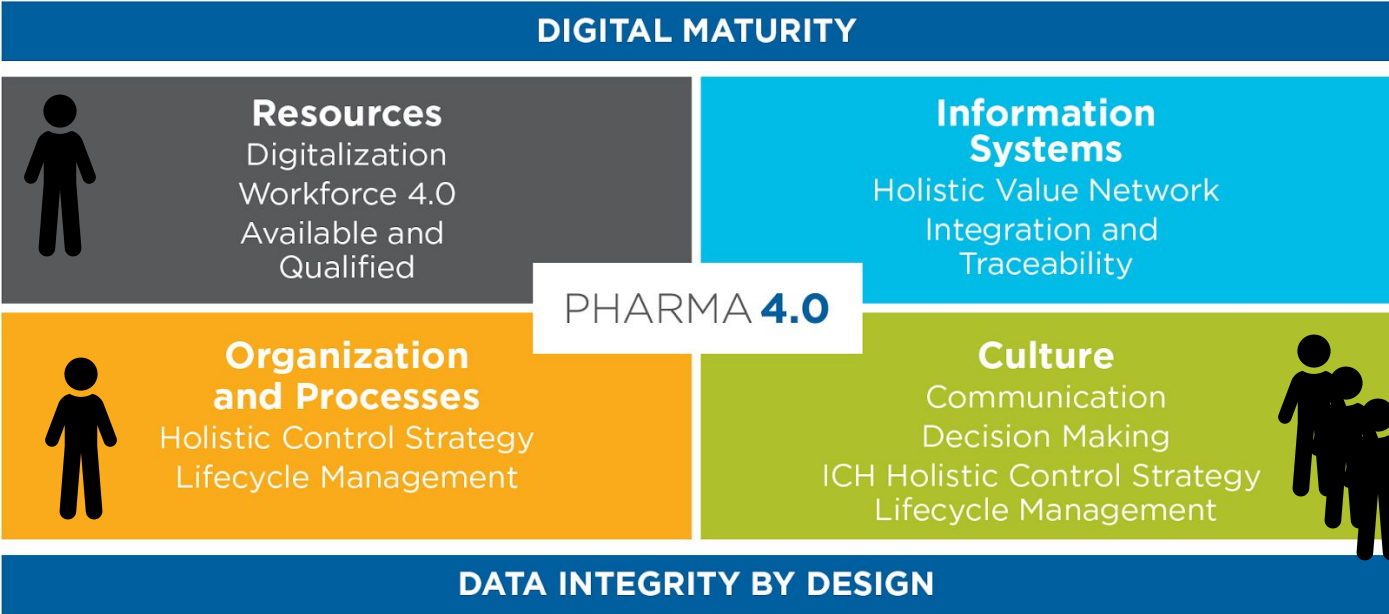


Human Centric



4.0

Pharma 4.0 is also very much “Human Centric”



