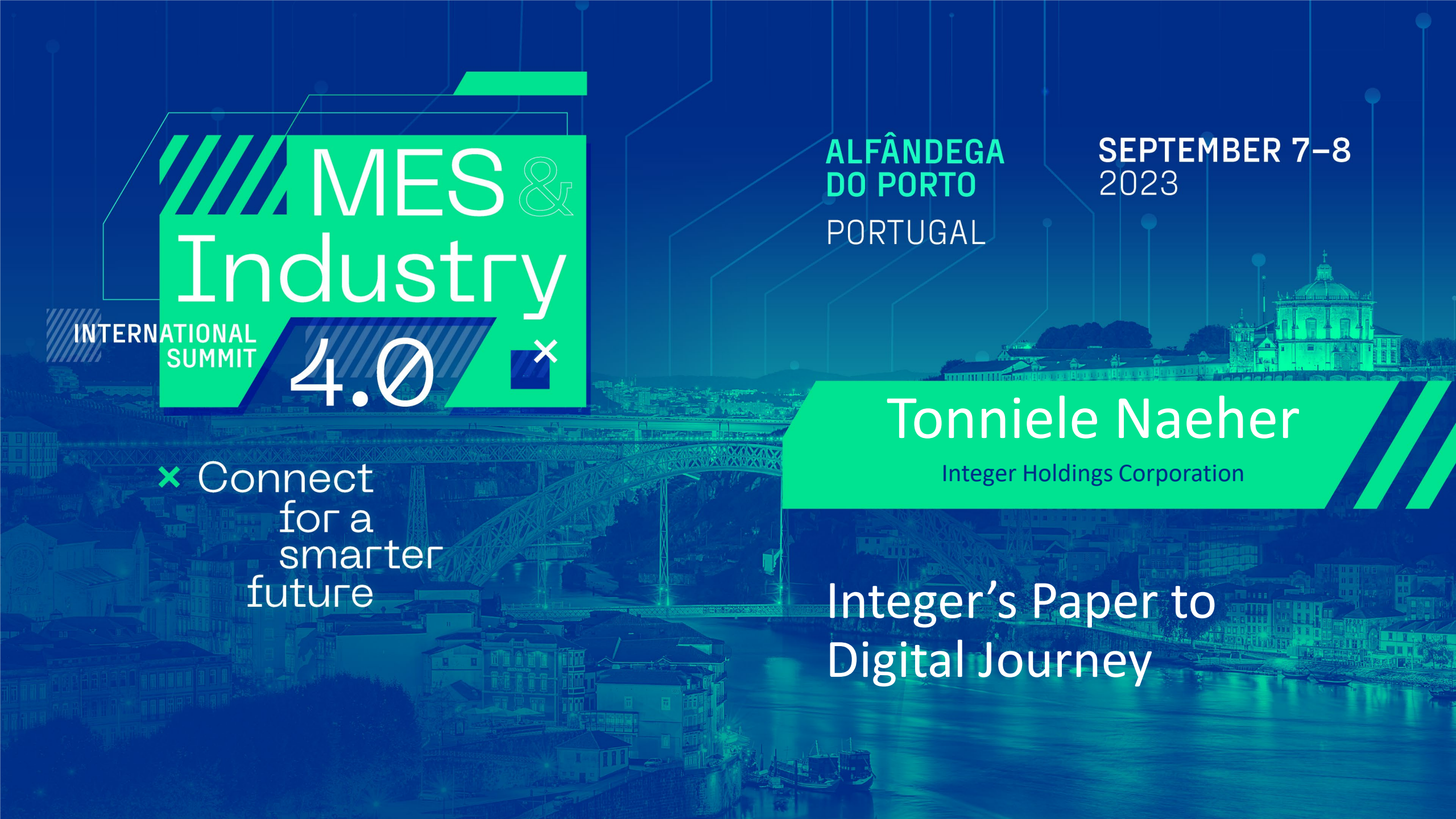
MES & Industry
INTERNATIONAL SUMMIT 4.0
Connect for a smarter future
ALFÂNDEGA DO PORTO
PORTUGAL
SEPTEMBER 7–8
2023
Tonniele Naeher
Integer Holdings Corporation
Integer's Paper to Digital Journey

Session Objectives

- Describe Integer's paper to electronic DHR journey
- Highlight benefits of moving to digital
- Benefits perspective from the shop floor
- Key lessons learned

Integer Holdings Corporation

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Integer® Holdings Corporation (NYSE:ITGR) is one of the largest medical device outsource (MDO) manufacturers in the world serving the cardiac, neuromodulation, vascular and portable medical markets. The company provides innovative, high-quality technologies and manufacturing to Medical Device OEM's to enhance the lives of patients worldwide. In addition, it develops batteries for high-end niche applications in energy, military, and environmental markets.

