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The future of manufacturing: MES to manage extreme vertical integration

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For manufacturers of sophisticated and fast-changing products, the need to move from paper-based processes to an intelligent manufacturing execution system (MES) is, arguably, not just necessary to drive efficiency and quality into value chains, but a basic need if the business is to stay relevant in the marketplace.

The first challenge in implementing an MES is to align very clearly with long-range strategic objectives and key results. There should be no doubt about the key benefits MES will deliver to manufacturing, how the project will be run, or how success will be measured. Challenge number two is to decide on a sustainable project approach and methodology that allows for quick wins, followed by continuous improvement and rapid scaling for years into the future. The third challenge is to educate key stakeholders and decide which low-risk manufacturing processes might be geared to a "paper-on-glass" implementation—as well as processes which require a fully-integrated MES implementation.

Once implementation is aligned to objectives and key results, then project methodology and MES risk-based approach are known. After that, a more detailed scope and pilot project planning can be undertaken to define a pilot model of an end-to-end value stream with significant volume, process characteristics, and product variety. This will demonstrate the potential of the MES to the wider business. The pilot should include, at minimum, the manufacturing model, IT and OT integrations, and (for regulated industries) a validation process.

Finally, a dedicated team of exemplary people is essential to a successful MES pilot and to the subsequent enterprise-wide roll-out. Plan to invest heavily in team education and training during the pilot phase.

MES ensures all plant activities are visible, managed and measured. Companies managing extreme vertical integration have complex and varied manufacturing operations, where a product of one operation, work cell, or department, is a component to the next. That's exactly what leading oral health product manufacturer, Ultradent Products, Inc. has done.

Case study: Ultradent

Based in Utah, USA, Ultradent prides itself on extreme vertical integration to deliver products used by dentists in over 120 countries. Providing a wide range of dental solutions, the Ultradent plant incorporates several in-house manufacturing departments including chemistry formulation, weighing, dispensing, primary package filling, secondary packaging, injection moulding, laboratory, CNC machining, assembly, printing, and other operations. Its production lines are both high volume / low mix and low volume / high mix. Ultradent also creates specialty and customised products for its customers that have a limited shelf life. As a result, traceability, genealogy, and first expired first out (FEFO) material handling at every process step are crucial to manufacturing operations.

After 40 years of business using paper-based systems, Ultradent made the strategic decision to move to an MES and fully electronic batch records. To narrow down potential suppliers, it started by looking at companies with experience in the medical sector. It looked for functional fit, configurability, extensibility, and the ability to customise. The complexity of manufacturing also required a system with a model-centric approach to enable integration with a variety of other systems on site. With highly capable IT and engineering teams in house, it was further looking for a partner who would also act as a systems integrator and provide Ultradent with greater

visibility and input into the roadmap for the MES.

Craig Pinegar, director of manufacturing IT at Ultradent, said: “Finding the right partner was crucial for us. We have excellent in-house capabilities and knew we would want and need to customise the MES. We selected Critical Manufacturing after a comprehensive review of systems available and a great deal of research into what MES can do.”

roject selection was the first critical step for the Ultradent/Critical Manufacturing roject team. Ultradent wanted a minimal viable product that would cover the end-)-end value stream of a product line that was representative of at least half of the usiness. Selection took time and a great deal of discussion. The next step was ıcredibly detailed project planning, considering IT and OT integrations to support ork order management, material management, labelling, optical verification, and :ale integration. The factory and processes were modelled in the MES with a focus n manufacturing execution, data collection, and exception management.

etailed vertical integration

ltradent worked in close partnership with Critical Manufacturing. The team decidec ıat PLM functions and document management would remain in PLM while planning :heduling, inventory, and cost management would remain in the ERP system. The ES would need to synchronise with the PLM, ERP, labelling, and more than 30 ustom services using REST APIs and JSON messaging handled by middleware and ıessage queuing. For Level 2 integration, (per ISA-95, the automation layer) drivers ere configured in the MES to communicate with IPCs, PLCs and other ıstrumentation using OPC-UA.

inegar continued: “After one year, we reached our first milestone with the ‘minimal able product’ pilot line up and running and gathering data we could have only reamed about. Our second milestone was a minimal scalable product. Robust ıange management is the next big challenge ahead. We can have as many as 500 ffected documents and items on pending change orders at any given time.”

ne of Ultradent’s primary goals was to convert paper process steps and data ollection points into electronic in the MES. Thus, the change management workloac ıd complexity are critical drivers for the MES.

inegar said: “Without great change management capability within the MES, ıanaging changes to the factory product and process model can be both time-)nsuming and error-prone. We are currently working closely with Critical Manufacturing to design and implement enhancements to facilitate high volume change management along with other improvements in areas such as weighing, dispensing, downloading, and filling.”

A shared development and vision

Both Ultradent and Critical Manufacturing have excellent development teams. To facilitate innovation, they are building a joint development operations pipeline, which merges code from both parties into deployable packages that can be validated together.

"We wanted a partner, not a supplier, and that is very much what we have with Critical Manufacturing," continued Pinegar. "Our MES roadmap looks about three years ahead and we have made a big change in how we will run this project by switching from a waterfall to agile methodology. For this to succeed, it is vital we take care of people and invest in them. Success lies in ongoing education and investment in all stakeholders at every level. We had never integrated IT and OT before, and we are learning from each other every day. But, gradually, MES is becoming the common language."

A highly adaptable project team: You never know what is around the corner…

The first phase of the Ultradent MES project was hit with the COVID-19 pandemic. This precipitated a drop in business as dental offices around the world were forced to close. Through necessity, Ultradent put some projects on hold, but not the MES implementation. Core teams at Ultradent and Critical Manufacturing worked from home to deliver the pilot project on time, only entering the factory when necessary to interact directly with equipment or personnel.

Pinegar concluded: "The pilot line looks great and we are excited about the possibilities for the future. Critical Manufacturing has proved itself as an invaluable and adaptable partner and its MES gives us the flexibility we need to incorporate our own modules. Executives have seen the potential and are asking what it would take to roll out the MES everywhere in half the time! What we can achieve depends on many different factors."

Additional advice from Craig Pinegar on delivering a successful MES project:

- Have a deep understanding of physical processes and information flows. There is no substitute for walking manufacturing processes, tracing information flows, and observing handoffs and decisions made by real people in the real world.
- The end game for the MES is to become data driven. Even while implementing, remember to collect and analyze data along the way.
- Focus first on collecting quality critical product attributes and process parameters.
- User experience matters—build GUI's that make following the recipe "stupid simple" for the operator.
- Direct observation, anecdotal data, and empirical feedback are tremendously powerful together.
- Remember to design the MES to adapt, scale, and last.
- Any MES needs incredibly high availability, security, and disaster recovery by default.
- MES needs to scale vertically and horizontally, retain data for many years, and yet adapt to constant changes in product mix, manufacturing processes, and procedures.
- In a project such as this, with many moving parts, bad news happens—make sure it is communicated early and often so you make adjustments as you go.
- Software and process validation is vital. Time spent validating the right things costs much less than time spent in remediation.
- Validated correctly, an MES can eliminate the need for double human

verification.

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