STREAMLINE SUPPLY CHAINS AND IMPROVE PRODUCTION EFFICIENCY WITH TRACK-AND-TRACE

Whitepaper

As of January 2019, IQMS is becoming DELMIAWORKS, joining the global manufacturing powerhouse Dassault Systèmes and its portfolio of innovative brands.

HOW TO STREAMLINE SUPPLY CHAINS AND IMPROVE PRODUCTION EFFICIENCY WITH TRACK-AND-TRACE

- Manufacturers are wasting over $275B a year on unnecessary product recalls that could have been averted with better supplier quality and traceability in place according to a recent NAM study.

- In 2017 alone, U.S. manufacturers spend more than $25B every year on product warranty claims, according to industry studies from NAM and the U.S. Department of Commerce.

- Manufacturers who scale track-and-trace deep into their supply chains to control quality are averting recalls and costly retrofitting of products already sold to customers who are using them daily.

- One of the big three American auto and truck manufacturers averted a recall of their most popular selling Sport Utility Vehicle (SUV) by combining supplier inspection and quality management with track-and-trace. The track-and-trace system saved the manufacturer an estimated $2.3B in a year.

- Track-and-trace is a requirement for aerospace and defense (A&D) manufacturers who need to stay in compliance with International Traffic in Arms Regulations (ITAR) to grow their companies. Track-and-trace software applications enable A&D suppliers to achieve and stay compliant with AS 9100 Rev. C and Defense Contract Audit Agency DCAA) requirements in addition to several more.

INTRODUCTION

Supply chains are the lifeblood of any manufacturing business. Reducing and eliminating risks while increasing supply chains' speed and scale are how track-and-trace applications help manufacturers grow. This whitepaper is for manufacturers who want to enable their suppliers to be collaborators in producing excellent products daily, winning new customers and excelling in fulfilling every order for existing ones.

Track-and-trace adoption is accelerating quickly in manufacturing, directly as a result of costly product recalls, quality incidents caused by a lack of supply chain visibility and unethical production practices including the creation of counterfeit products. The need for greater supplier control, improved product and process quality and faster track-and-trace speeds to minimize the impacts and costs of recalls are all contributing to soaring adoption rates across all industries. Markets&Markets research firm predicts that the global market for track-and-trace technology solutions will increase from $1.65B in 2018 to $3.93B in 2023, attaining a Compound Annual Growth Rate (CAGR) of 18.9%.

Reducing Risks And Excelling At Compliance, Enabling Faster Growth

Regulatory requirements across a diverse array of industries now require track-and-trace compliance and reporting to government agencies on an ongoing basis. From Aerospace & Defense, Automotive, Chemicals, Consumer Packaged Goods (CPG), Distribution & Logistics, Food & Beverage, Medical Device Manufacturing, Medical & Patient Services, to Maintenance and Pharmaceuticals manufacturers, all must meet federally mandated track-and-trace compliance requirements to stay in business. Track-and-trace solutions are scaling and adapting to new regulations quickly, enabling manufacturers to design and produce innovative product lines while staying in compliance with regulatory requirements. A recent informal survey of manufacturers found that the majority believe that by 2021, 40% of countries will either have enacted legislation requiring track-and-trace and product authentication or have compliance legislation in final approval stages.

Balancing supplier risks, compliance requirements, and ongoing delivery of customer orders is a challenge for any manufacturer. The greater the regulatory requirements for reporting track-and-trace in a given industry, the more challenging it gets for a manufacturer to grow. That's why track and trace systems are essential to the future growth of manufacturers. Standardizing track-and-trace integration across a supplier network, defining a clear set of KPIs, and measuring progress on shared goals with suppliers is a strong, proven catalyst for growth.

For manufacturers competing for new business where there's extensive product customization including engineer-to-order combined with track-and-traceability reporting requirements, having a track-and-trace system integrated with their Enterprise Resource Planning (ERP), Manufacturing Execution System (MES) and Quality Management System (QMS) is essential. When these systems are built on single database architecture, they scale and provide manufacturers the ability to flex fast in response to new customer requests for short production runs and win new business.