Greatbatch Medical Lake Region MEDICAL ELECTROCHEM

Our Journey from Paper to Digital

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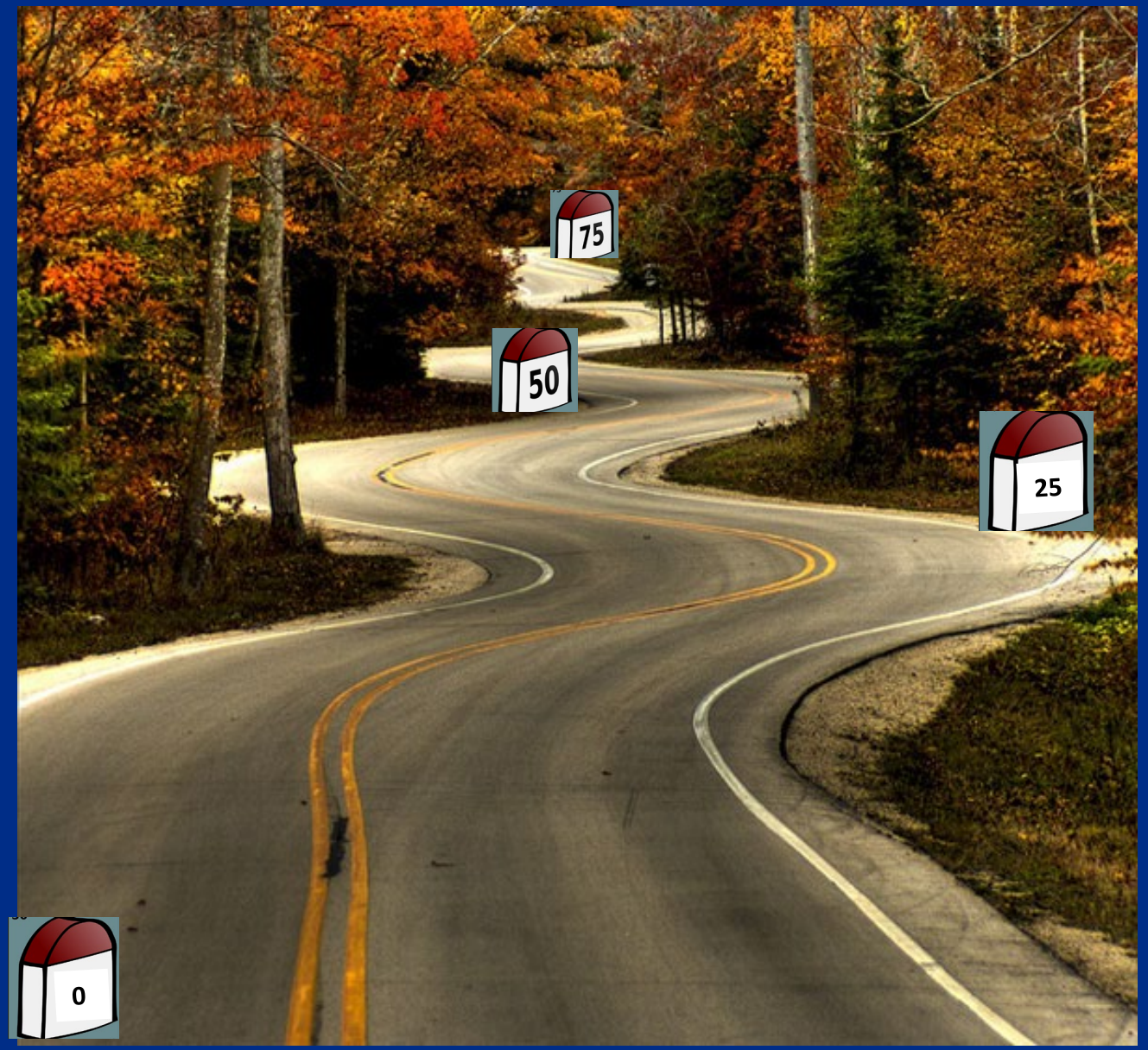

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Integer's Problem Statement

- Complexity of record keeping for production and inspection of medical devices continues to rise
- Sites operate using paper and manual processes for manufacturing
  - Manual processes are prone to data errors this requires extensive quality checks throughout the manufacturing process
  - Hardcopy paper management and storage is costly
  - Tracking, tracing and reporting on products is cumbersome and time consuming
  - With company growth and increasing demand, continuing in this manner will not be sustainable

Project Charter Deliverables

- Configured MES System for all manufacturing operations at the NRO site
- Manufacturing Workflow Alerts and Checks
- Template Configuration using OOB Functionality
- Report Development, such as the eDHR
- Integration with ERP and QMS to link to SOP/JBS/Drawings
- Integration with Barcode Scanners, Document Scanners, Label Printers and Break Strength Gauges
- Work in Progress Label Printing
- Purchase & Installation of Hardware/Technology, Network Updates as needed
- Master Validation Plan and Related Activities
- Change Management Plan & Execution
- Training Documentation & Delivery of Training
- Enable NCR/CAPA process controls, electronic signatures to begin, hold & release product as needed

Integer's Paper to Electronic Journey

2019

- Start MES Evaluation
- RFPs Analysis & Scoring

2020

- Demo MES Systems
- Select MES Vendor
- Project Kick-off

2021

- Pivot to CMF
- Project Kick-off

2022

- MES Project in Progress
- CoE Planning

2023

- 1st Go-Live of 4
- Remaining Go-Lives
- CoE Development
- Designing for the Future
- Planning for 2nd site