Fundamentals of digital manufacturing

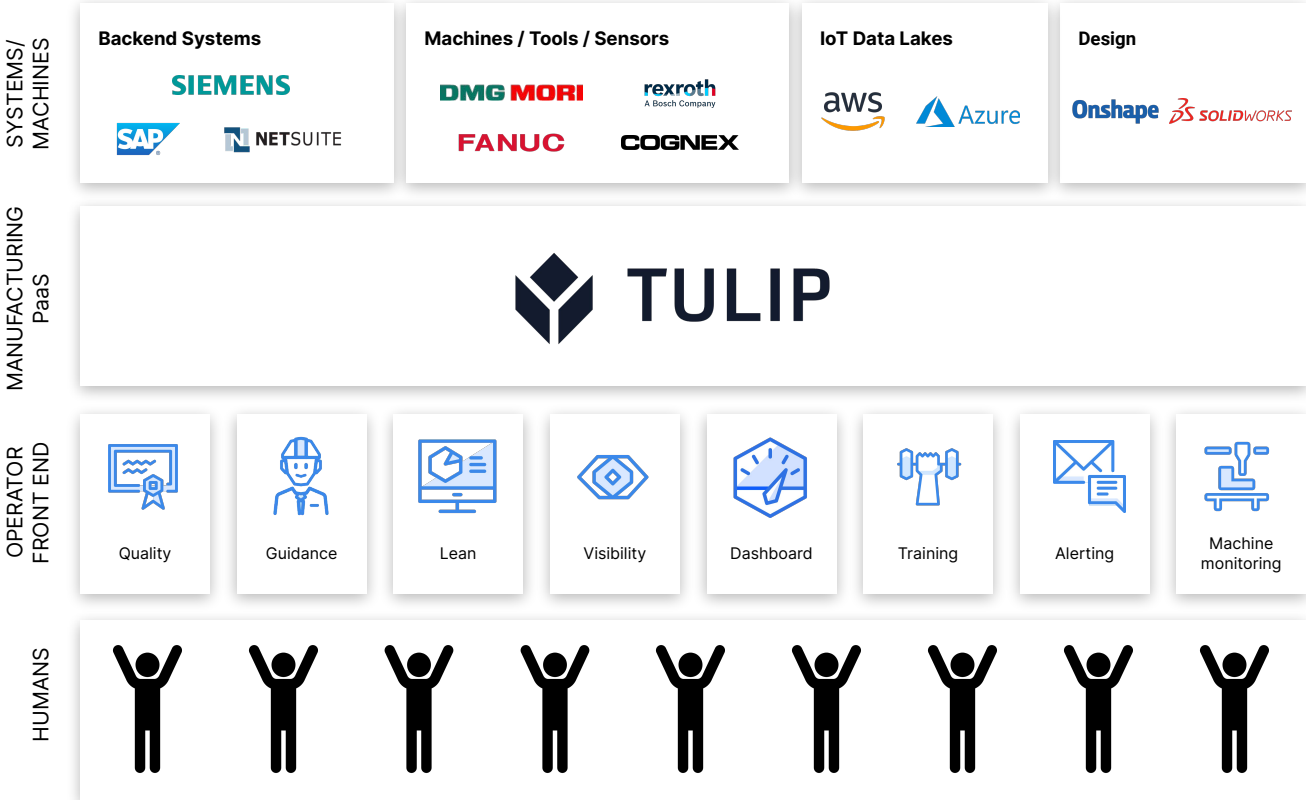
- + Connected machines and devices
- + Connected digital workflows
- + Cloud computing

The screenshot displays a digital manufacturing workstation interface. The top navigation bar includes 'Apps / 3. New Demos / Word Clock Assembly / Word Clock Assembly Station' and buttons for 'Run', 'Create Snapshot', and 'Publish'. Below the navigation bar is a toolbar with icons for 'Add', 'Assets', 'Buttons', 'Inputs', 'Text', 'Embed', 'Camera', 'Timers', 'Forward', 'Back', 'Cut', 'Copy', and 'Paste'. The main interface is divided into three sections: 'STEPS', 'RECORDS', and a central workspace. The 'STEPS' section on the left lists 12 steps, with step 5, 'Remove RTC module from jig', highlighted. The central workspace shows a video feed of a workstation with a 'REPORT DEFECT' button overlaid. The 'RECORDS' section on the right contains a 'Work Order' table with columns for ID, Product, and Color, and a 'Parts' section listing '1 Circuit board' and '1 RTC Module'. The bottom of the interface features a navigation bar with 'CALL FOR HELP' and 'SEND MESSAGE' buttons.