The essence of track-and-trace is designed to minimize and manage variable, unforeseen risks to suppliers, distributors, trading and technology providers and most importantly, customers. The goal of any track-and-trace solution needs to first focus on how to attain greater supplier control, quantify and measure product quality and have a reliable system of record to track to the lot or container level. Finally, all track-and-trace solutions need to combine speed and scale to solve time-sensitive problems quickly. Real-time speed and scale are especially important in pharmaceutical supply chains where serialized packaging needs to support full traceability, product integrity, supply chain security and patient safety.
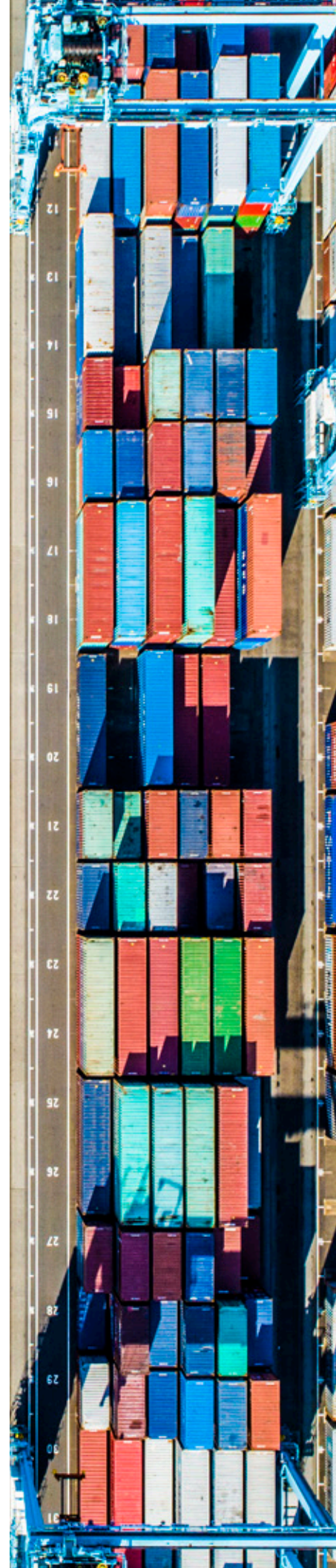
HOW TRACK-AND-TRACE IMPROVES SUPPLIER CONTROL, QUALITY, AND SCALE

Track-and-trace was limited to first-tier suppliers in the past, yet today scales several layers deep into every manufacturing industry's supply chain. Every manufacturer needs greater supplier visibility to mitigate risks, and together with more stringent compliance requirements, track-and-trace is getting embedded deeper into supplier networks than ever before. Advances in integration platforms that enable real-time data monitoring are making it possible to attain both scale and speed across diverse, globally distributed supplier networks.

Improving supplier collaboration and visibility using track-and-trace reduces many supply chain risks including improving order fulfillment accuracy and resolving potential quality problems early before they escalate through supplier networks. Track-and-trace improves quality by improving demand visibility from manufacturers to suppliers, averting incorrect and low-quality orders. Most importantly, track-and-track brings exceptional speed and scale to minimizing and reducing risks across supplier networks, protecting customers by providing real-time responsiveness to recall, product quality and counterfeit product risks. The following are how track-and-trace improves supplier control, quality, and scale:

- **Track-and-trace is reducing the risks, expenses, and impact of product recalls by providing accurate product genealogies in real-time.** Minimizing the impact of part failures that often signal the start of a product recall by tracking to the lot, batch or bin level where a defective part originated from can save millions of dollars. Product genealogies are priceless from a product recall standpoint; they are the roadmaps that help avert recalls from spreading. Using track-and-trace systems that support real-time genealogy search, it's possible to discover how and where a defective part was first introduced into production. This data and insight alone are invaluable in averting more costly and widespread recalls. With a given part's genealogy tracked and traced it's possible to isolate finished products at risk and make more informed decisions regarding how best to handle the products already with customers. Streamlining the warranty claims process and averting large-scale recalls are two of the many benefits of having genealogies created with track and trace workflows.