2024

- Second Site Project Kick-off

Benefits

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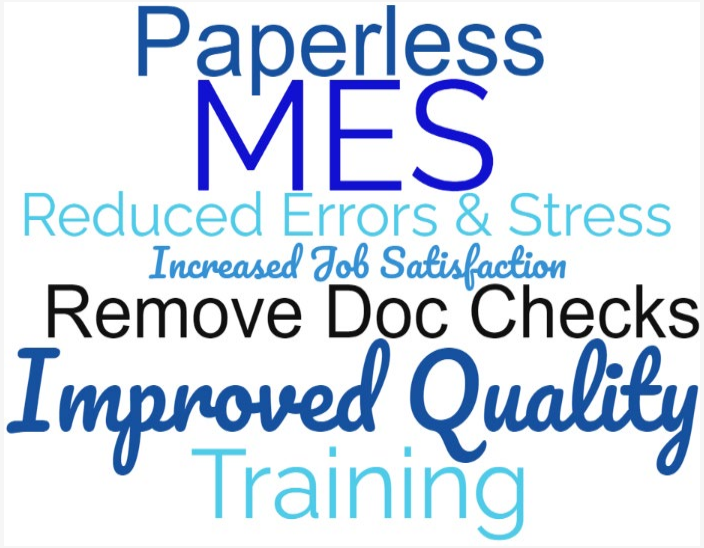
Cost Savings and Avoidances

Expectation that cost reductions and avoidances will be realized.

Such as reducing:

- Resources needed to collect and enter production data
- The number of paperwork checks
- Offsite storage and warehousing of paper records
- The need for DHR final documentation audit resources
- NCRs, customer complaints and lot rejections
- Shipping and handling costs due to returns
- Rework and scrap
- The effort needed to track and trace DHR information due to complaints
- The effort to compile process control records for COAs



Pilot Cost Savings: Reduction in Documentation Time and Efficiency Gains

69% reduction in time needed to perform Work Order documentation tasks

- Documentation Tasks Removed, no need with MES
- ~4 FTE Reduction Annually

25% reduction of machine downtime

- Reduction in time needed for documentation tasks allows Operators to run machines more often
- Improvement in efficiency by 1.1%

Pilot Area Savings of ~300K Annually

Documentation Improvements

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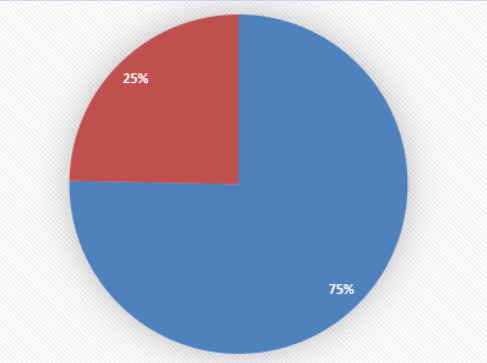
NCR Reduction

MES verification at the source. Reduction in documentation errors will improve accuracy of manufacturing records & reduce NCRs up to 25%.



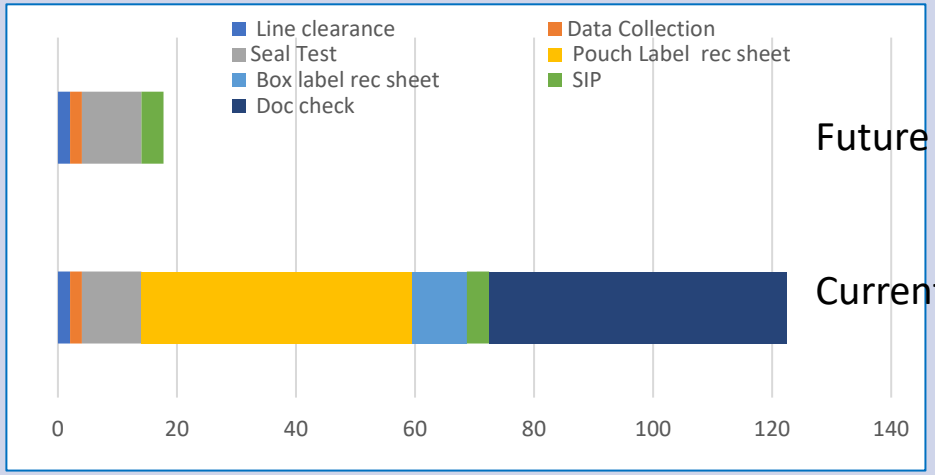
Improve OTD

On average 1 week is needed to investigate, document and close NCRs. The product remains on hold during this time.

With improved traceability, investigations will be completed more quickly.