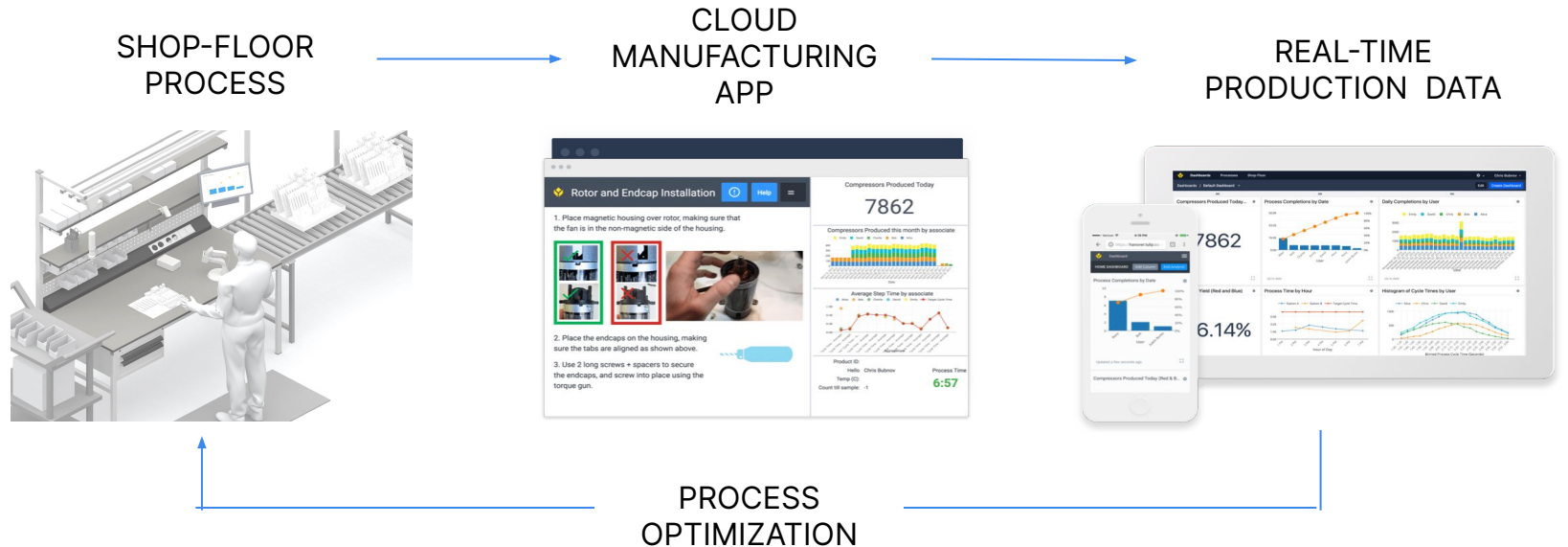
Work Order
Work Order #
Work Order #
Product
Color
Product
Color

Parts
1 Circuit board
1 RTC Module

Humans are the **Foundation of the Factory Stack**



Tulip is used to augment & optimize human centric processes



✓ SAAS DELIVERY

✓ SELF-SERVICE

✓ RAPID TIME TO VALUE

Some Additional Features

- ✓ Digital checklists
- ✓ Digital forms for capturing notes and other use inputs
- ✓ Capture pictures for quality checks
- ✓ Implement required fields to ensure completion

Punch & Die Inspection form (check off each punch and die set after inspection) [D ECM]

✓ #1 Die & Punch	#11 Die & Punch	#21 Die & Punch
✓ #2 Die & Punch	#12 Die & Punch	Add any notes here Punch 5 was damaged
✓ #3 Die & Punch	#13 Die & Punch	
✓ #4 Die & Punch	#14 Die & Punch	Add any relevant pictures here Capture
#5 Die & Punch	#15 Die & Punch	
✓ #6 Die & Punch	#16 Die & Punch	
✓ #7 Die & Punch	#17 Die & Punch	
#8 Die & Punch	#18 Die & Punch	
#9 Die & Punch	#19 Die & Punch	
#10 Die & Punch	#20 Die & Punch	

Cancel Menu Submit

A view into


VERTEX[®]


→ Complex System:

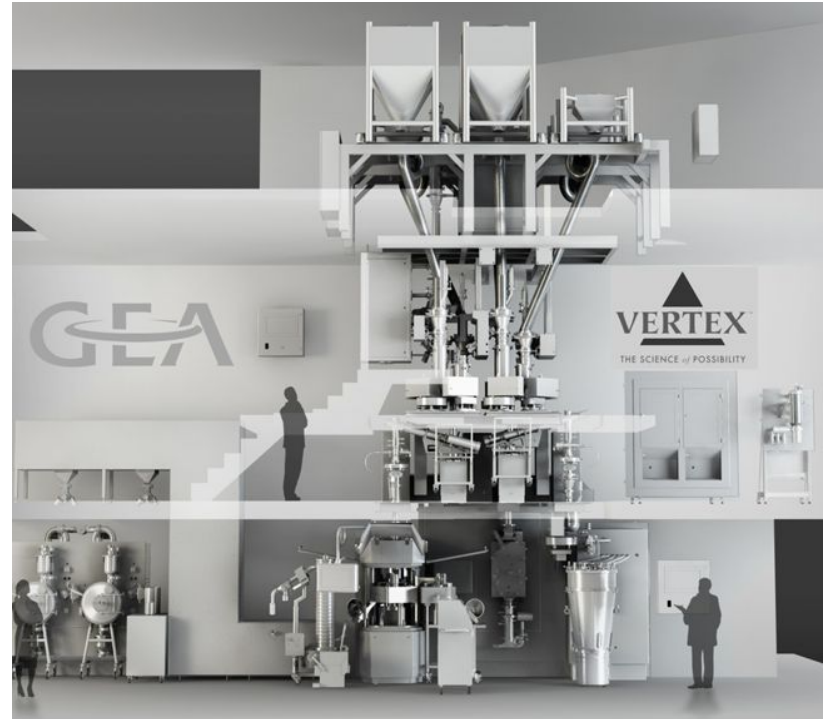
- Continuous oral solid dosage line with 3 configuration (WG/DG/DC)
- Over 2500 parts
- 10 day turnaround time (disassembly, cleaning, reassembly)
- Over 30 Standard Operating Procedures (SOPs) and Work Instructions (WI's) (up to 86 pages long)

