

TRACEABILITY IN MANUFACTURING



As a manufacturer, you face stringent regulations that undergo frequent changes to ensure the safety and effectiveness of products.

Traceability, the ability to identify and trace the product, process, operator, context, and detailed quality and component supplier and lot information for every item that moved through manufacturing, is a must-have for manufacturing success. A robust traceability framework that envelopes the total process, product, and material traceability, is a critical component for manufacturers facing stringent regulations while seeking to reduce the overall cost of compliance.

In this whitepaper, we explore the **evolution of traceability in manufacturing and the current reactive methods used when applying it.** We'll also consider a future where effortless data collection acquires big data in manufacturing that, when properly mined, can produce the traceability required by any customer or regulatory authority.



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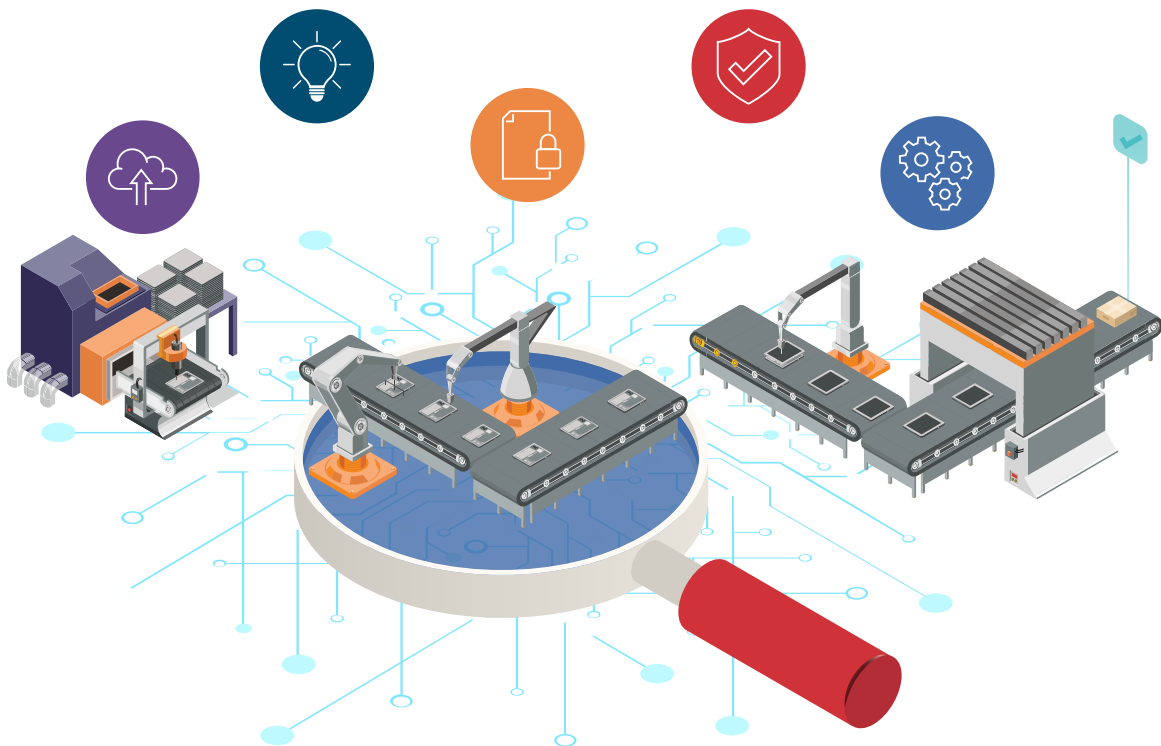
Evolution of Product & Manufacturing Traceability

Product and process traceability was once a requirement of mission-critical or extreme reliability applications and industries alone. Manufacturing has long grappled with achieving traceability to satisfy either regulatory requirements, or to limit potential recalls and the costs and liability associated with them. Over the last decade, these niche and esoteric requirements have become mainstream. **Now, manufacturers in many sectors are expected to provide traceability.** It has become a challenge for a large percentage of discrete manufacturers, particularly when manufacturing products that include reasonably advanced technologies.