- **Having quality and traceability data available at all production locations increases manufacturing efficiency quickly.** Improving the accuracy and speed of track-and-traceability information across all production locations enables greater collaboration and knowledge sharing company-wide. Studies of the Toyota Production System have shown that supplier-level quality, track-and- traceability data is valued more than money because its impact can easily lead to new sales and higher profits. The more expensive an asset, the more valuable the real-time tack-and-traceability data.

- **Track-and-trace is critical for staying compliant with many of the manufacturing industry's most stringent standards** including FDA 21 CFR Part 820. In conversations with local aerospace & defense manufacturers who sell to the U.S. and foreign governments, the consensus is that at least 40% of the nations they sell to will require track-and-traceability in the next two years. The costs of compliance continue to escalate in manufacturing. Track and traceability techniques can help to reduce these costs by improving supply chain, in-plant, fulfillment efficiency, and compliance. Track and traceability are proving to be one of the most effective strategies for ensuring compliance and reducing operating costs at the same time. Reducing inventory carrying costs, inventory obsolescence by mitigating risk, and reducing days sales outstanding (DSO) are a few of the many ways track-and-trace is making a financial contribution to manufacturers. Track-and-trace also helps to reduce stock-outs, eliminating duplicate chargebacks and reducing lost sales due to products being on allocation.

- **Prioritizing track-and-trace as a foundational part of supply chain management (SCM) and manufacturing strategy mitigates risk and reduces fines for non-compliance, litigation costs, and possible class-action lawsuits.** Manufacturers who prioritize track-and-trace as a core part of their SCM and manufacturing operations gain the immediate benefits of being able to reduce the risks of litigation and class-action lawsuits by having real-time access to product genealogy data. Access to this data is invaluable in meeting regulatory filing dates to government agencies for all the nations a given manufacturer is operating in or does business with. In the most stringent industries including medical device manufacturing, track-and-trace is proving to be invaluable in reducing non-compliance errors and eliminating costly legal fees and fines.

- **Increasing inventory accuracy and forecasting, enabling production planning to optimize manufacturing schedules and improve supplier collaboration are all made more accurate with real-time track-and-trace insights.** A track-and-trace system that can scale quickly across an entire supplier network is critical to ensuring high levels of inventory accuracy and forecasting precision. Knowing the specific levels of inventory and their relative status across a supply chain is invaluable in attaining higher production rates in each manufacturing center as well. Also, track-and-trace systems over time generate data sets that tend to show patterns, making it possible to anticipate shifts in demand. This insight contributes to greater forecast accuracy and the potential to optimize manufacturing schedules.

TRACK AND TRACE IMPROVES PRODUCTION EFFICIENCY

The passion for pursuing quality is visible in every area of growing, successful manufacturers who are attracting new customers. Market leaders defy uncertainty and market conditions by returning to the true north of customer value which is their obsession with delivering excellent quality. From the shop floor to the top floor, this commitment to quality permeates every process workflow, supply chain interaction, production plan, and finished product quality. Choosing to excel and track and traceability is the cornerstone of many market-leading manufacturer's success:

- **Track and traceability provides medical device manufacturers with the data, insights, and information they need to stay in compliance with many of the most demanding compliance requirements in manufacturing today.** ISO 13485 and 9001 standards, Current Good Manufacturing Practice (CGMP) and CFR and FDA requirements are just a few of the many compliance requirements medical device manufacturers are required to meet to stay in business. Market leaders use these compliance requirements as fuel to drive even greater levels of production and process efficiency throughout their multiple plant locations.

- **Excelling at FDA 21 CFR Part 820 compliance while reducing manufacturing costs with track and traceability is the path to profitable growth for all medical device manufacturers today.** Reducing manufacturing costs, staying in compliance with 21 CFR Part 820, and gaining greater accuracy and speed in supply chains is all dependent on having a proven track and traceability framework in place. Add to this the requirement of delivering the complete medical device history for each unit produced, and it's clear that track and traceability has a direct impact on production efficiency.

