Paperless medical device manufacturing

Features - Operations

Companies turn to manufacturing execution systems (MES) in a drive for efficiency, quality, and traceability.

June 1, 2018

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Modern manufacturing execution systems (MES) (http://www.criticalmanufacturing.com)help medical device manufacturers achieve efficient, competitive production; deliver new product developments as quickly as possible; and ensure high quality and complete traceability to meet regulatory demands. MES strategic tools facilitate innovation and provide security for the future of the business.

Bye bye paper

MES can replace paper-based processes and records throughout the shop floor with completely electronic systems. Compliant with the requirements of the U.S. Food and Drug Administration (FDA) title 21 CFR Part 11 for electronic records and signatures, modern MES remove inefficient handling of paper records and enable integration of multiple processes and data. This can improve overall plant efficiency, reduce re-work, increase yields, optimize process cycle times, improve delivery fulfilment, and enhance product quality.

The FDA is encouraging businesses to use electronic systems for continuous process improvement to reduce the number of regulatory actions, recalls, and manufacturing related incidents. The FDA initiative, the Case for Quality, is intended to engage medical device manufacturers to focus resources on product quality rather than compliance.

Reviewing and archiving paper-based data is prone to error. Performance analysis can only be done after processing, delaying capture of non-conformances. Measuring overall productivity, efficiency, and process performance is difficult; and advanced engineering

analysis nearly impossible. Integrated electronic data capture and self-auditing processes contained in MES lead to continuous process improvements, built-in quality, production consistency, and actionable information.

CASE STUDY

A LEADING INTERNATIONAL medical device manufacturer fabricating complex imaging devices deployed a Critical Manufacturing (CM) MES at a U.S. site to move from product development to full-scale production. Production at the customers' site included intricate front-end semiconductor processing in a cleanroom environment. The MES needed to handle flows, material model, data collection, and recipe management.

Before implementing the CM MES, the site operated with paper-based tracking in combination with several island solutions into which data was manually re-entered from shop floor orders, retrieving information from equipment, and managing maintenance plans. Quality, traceability, and operations planning were manual, and information was scattered in multiple locations across the factory, making regulatory audits painful. Documents were reviewed manually and archived off-site, making it difficult to ensure flows, steps, sequences, operations, and procedures were strictly followed as required by the U.S. Food and Drug Administration (FDA).

The CM MES was implemented in three months after the infrastructure requirements from corporate central IT were in place. Key project parameters included:

Complex traceability with traditional medical device and semiconductor front-end (wafer processing) assembly steps: Can create lots with several panels at once in the semiconductor front-end; hierarchical model allows two levels of materials to co-exist; lots can be split with child lots created and merged later, making product dispatch easier while keeping full traceability of splits/merges; back-end (test and assembly) process panels can be processed individually while maintaining information of the lot number from the front-end process

Continuous development of processes with frequent modification, adjustment to processing steps: Product development environment supports different processes across front-end, back-end, assembly stages

Complex production flows, long cycle times, several re-work possibilities: Cycle times range from 4 to 12 weeks, including 2 to 4 weeks for semiconductor front-end; MES handles complex work flows, reducing the amount of high value, work in progress (WIP) materials/semi-finished product

Requirement for shop floor digital twin for real-time visual representation of operations: CM fabLIVE 3D visualization tool generates a single view of all tools on the shop floor and information collected from each MES object deployed in production; management, technicians can see which lots are running, at what step, and tool status as well as detailed asset location tracking

Advanced statistical process control (SPC) requirements: MES supports 80+ SPC charts in 10 process steps with 600+ data collection parameters, automatic triggers of quality protocols

Specific quality protocols/exception management: Embedded quality business procedures for major issues, events; more than 10 phases, defined checklists included

User-configurable reporting based on continually evolving needs: Easily build reports alongside a complete set of interactive, standard reports

Compliance without paper: Provides all functionality for regulatory compliance including double signatures, version-controlled documentation, electronic records, signatures in line with the FDA 21 CFR Part 11

Fault tolerance: Configured to alleviate concerns about dependency upon the system; three different systems were set up for production, staging, development purposes

Traceability

A modern MES solution provides end-to-end product traceability, meeting mandates to show all materials, components, and assemblies meet specification and processing requirements. It can track complex production processes and incorporate products being batched, split, merged, or inserted as components in new assemblies along with managing all back end and assembly processes.

Reducing painful audits

Automatically logging data throughout the production line makes regulatory compliance an outcome of the process rather than a separate activity. The system provides complete, secure electronic Devices History Records (eDHR) and electronic records and signatures in line with FDA 21 CFR Part 11.