The very nature of traceability itself has also evolved. Originally, if serialized products could be recalled against a certain range of component lots the issue was considered solved. This often meant a recall that was broader than it needed to be, but the manufacturer was assured at least that all at-risk products were included, and that was considered acceptable. Today, the situation is very different from both accuracy and a data scope perspective. When a recall occurs, the cost and brand image ramifications of any 'good' units being recalled is significant. The traceability system must achieve the goal of ensuring absolutely that every faulty unit is identified and recalled, while avoiding the recall of any 'good' units unaffected by the problem. Erring on the side of caution resulting in the recall of many additional units is no longer acceptable.

Traceability can no longer be about component batches alone. Now, traceability can provide operator data, showing who was present when a product passed through a specific workstation, process variables from equipment, a chemical or tool used, or even support full forensic-style investigation of all electronic approvals and multi-level confirmations of actions taken on the product.

The entire production flow from start to finish, including materials used, tools, operator and machines involved, and every environment variable must be available to provide 'keys' against which a group of serialized units can be recalled. **Traceability now extends back into the process planning** and even to R&D and design via CAD data.



The Traditional Approach to Traceability

The typical tools and systems to meet the traceability challenge of the past were most often adopted out of grudging necessity placed upon the manufacturer by the market, regulatory agencies, or customers. As such, the approach was often one of 'do as little as will meet the requirement'.

Consequently, systems were bought or built that would satisfy only the specific scope of traceability demanded, and in many cases only on the particular assemblies or products that required it. This approach answered the immediate need of the company, but failed to achieve anything further.

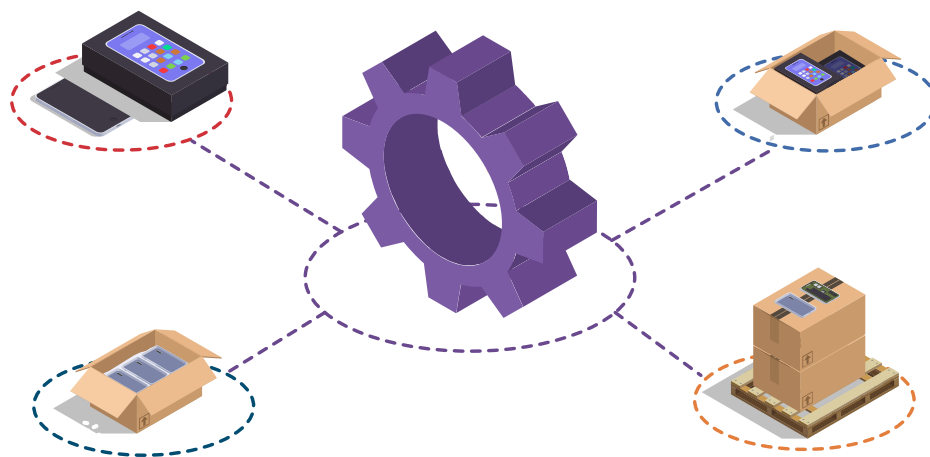
This narrow approach is fraught with missed opportunity. By adopting such a narrow scope and application of traceability, the entire manufacturing culture is trained to see traceability and data acquisition and management as a burden rather than part of the way business is done with inherent benefits. Furthermore, the solution built has to be customized and extended every time the requirements evolve, incurring additional costs and management time.

The biggest lost opportunity is process and manufacturing improvement. Consider the scope and depth of data available. That information can really drive operational excellence when properly utilized. It can flow back to R&D to improve future designs and it can drive real-time improvement by giving process engineers, operators, and managers a view into the reality of the process.

The data set included in modern traceability effectively becomes the definition of 'Manufacturing Big Data'. When that data is leveraged for more than just answering the traceability challenge, it becomes the most powerful process and product improvement tool imaginable.

Traceability, should no longer be a primary goal for manufacturers, even if it is a core regulatory, market or customer requirement. The goal should be achieving manufacturing Big Data across the full scope of operations, and the full depth of product, process, and machinery data. **Once manufacturing big data is harnessed, traceability becomes a natural by product.** More importantly, the analytical and process improvements that come from leveraging this Big Data are gateways to Operational Excellence.

By having operational excellence via Big Data as the real corporate goal, traceability ceases to be a burden or cost and becomes part of a valuable culture of improvement that pervades the manufacturing enterprise and drives differentiation and success.