- **Track and traceability are invaluable for troubleshooting supplier quality problems and averting larger challenges in the future.** The more production locations a manufacturer has, the more important supply chain visibility is to maintaining quality levels and meeting production forecasts. Track and traceability saves many manufacturers from the high, unpredictable expenses of a product recall by catching product quality problems early.

HOW TRACK-AND-TRACE IMPROVES PRODUCTION EFFICIENCY

Track and traceability provides the data, insights and intelligence manufacturers need to become competitively stronger. How fast a given manufacturer gains insights and takes action on quality challenges can mean the difference between winning new customers and expanding into new markets. At the center of how manufacturers can get stronger competitively is a commitment to excel at track and trace. The following are how track-and-trace is improving production efficiency and enabling manufacturers to become stronger competitively:

- **Increasing inventory accuracy and forecasting, enabling production planning to optimize manufacturing schedules better.** Knowing inventory levels throughout supply chains makes inventory planning and management more efficient for each production center. Track and traceability systems over time generate data sets that tend to show patterns, making it possible to anticipate shifts in demand. This insight contributes to greater forecast accuracy and the potential to optimize manufacturing schedules.

- **Improving manufacturing efficiency by making quality and traceability data available at all production locations.** Improving the accuracy and speed of track and traceability data across all production locations fuels greater collaboration and knowledge sharing. Studies of the Toyota Production System have shown that supplier-level quality, track, and traceability data is valued more than money because its impact can easily lead to new sales and higher profits (Dyer & Nobeoka, 2000).

- **Improving order accuracy by enabling manufacturers to deliver high-quality products on time to customers when they expect them.** Track and traceability make it possible for manufacturers to improve their perfect order performance by providing accurate data on when parts, components, and subassemblies will arrive to complete orders. The most challenging aspect of consistently delivering perfect order performance is visibility into logistics-based data (Novack, Thomas, 2004). Track and traceability bridges this gap, making perfect order performance more achievable on a consistent basis.