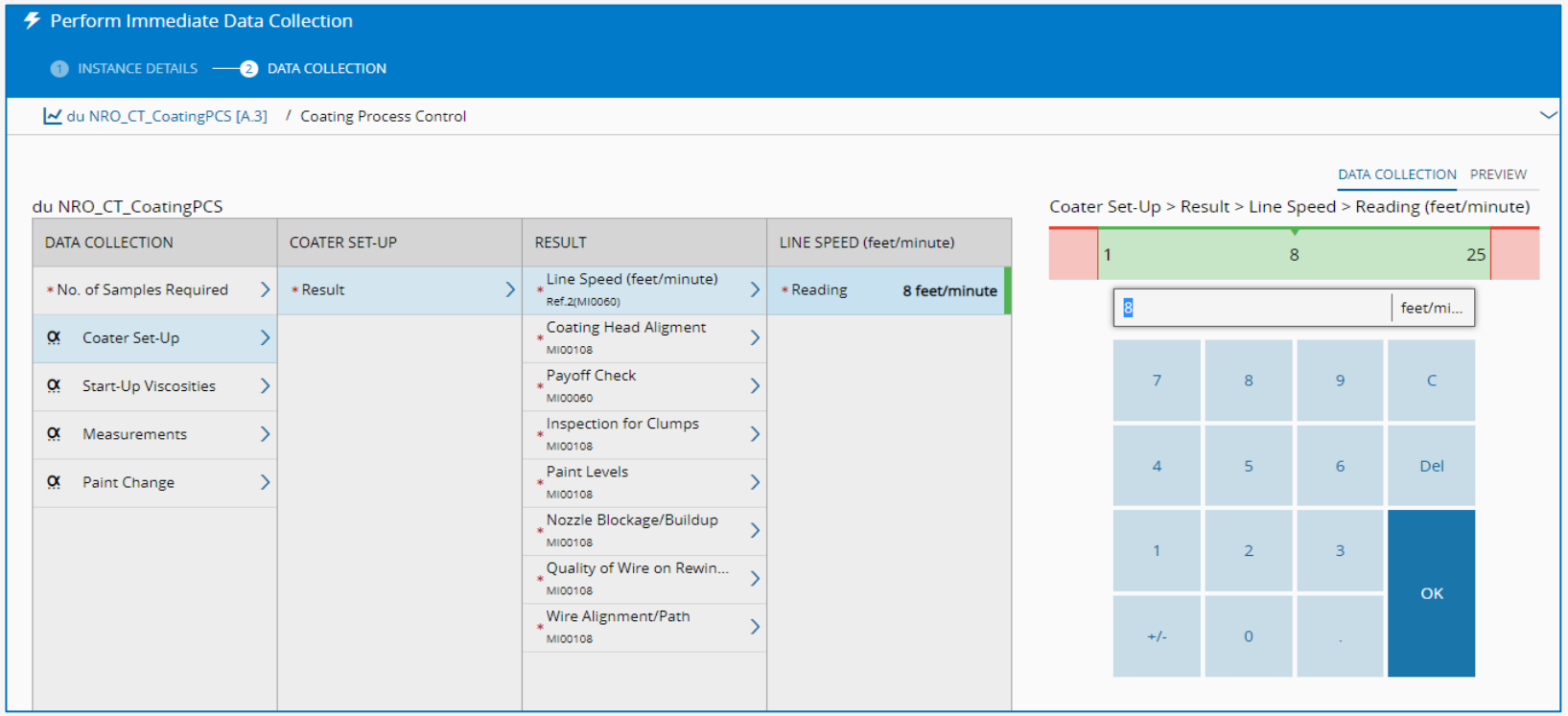
Reduce Documentation Checks

MES self-auditing eDHR will enable removal of several manual documentation checks.



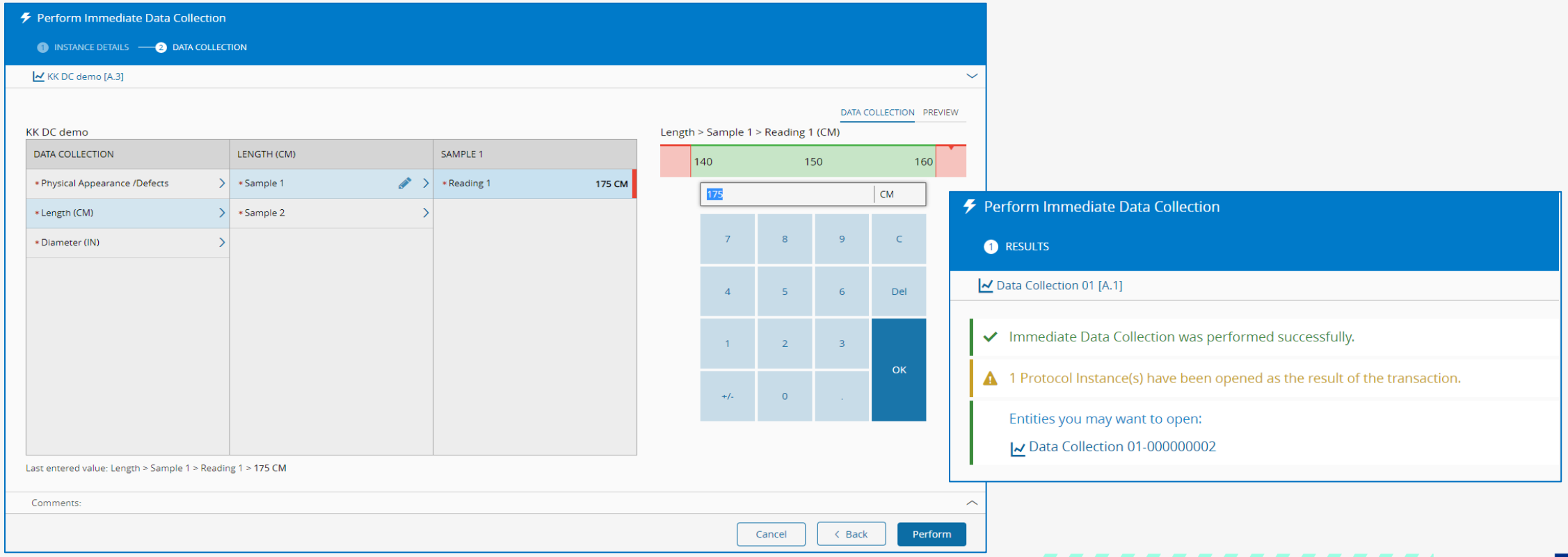
Process Control

- All manufacturing MES process steps performed in the correct order, with a certified Operator
- All inspections enforced at the correct steps, ensure sampling plan is fulfilled
- Ability to collect attribute and/or variable data at required processing points