The Big Data Approach to Traceability

Manufacturing Big Data is a term used increasingly in manufacturing but rarely discussed at a tangible level.

The enormity of the concept has to be grasped before discussing applications that offer operational excellence and traceability.

First, consider the scope of manufacturing operations from when R&D finishes the CAD design and the bill of materials (BOM) is locked down in PLM and/or ERP. This is the moment at which the readiness of the product configuration is achieved. **There is a good deal of data involved in the mapping of that BOM to the associated CAD and revision data.**

The process, quality, test, industrial, and manufacturing engineers along with planners then go to work on that data to transform the design into a detailed process complete with robotic assembly, inspection, test and process machinery programs. The quality plan and route control logic must be developed and laid in. The visual assembly instructions for every station of the process flow must be designed and digitized along the process. This New Product Introduction (NPI) process yields a lot of data mapped to the CAD design and the BOM including revisions, people involved and the work output they created.

We've not even reached the factory floor itself and there is already a large body of 'Manufacturing Big Data' to store and eventually mine.

So the product is ready to launch into manufacturing and the lines are ready to start? Not yet. This is the 'value add' axis of operations, and **without materials being in the right place at the right time, manufacturing cannot begin.** When the production schedule initiates a build, a hand-off from ERP materials management in the warehouse to the more granular shop-floor control provided by the Manufacturing Operations Management system must begin.

Organization of materials into transport orders targeted to the proper process point, the management of local stores, kanbans, and even the interception of materials into delivery or feeder systems and the exact point of use are all needed.

All of those functions must be traced down to the part, lot, and delivery package so that materials traceability has a record from the incoming loading dock to the point where the material or part is consumed into the product or process. **This critical engine of operations must run constantly in the background, feeding the flow of materials to production, and the flow of unused parts back into the warehouse all with precise tracking.**

These activities alone yield vast, valuable and critical data sets within the 'Manufacturing Big Data'.

With materials present and correct at each station, the manufacturing process itself can begin with the serialization range and work order information flowing into operations from ERP. The flow of the product begins, and data starts flowing in from conveyors, the assembly and process data feeds, the operator actions and confirmed presences at each station, the materials, chemicals and tools consumed or utilized as a product entered each station. **Vast amounts of information can be gathered about every conceivable environmental variable,** as well as any entity or material that was added to the product in addition to how it was added and by whom. This data acquisition continues through inspection, repair, test, component replacement, and all the way out to packaging and shipment.