- **Attaining and continually staying compliant with many of the manufacturing industry's most stringent standards including FDA 21 CFR Part 820.** The costs of compliance continue to escalate in manufacturing. Track and traceability techniques can help to reduce these costs by improving supply chain, in-plant and fulfillment efficiency. Track and traceability strategies enable more consistent compliance, reducing costs at the same time. Reducing inventory carrying costs, inventory obsolescence, and days sales outstanding (DSO) are a few of the many costs track and trace initiatives have a positive impact on. Reducing stock outs, eliminating duplicate chargebacks and reducing lost sales due to allocation are additional cost and time savings gained.
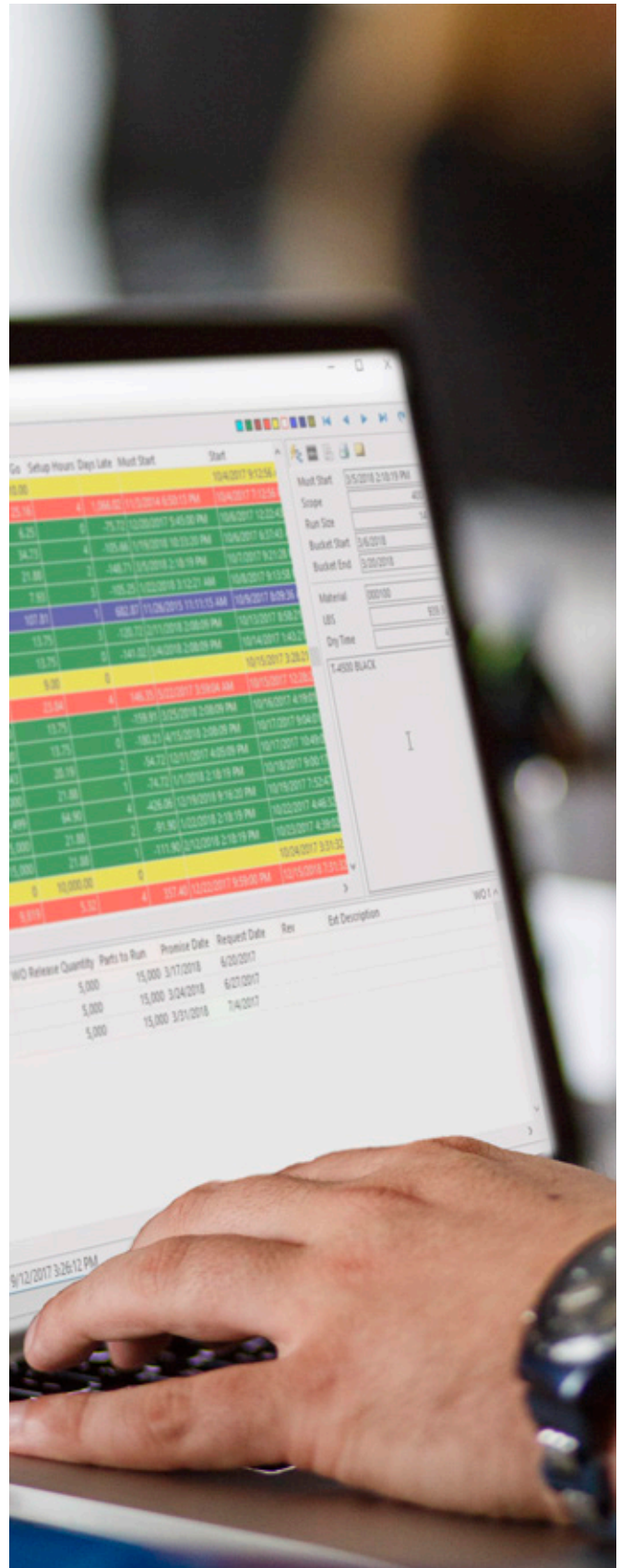
- **Reducing the expense, impact, and risk of product recalls by having accurate genealogies of each product available in real-time.** Minimizing the impact of part failures by tracking to the lot, batch or bin level where a defective part originated from can save millions of dollars in product recall costs. Using genealogies to discover how a defective part was first introduced into production is invaluable. With a given part's genealogy recorded it's possible to isolate finished products at risk and make more informed decisions regarding how best to handle the products already with customers. Streamlining the warranty claims process and averting large-scale recalls are two of the many benefits of having genealogies created with track and trace workflows.

- **Increasing machine and tool capacity utilization that contributes to improved Overall Equipment Effectiveness (OEE) improvements.** Manufacturers relying on track and traceability techniques can define a roadmap to higher OEE and greater productivity across all their plant locations. By tracking and tracing the quality of produced part, component or material to a given machine or tool, engineering and quality management have the data they need to increase tool capacity utilization and effectiveness.

- **Reducing scrap and rework by screening out defective parts, components, and subassemblies before production of the final products.** When track and traceability workflows are integrated with inbound inspection and quality management, it's possible to stop entire lots of defective parts before they even enter the warehouse. As more data is collected over time, it's possible to also predict patterns in quality by the supplier, further reducing scrap and rework by anticipating when defective parts are in a supplier delivery.

- **Reduce inventory shrinkage and theft due to greater visibility and reporting that quickly catches inconsistencies in inventory levels.** When a track and traceability system is managing all inbound shipments to the batch, lot and container level, it's relatively easy to see at what point inventory is lost or stolen. Automotive, aerospace and defense (A&D), high-tech and medical device manufacturers are early adopters of Radio Frequency Identification (RFID) tagging which increases the accuracy and precision of track and trace data, further ensuring inventory stability.

- **Reducing fines for non-compliance, litigation costs, and possible class-action lawsuits.** The many examples of manufacturers being fined by regulatory agencies for operating out of compliance, the high costs of litigation and lawsuits, and missed regulatory filing dates often are signs of a quality management system that needs an overhaul. In the most stringent industries including medical device manufacturing, track and traceability have been able to reduce non-compliance errors and eliminate litigation costs.