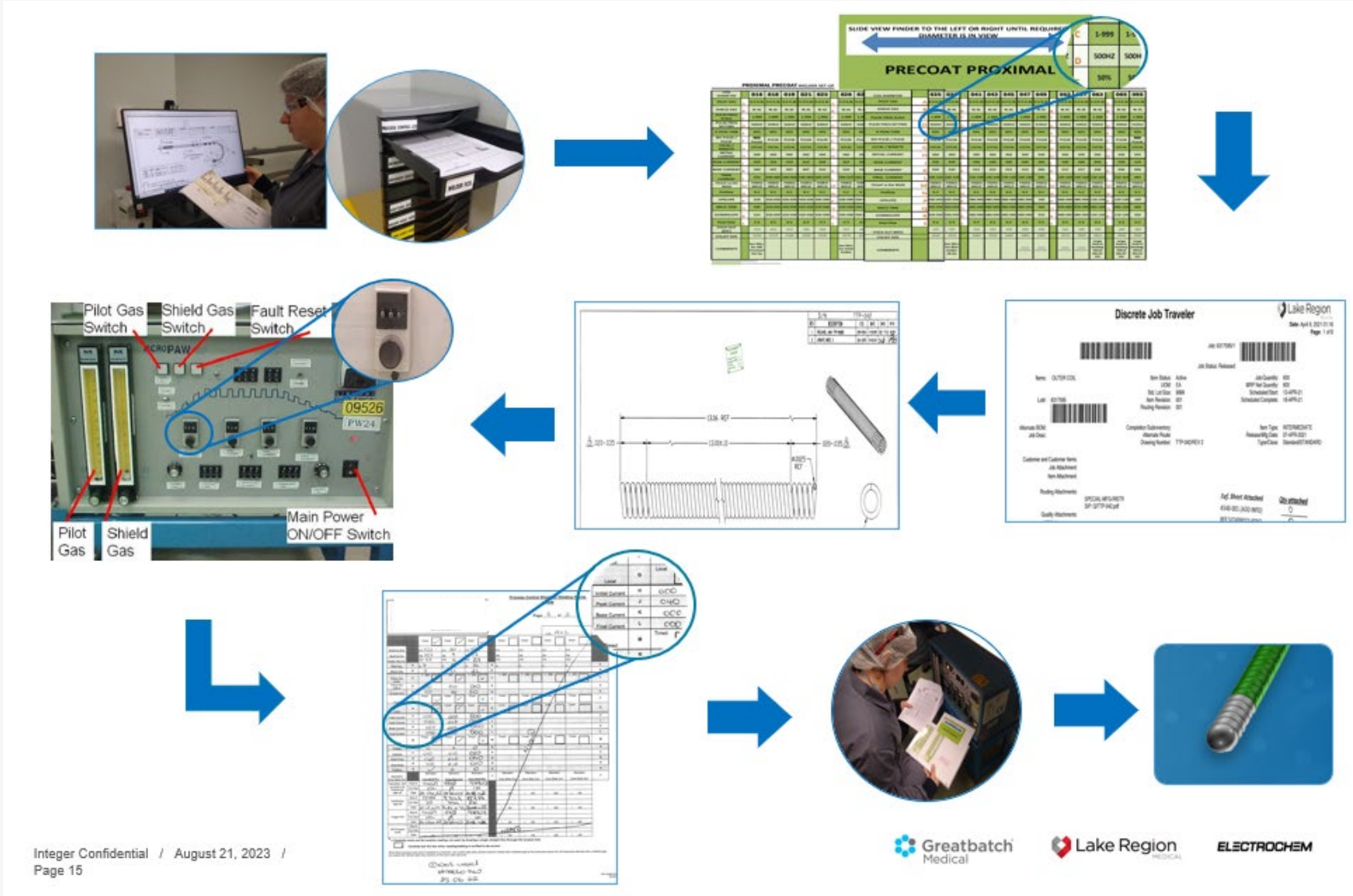


Exception Management

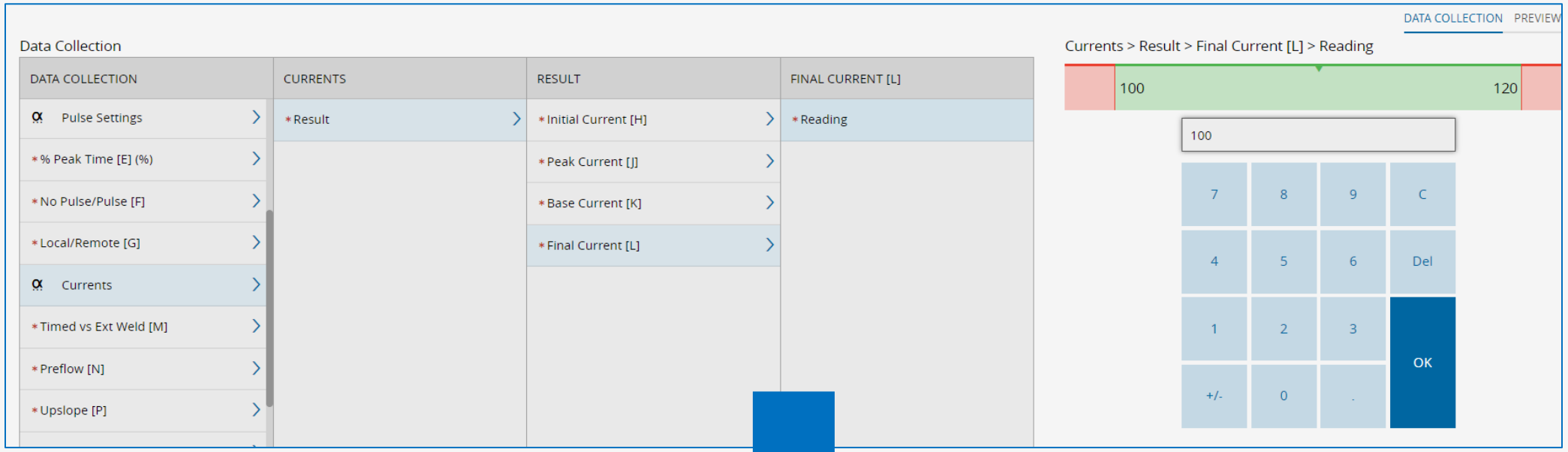
Quality check will review by exceptions only – like holds, protocols or any other non-standard transactions.