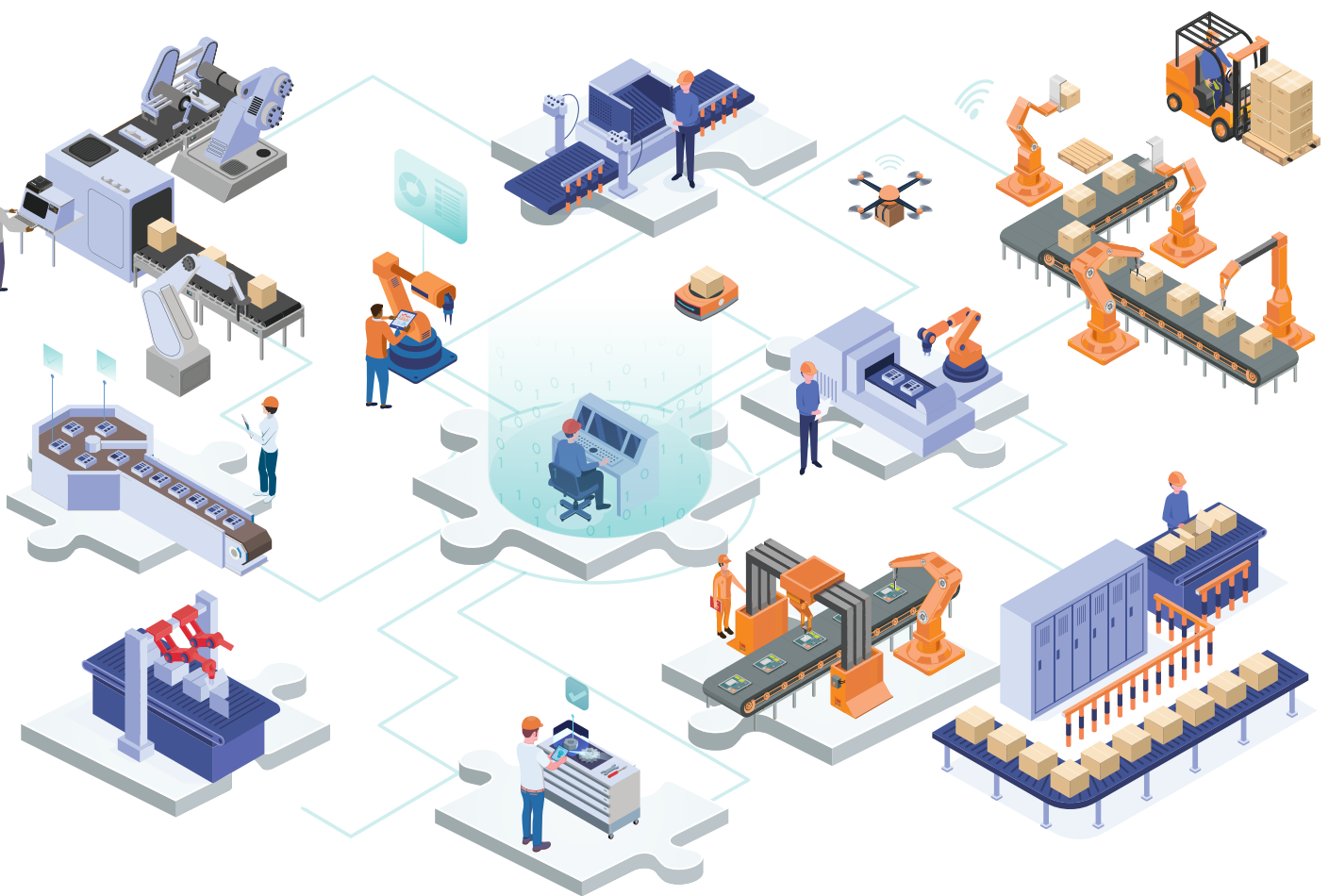
A mountain of context data is gathered. This is 'Manufacturing Big Data'. And all this data is relationally linked, connecting back to the CAD data and the BOM. The product definition itself, embodied in the CAD and BOM, is the binding element of that massive mountain of data.

Where Does Traceability Fit In?

So where does traceability fit in? Simple, when the 'big data' is considered, the traceability required by a given regulatory agency, customer, or market is simply a forward or reverse query against the data set, or a subset of it.

When a manufacturing enterprise adopts a Manufacturing Operations Management (MOM) system capable of managing the entire scope of operations as discussed, **traceability is no longer something an enterprise strives to achieve, it already has it as a natural byproduct of that system.**

Considered from the inverse perspective, total process, product and materials traceability is the essential building block when pursuing operational excellence through the use 'Manufacturing Big Data'.



Four Key Benefits of the Big Data



1 Continuous Process Improvement

A point-solution to answer a traceability requirement is not typically intended to support process improvement. The data set it generates is meant to satisfy a trace requirement but little else. The big data approach gives the enterprise all the information it needs to leverage data toward process improvement and achieving operational excellence. A big data solution provides this by supporting analytics for managers, engineers and line operators so they are armed with actionable information to make better decisions. A big data solution also involves automated process interlocking and fail-safing to keep processes from going out of control even when humans fail to detect such conditions.

A big data solution provides a view into the entirety of operations that otherwise would be extremely difficult to achieve. Real-time dashboards informing operators of impending issues or process performance, condition-generated reports sent immediately to mobile devices when needed, real-time process interlocking of machines and conveyors based on control conditions, visual quality data collection, repair guidance, diagnostics support, real-time detailed work in process monitoring, predictive process flow analysis, and much more can all be achieved simply and efficiently. And all supporting greater control of variability, improved quality, and continuous operational improvement.



2 Shifting from the Psychology of Cost and Burden to Cultural Adoption

A critical factor in the success of any software solution in a manufacturing enterprise is cultural adoption by management and operators. The most powerful and capable software system if considered a burden will rarely succeed. The perception of burden can be the result of a poor user interface, additional transactional overhead slowing work down, or merely confusion as to why it is even necessary at all.