Complete audit trails for traceability of every process step and parameter includes equipment, maintenance, and calibration status and certification management of personnel and equipment. With correct access permissions, records are accessible via the system interface. Data can be exported for inspection, review, and copying. Changes at all levels are recorded in the system history and are fully traceable with an in-line time-stamp history.

Summary

The decision to invest in a modern MES can allow a business to evolve as it needs to in the future, while harnessing and analyzing masses of processing data – producing valuable, intelligent information on which to base sound strategic decisions and product roadmaps.

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POLL

What are the biggest challenges you see the medical device manufacturing industry facing in 2019?

- Ability to invest in technology
- Access to capital/credit/financing
- Changing regulatory environment
- Increased market competition
- New product development
- Pricing pressures
- Retaining/growing a skilled workforce

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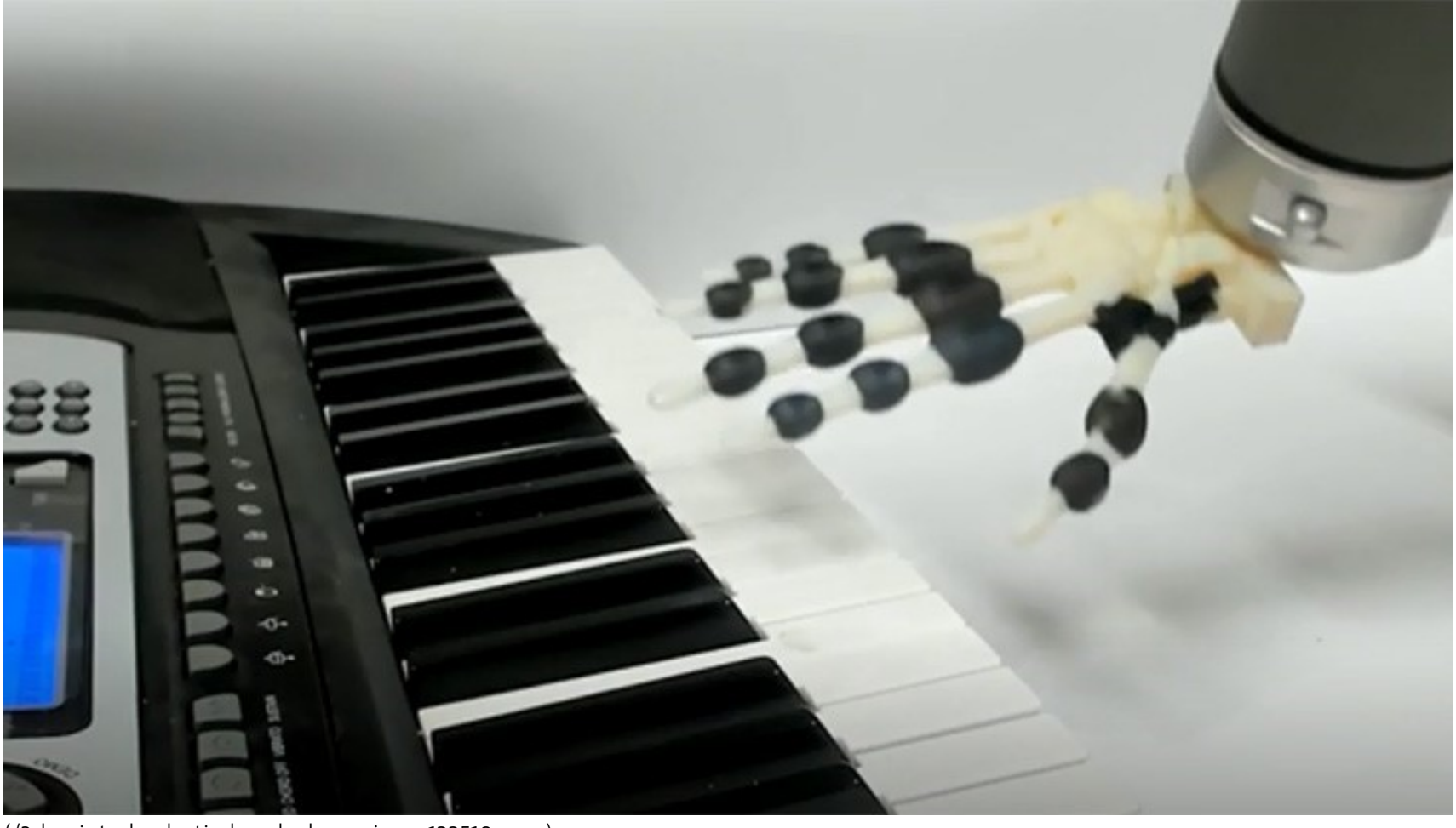

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