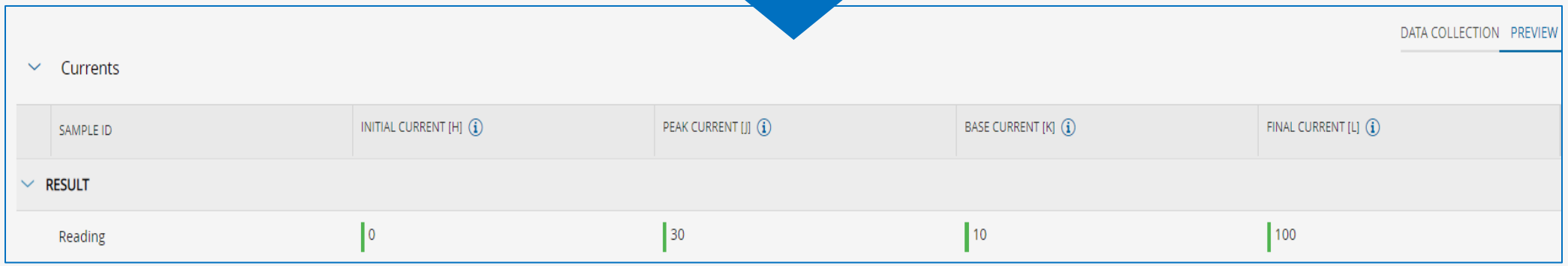


Data Collection – Plasma Welding Setup Today



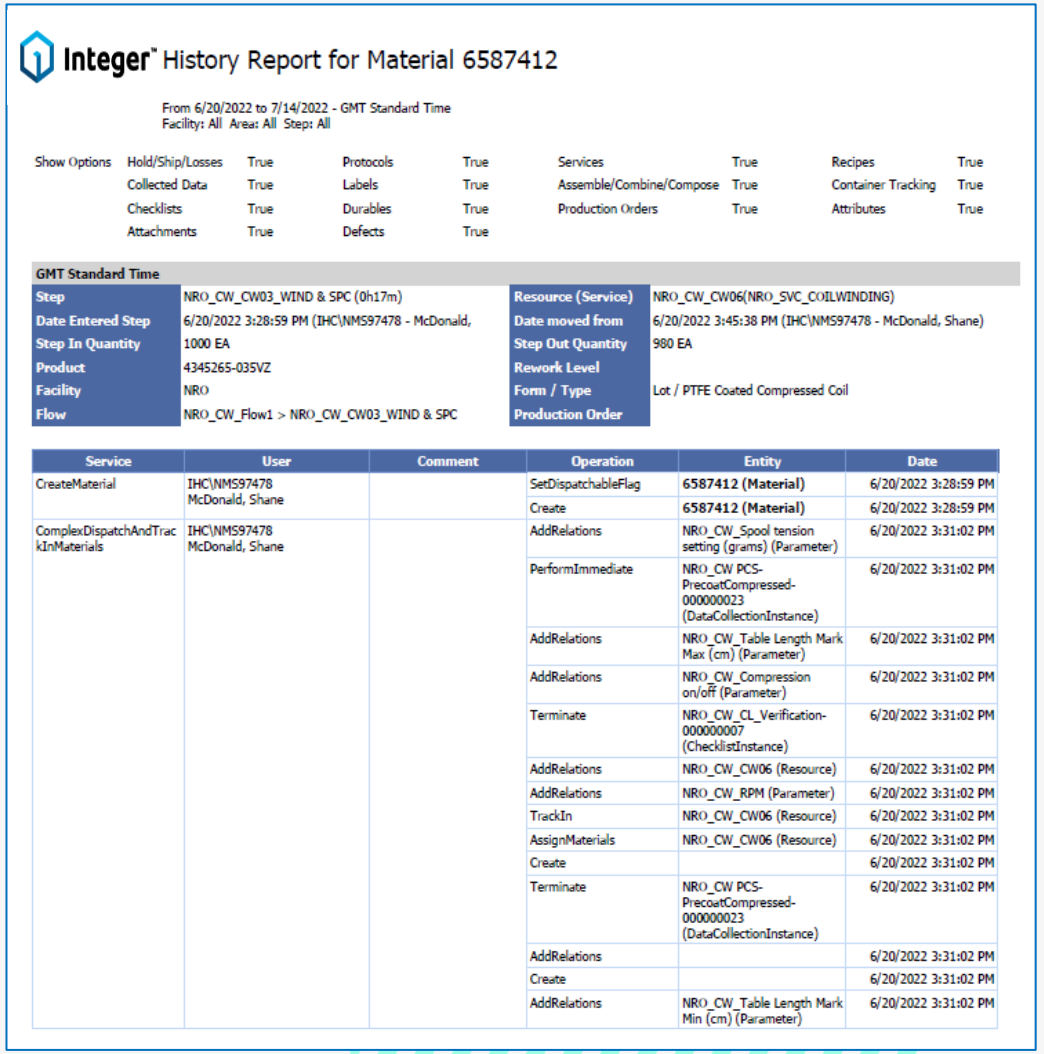
Data Collection – Plasma Welding Setup Tomorrow