All these problems are common with narrow traceability systems. It is not a problem with the big data approach because of the holistic nature of the system and the tangible benefits that go beyond traceability.

Adoption of a system to harness all manufacturing data becomes part of the operational culture. It simply is the way business is done. This perspective evokes more enthusiastic adoption by operators as it is much like switching the entire factory over to a new data system and the old methods no longer exist.

Additionally, the big data solution yields visible benefits to management and operators and everyone in between. Dashboards, reports, realtime process interlocking, simplified quality data collection and feedback, real-time detailed work in process monitoring, predictive process flow analysis, etc. all give personnel real benefits to their daily work that results in an appreciation of the business's implementation of such a solution.



Enables a Future-Proof Solution

A point-solution for delivering a specific set of traceability to meet a demand soon requires modification to meet an expanded demand as regulatory requirements evolve, or where a customer demands greater traceability. **This neverending cycle of customization, costs and delays results in a clumsy and complex solution that is difficult to maintain.**

The big data approach does not suffer from such issues. It provides an infrastructure to gather all data, and, as requirements evolve, it is simply a matter of querying that data. The solution is inherently gathering the entirety of the data set from the product, process, and materials context of production, or, if deployed incrementally, is architecturally able to add data sources into the system elegantly with little or no customization.



Provides a Lower True Cost

When traceability is approached as the endgoal rather than a byproduct of harnessing manufacturing big data, the true cost of the initiative is greater. A point solution offers no additional benefits from which to gain ROI for the system investment. A narrow solution for delivering traceability essentially incurs only costs by existing as a layer of complexity used only to satisfy an externally imposed requirement. As it has no other benefits for the enterprise, its **ROI is based only on answering an external demand for traceability**. It may avoid risk, but it creates no benefit and is consequently expensive.

When approached as a natural byproduct of harnessing manufacturing big data, it becomes a 'free' benefit of a system that is yielding analytical and process improvement.

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Key Requirements of a Big Data Solution for Manufacturing

Having taken the decision to implement a big data solution as part of an operational excellence initiative, the next step of course is system selection. **There are a few key capabilities and business approaches a manufacturer should demand of any MOM vendor to maximize success.**

Consider the data model the system sits upon. It is not sufficient for potential vendors to simply state 'yes we can store that data' or 'yes we can acquire that data'. It is important to examine two specific and critical data acquisition and data model issues.



First, **how does the system go about acquiring data from the industrial automation layer of the factory** including robots, conveyors, testers, inspectors, sensors, scanners process equipment etc..? Does the vendor build customized connectors for every data source, or does the system have a scalable and standards-based data acquisition engine for easy adaptation to the automation layer such that the adapters are productized, consistent and maintainable?



Second, **determine if the system actually holds the CAD design data in its data model** such that incoming variables are related to elements within the design itself. This is critical to analytics and to data volume efficiency as the storing of the data against the CAD data reduces redundancy.