- **Avoiding damage to a manufacturer's company reputation and brand.** Stopping defective products from reaching customers by using genealogies to find and eradicate bad parts from production and managing suppliers and inventories to meet delivery dates both strengthen a company's reputation. Manufacturers earn their great reputations every day by doing more than they commit to. Using track and traceability as a means to deliver excellent products is another investment made in keeping the promise to customers of giving them the best quality product every day.
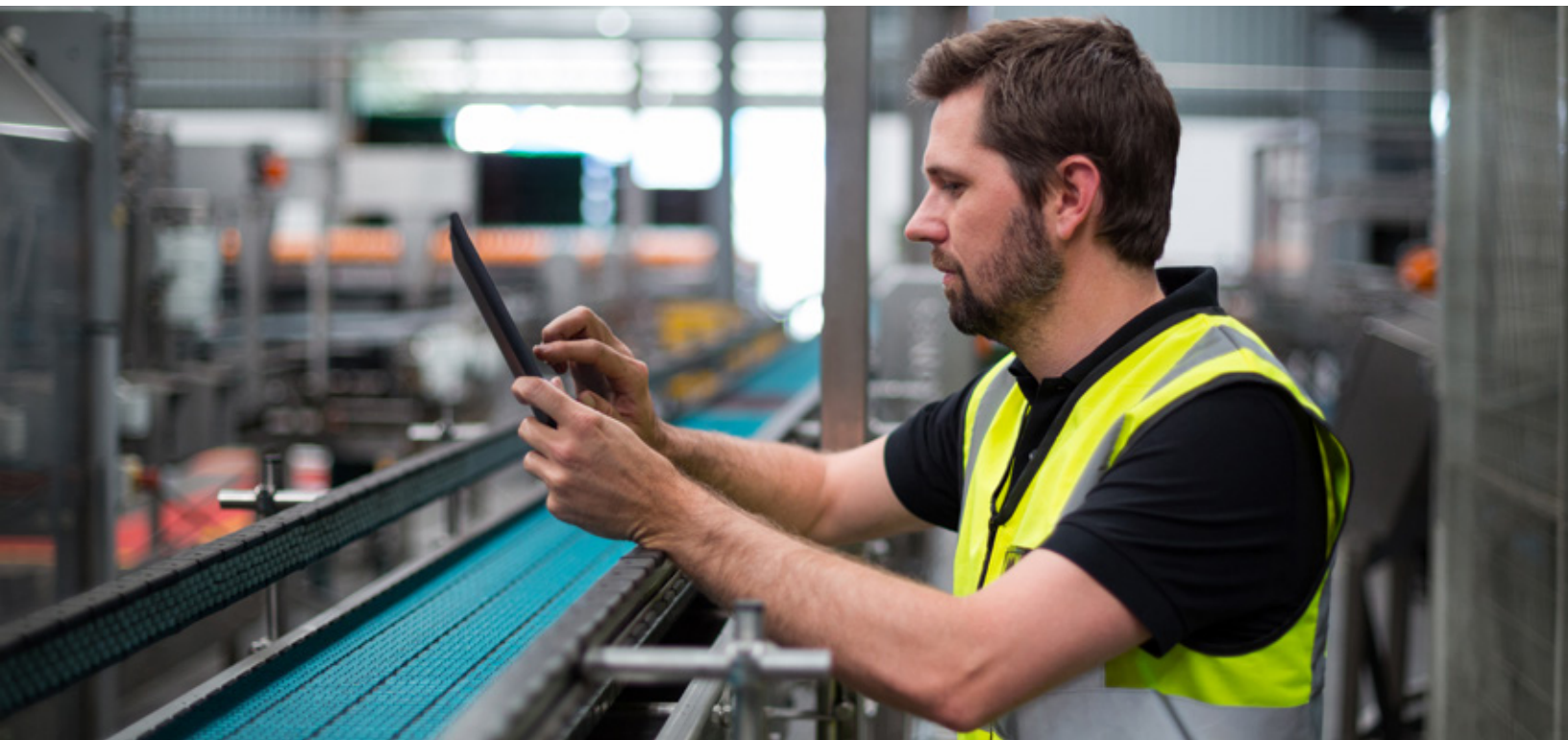
CONCLUSION

Improving supply chain visibility, contributing to optimized inventory and expiry management, providing higher quality data that drives better forecasting, reducing inventory shrinkage throughout the supply chain are a few of the many benefits of automating track-and-trace. Track-and-trace systems are designed to capture their contribution across a supplier network, providing metrics and KPIs on dashboards accessible on any Internet-capable device anywhere, anytime.