Electronic Device History Record (eDHR)

- Easy access to eDHR, data at your fingertips
- Pre-defined customized report shows comprehensive and detailed set of transactions that were completed throughout the material's life cycle.
- Full traceability through audit trail



Integer History Report for Material 6587412

From 6/20/2022 to 7/14/2022 - GMT Standard Time
Facility: All Area: All Step: All

Show Options	Hold/Ship/Losses	True	Protocols	True	Services	True	Recipes	True
	Collected Data	True	Labels	True	Assemble/Combine/Compose	True	Container Tracking	True
	Checklists	True	Durables	True	Production Orders	True	Attributes	True
	Attachments	True	Defects	True				

GMT Standard Time

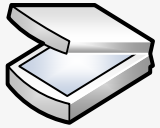
Step	NRO_CW_CW03_WIND & SPC (0h17m)	**Resource (Service)**	NRO_CW_CW06(NRO_SVC_COILWINDING)
Date Entered Step	6/20/2022 3:28:59 PM (IHC\NMS97478 - McDonald,	**Date moved from**	6/20/2022 3:45:38 PM (IHC\NMS97478 - McDonald, Shane)
Step In Quantity	1000 EA	**Step Out Quantity**	980 EA
Product	4345265-035VZ	**Rework Level**	
Facility	NRO	**Form / Type**	Lot / PTFE Coated Compressed Coil
Flow	NRO_CW_Flow1 > NRO_CW_CW03_WIND & SPC	**Production Order**	

Service	User	Comment	Operation	Entity	Date
CreateMaterial	IHC\NMS97478 McDonald, Shane		SetDispatchableFlag	**6587412 (Material)**	6/20/2022 3:28:59 PM
			Create	**6587412 (Material)**	6/20/2022 3:28:59 PM
ComplexDispatchAndTrackInMaterials	IHC\NMS97478 McDonald, Shane		AddRelations	NRO_CW_Spool tension setting (grams) (Parameter)	6/20/2022 3:31:02 PM
			PerformImmediate	NRO_CW PCS-PrecoatCompressed-000000023 (DataCollectionInstance)	6/20/2022 3:31:02 PM
			AddRelations	NRO_CW_Table Length Mark Max (cm) (Parameter)	6/20/2022 3:31:02 PM
			AddRelations	NRO_CW_Compression on/off (Parameter)	6/20/2022 3:31:02 PM
			Terminate	NRO_CW_CL_Verification-000000007 (ChecklistInstance)	6/20/2022 3:31:02 PM
			AddRelations	NRO_CW_CW06 (Resource)	6/20/2022 3:31:02 PM
			AddRelations	NRO_CW_RPM (Parameter)	6/20/2022 3:31:02 PM
			TrackIn	NRO_CW_CW06 (Resource)	6/20/2022 3:31:02 PM
			AssignMaterials	NRO_CW_CW06 (Resource)	6/20/2022 3:31:02 PM
			Create		6/20/2022 3:31:02 PM
			Terminate	NRO_CW PCS-PrecoatCompressed-000000023 (DataCollectionInstance)	6/20/2022 3:31:02 PM
			AddRelations		6/20/2022 3:31:02 PM
			Create		6/20/2022 3:31:02 PM
			AddRelations	NRO_CW_Table Length Mark Min (cm) (Parameter)	6/20/2022 3:31:02 PM

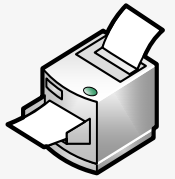
Integrations

- Integration to ERP system. Allows for Orders and inventory details to be shared in almost real-time.