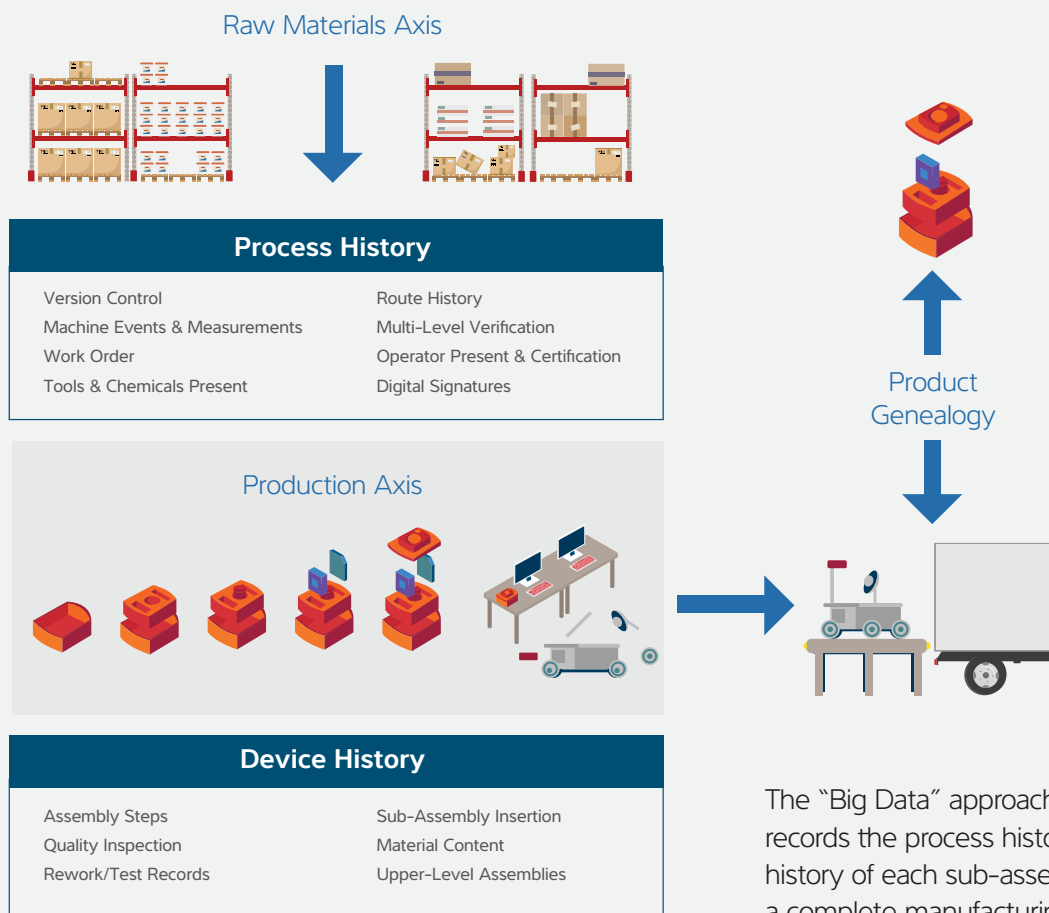
These questions should then lead to another related issue. **Once the data is within the system, how is it made useful through alarms, control reactions, dashboards, and reporting?** Is the data stored in a manner that is meaningful such that reports and dashboards can be made through a graphical user interface without requiring SQL or coding knowledge of the database?

True drag-and-drop construction of real time dashboards and reports is only possible if the structure of the system is **designed in such a manner that any incoming data, whether implemented today or four years from now on new machine types, are normalized and stored in a meaningful way.** The question is a simple one. If a new machine is connected to the system to acquire its real-time data, is any SQL or coding required to change reporting? The answer should be an unqualified 'no'.

The scope of the system must also be considered. To properly harness 'big data for manufacturing', every activity from the handoff of the CAD data from R&D to the process design and NPI activities, through materials management and then out from the start of manufacture to shipment must be part of the fundamental scope of the system's coverage. Anything less will yield only a subset of the data needed.

The final consideration is not a technical one, but rather the business approach and model of the vendor. Is the vendor providing a 'core' of a system that then must be heavily customized to work in your environment? Or, does the vendor have vast stock capability that adapts through configuration to your process, minimizing customization and costs? **This customize vs. configure question is the single greatest determining factor in the rollout speed and total cost of the project.** A means to truly determine the extent of customization from a given vendor is to insist on a highly detailed statement of work that defines exactly what the system will and will not provide, and insist the vendor's quote contains a fixed cost to achieve that functionality.

To do otherwise invites endless customization and costs as you discover after the sale that the system, when you realize it, does not actually have the capabilities you believed it would have and customization is required.



Conclusion

Software technology has **advanced to the point where harnessing the big data of a manufacturing enterprise is a practical reality.** Leading manufacturers will see initiatives such as traceability, continuous improvement, yield and OEE optimization, etc. as best handled as part of a true operations-wide big data solution. Those manufacturers will leverage the incredible depth and scope of data of that approach to achieve world-class operational excellence.

You can only improve what you can measure, with big data expect big improvements!

FactoryLogix®

Aegis' FactoryLogix is a powerful solution is designed for today's manufacturing reality and connects the entire enterprise while improving traceability across all areas of the business. This uniquely adaptive solution drives enterprise-wide compliance, quality, and efficiency, helping manufacturers discover transformative returns.

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