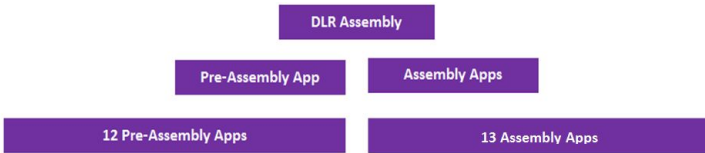
→ Infrequent Turnarounds:

- 5 to 10 turnarounds per year depending on the production schedule

→ Employee Flux:

- Challenge training new employees on system assembly
- Need to capture all knowledge and best known methods
- Effective and efficient training process is needed





~2300 pages

Tulip Job Aid Applications

- High level overview of process with ability to drill down
- Detailed assembly instructions with videos/pictures
- Assembly order logic in place
- View assembly status from anywhere
- Tracked assembly data used for continuous improvement
- Link to any other system with an API endpoint
- Improve training based on usage

Assembly Application Example – Roller Compactor

RC PA Summary

← Previous

☰ Menu

Reference Materials

Petrus Geldenhuis
Development Version

Roller Compactor Pre-Assembly

Select a sub-assembly to start the pre-assembly process

Completed
Jordan Berrios

Tamp Auger Assembly

Completed
Jordan Berrios

Side Seal Assembly

Completed
Jordan Berrios

Rolls & Scrapers Assemblies

Completed
Jordan Berrios

Granulator Exit

Completed
Jordan Berrios

Outlet Valve & Collection Tube Assembly

Inlet Tube, Feed Hopper & Auger Assembly

Completed
Jordan Berrios

Door Assembly

Completed
Jordan Berrios

Granulator Assembly

Completed
Jordan Berrios

Suction Shoe

Completed
Jordan Berrios

Step Details – Coater Air Knife Gap Check



Step 1.1 - C1AK1: Gap Check
(< 0.5 mm)

← Previous

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SOP-0610

Petrus Geldenhuis
Development Version

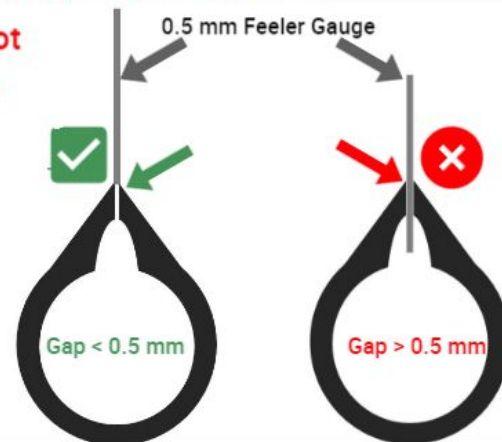
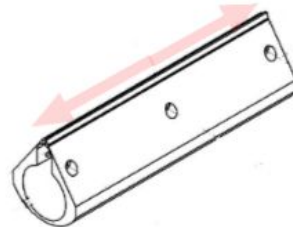
Step 1.1 - C1AK1: Gap Check (< 0.5 mm)

NOTE: The gap should be between 0.4 mm and 0.5 mm

1. Use a 0.5 mm feeler gauge to check the air knife gap
2. Make sure the feeler gauge CANNOT pass through the gap through the entire range

Quality Check

The feeler gauge cannot pass through the gap anywhere







Select one:


Feeler gauge CANNOT pass through gap

Feeler gauge CAN pass through gap

Step Details – Coater Bioprene Tube Install

	Step 1 - Suspension Recirculation Pump	← Previous	☰ Menu	Reference Material	Petrus Geldenhuis Development Version
Step 1 - Suspension Recirculation Pump Bioprene Tube Install					
	<ol style="list-style-type: none">1. Open the suspension recirculation pump (SC6790)2. Attach the left side of the bioprene tube to the stationary clamp3. Seat the bioprene tube over the pump rolls4. Cut the bioprene tube to the appropriate length 				
	Parts	Quality Check			
	 <p>Biopren Tube (#24) 6.4 mm Bore 2.4 mm Wall 15 m</p>	<p>Ensure the bioprene tubing is properly seated on the rolls</p> <p>Completed</p>			

Step Details – Coater Pump Head Checks



Coater Pump Head Checks

← Previous Menu Reference Material

Petrus Geldenhuis
Development Version

Coater Pump Head Checks

Click HERE for pump head size location details

Coater B

Pump head: 1.6 mm
SC6755

XS6765 XS6775

FT6705

Pump head: 2.4 mm
SC6705

Coater A

Pump head: 1.6 mm
SC6750

XS6760 XS6775

FT6700

Pump head: 2.4 mm
SC6700

Pump head: 2.4 mm
SC6790

1. Confirm that the size of each installed pump head matches the pump head size on the diagram
2. Check each checkbox to confirm the correct size
3. Press continue to proceed

Continue Confirm the pump head size on each pump and check the checkbox next to each pump to continue

Some Additional Features Continued

Part	Part # & Description	Update Quantity	Selected Quantity	Order Status	Last Ordered Quantity	Last Updated By	Reason For Order
	Seal Silicone DN150 Part # L60320226000001 BOS # XXXXXXXX	Add Remove	2		1		Missing Damaged Single Use Missing
	Seal NW150 Part # 526150000 BOS # XXXXXXXX	Add Remove	1		1		Missing Damaged Single Use Damaged
	DN200 MEI Butterfly Valve Seal Part # AF194555 BOS # XXXXXXXX	Add Remove	1		1		Missing Damaged Single Use Damaged
	Bellow DN150 Part # 8000454855 BOS # XXXXXXXX	Add Remove	1		1		Missing Damaged Single Use Single Use
	6" Silicone Tri-Clover Seal Part # 4523060000 BOS # XXXXXXXX	Add Remove	1		1		Missing Damaged Single Use Single Use
← Previous	Click HERE to process order	Quantity Ordered	Ordered By	Delivered By	Click When Delivered	Click When Received	Add dit Notes

- ✓ Parts ordering function
- ✓ Show status of parts
- ✓ Ordered, in process, delivered, received
- ✓ Log reason for ordering
- ✓ Log reason with a single button
- ✓ Capture pictures of damaged parts
- ✓ Analyze data for continuous improvement
- ✓ Email and text notifications
- ✓ Assignment tool
- ✓ Assign assembly tasks to different personal



Where do we go **now**?

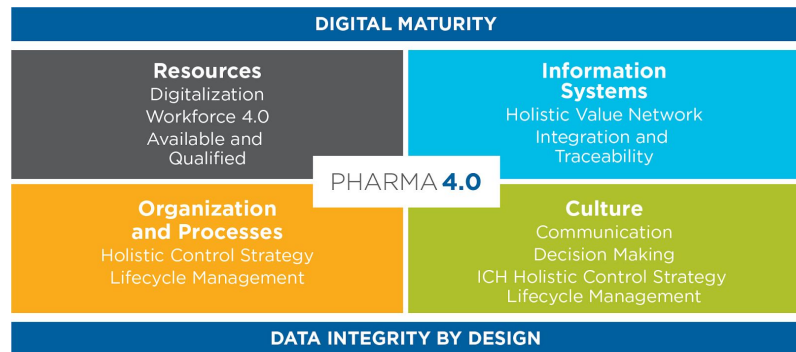
Benefits of connecting & augmenting workers

Manufacturing benefits

- ↓ Fewer Errors
- ↑ Higher Quality
- ↑ Higher Throughput
- ↑ Faster Changeovers
- ↓ Less Downtime