Track-and-trace immediately contributes to production scheduling by providing greater visibility into products, parts, components and subassemblies availability and inventory levels across an entire supplier network. Having this data averts stock-outs and can stop allocations before they begin. Over time track-and-trace also increases customer satisfaction with timely and accurate order status information. For manufacturers who rely on complex product configurations to support build-to-order, configure-to-order and engineer-to-order manufacturing strategies, track-and-trace provides greater visibility into each product's lifecycle early so potentially defective parts can be found and removed from designs and finished products.

Where track-and-trace provides its greatest competitive strength is in being able to isolate and identify finished goods, components, and raw materials associated with a recall by lot number, serial number, and other identifiers as they move up and down the supply chain. Having this level of detailed data is averting recalls and massive retrofit programs that manufacturers would otherwise have to rely on. Track-and-trace is also indispensable in troubleshooting product quality problems as the system is providing visibility into machine and work center metrics and KPIs of performance. By combining quality management and track-and-trace systems, manufacturers can predict patterns in product quality and anticipate when defective parts are in a supplier delivery.

Track-and-trace is now the cornerstone of every manufacturer's quality strategy who competes in highly regulated industries. Manufacturers competing in Aerospace & Defense, Automotive, Chemicals, Consumer Packaged Goods (CPG), Distribution & Logistics, Food & Beverage, Medical Device Manufacturing, Medical & Patient Services, Asset Maintenance and Pharmaceuticals all have track-and-trace systems that can troubleshoot supplier performance and quality problems in real-time. Track-and-trace systems are tailorable for specific industries as well. For food & beverage manufacturers, track-and-trace provides visibility into raw materials' expiration dates and perishable asset dates. And these systems can also provide real-time medical device production histories as required by the U.S. Food & Drug Administration (FDA) as part of the 21 CFR Part 820 requirement.
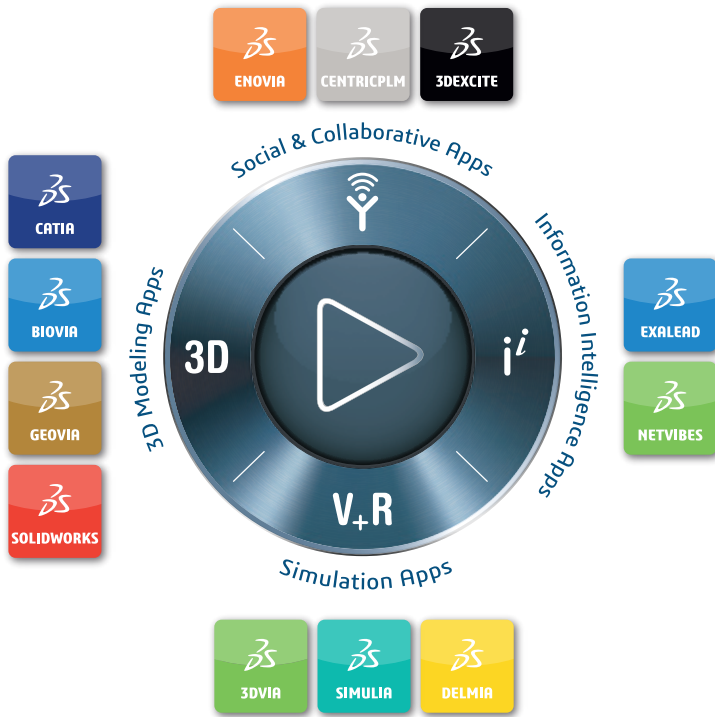
Our **3DEXPERIENCE**® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE**® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 210,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan

DASSAULT SYSTEMES | The **3DEXPERIENCE**® Company