- Barcode scanners to allow for work order number scanning



- Flatbed scanner integration to allow for scanning documents that need to be appended to the eDHR



- MES label printing to print internal tray labels

- Pull-strength tester integration to communicate directly with MES and pull results into eDHR

Employee Retention

Pre-MES	Post-MES
Current processes & systems – complex and rigid	System guides the user in doing their job
Hundreds of opportunities for clerical error in a typical DHR. Possible NCRs	Less documentation errors
Errors by an Associate leads to re-training and Associate stress	Less re-training
Requires Associate recall and laser focus	Associates can now focus on value add work and experience less stress

Benefits Perspective from the Shop Floor Associate Feedback

"MES is a big help, it's guiding me through the order, and I can see information recorded from previous shifts very easily"

"While my handwriting is better than most not having pen on paper legibility issues is great"

"Having to count & reconcile hundreds of scrap labels is so time consuming. It's super that MES/CVS will remove this task from my job."

"I need to be so careful when completing the router documentation checks – and it is easy to make a mistake. MES will be a big help, to guide the associates and highlight if they are going wrong."

"I have to remember and follow up with associates to complete or fix SQC data entries each day. MES being able to prompt the associates and the having a dashboard will be great."

Benefits Perspective from the Shop Floor

- Associates would NOT go back to paper although many were originally anxious about converting to MES
- Associates can’t pick the wrong materials with MES
- Operators are finding quality issues immediately; Operator needs to resolve the issue before going home
- MES is highlighting inaccuracies that were always there but perhaps not caught previously
- Machine switchover is quicker with MES, less paperwork involved

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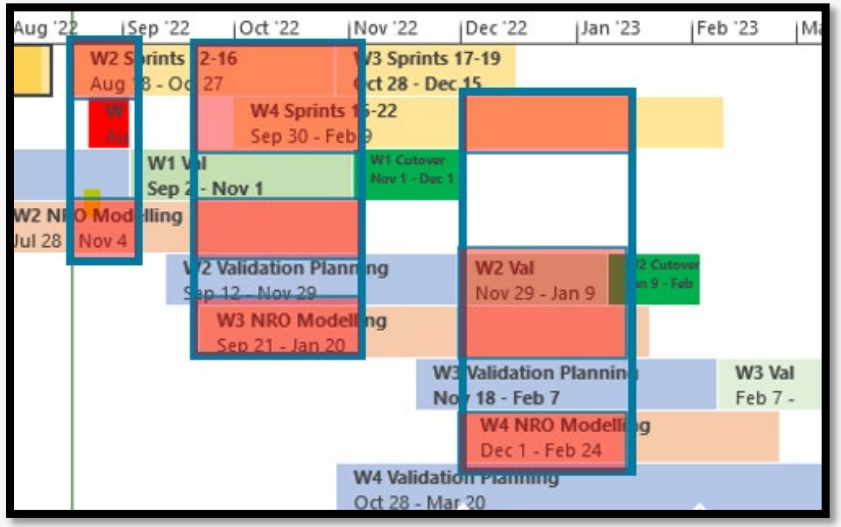
Lessons Learned – Resources

- Multiple phases for go-live can cause resource constraints
- Adding resources onto the team mid-project to help address resource constraints will result in diminishing returns



Lessons Learned – Development/Testing/Modeling

- Agile methodology is iterative, rework will occur … devise a plan that controls the rework cycle as much as possible.
  - Avoid increasing costs and schedule delays
- Lots of testing, unit, regression, end to end, is key before going into Validation to avoid deviations
- Modeling effort can be easily underestimated
  - Quantify your number of products and the level of control you want MES to bring to data collections

Lessons Learned - Reporting

- Avoid building numerous custom reports for the first implementation
  - Build key reports such as eDHR, inventory and maybe some quality reports
  - Allow time to use the system and see what types of data are now available
  - Work with teams post go-live to define report needs
  - Don’t end up building a lot of reports that go unused or do not hit the mark on actual requirements

Lessons Learned – Training

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- Training an entire site on MES is not easy, huge effort
- Determine if you need budget for training
- Consider different ways to train and to have the least impact to production
- Check-in with Associates and see how the training is going by conducting surveys
- The Operations team needs to be explicitly involved in training. Build a team of trainers to help manage and conduct training sessions ahead of go-live

Lessons Learned – Go-Live

- 24/7 project team support is difficult to sustain while the team continues to work on remaining project work for future rollouts
- Move ownership of cutover support from the project team to your Super Users and Trainers to help with level 1 cutover and go-live support
  - This way you will have coverage across shifts
  - Only engage project team for escalated issues

A Few Successes!

- If you are looking to roll out in more than one location keep a global mindset. Build the system with the intent to make it scalable.
- Take your rollout took-kit and improve it as you go from site to site
- Cohesive Cross-functional Motivated Team with top talent is KEY to Success
- We found it is BEST to have an experienced, resident engineer or trainer fill the Lead Training role
- Badging into the MES system to reduce logon time maintain high security levels
- Automation of MES accounts for new onboards removes burden to create accounts manually
- Set up a Change Champions team with key stakeholders and supports of the change

Summary

- Benefits to be realized are many. From cost savings to quality benefits and even Employee benefits, we continue to track our expected benefits but we recognize that there are likely numerous benefits that may not have been identified!
- As we work to complete our first full rollout and start the process to expand to other sites, our MES journey has offered us many learnings that we can apply to our next implementations. We expect to get better, be faster and be more efficient each rollout we do.

THANK YOU

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