Human benefits

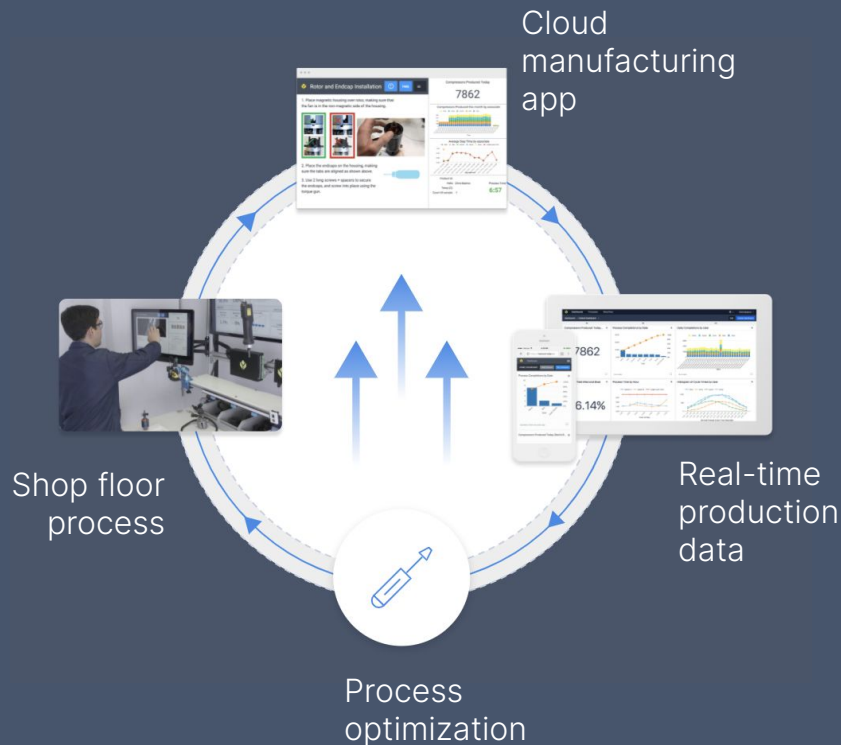
- ↑ Better Attention
- ↑ More Comfortable Conditions
- ↑ More Innovative Thinking
- ↑ Long Term Worker Well-Being



In an agile system flexibility reigns

Moving fast means:

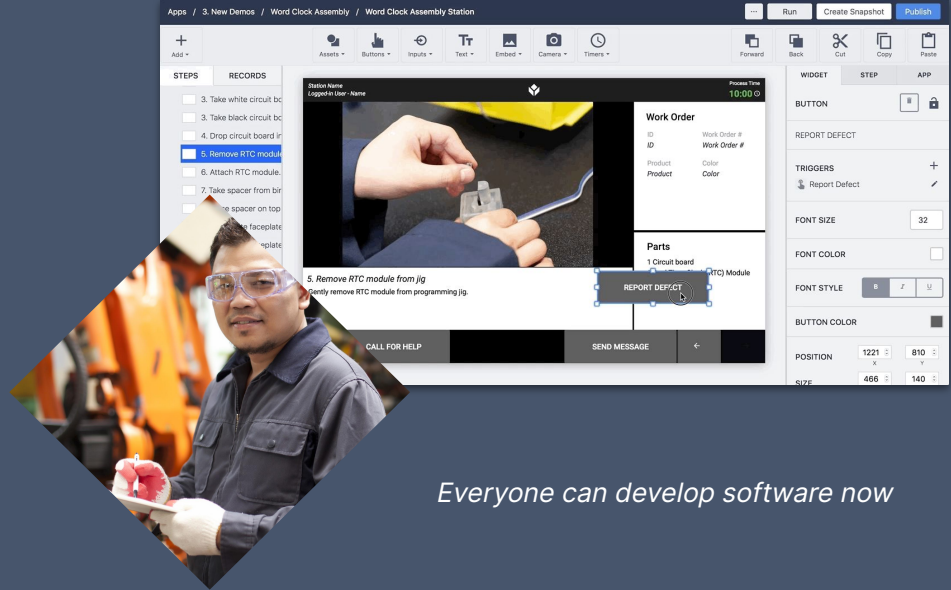
- Software development cycle is hours, not weeks
- Process visibility in the moment, not in retrospect
- Information when you need it
- Empowered front-line workforce



Democratize the shop floor

Give the frontline workforce control over their processes:

- Build apps without writing code
- Empower manufacturing experts to improve processes
- Speed development cycles
- Improve collaboration and decision making with better data



Everyone can develop software now

Thank you for joining!

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