



Mitigating Medical Device Product Liability Risk



IQMS
Manufacturing ERP

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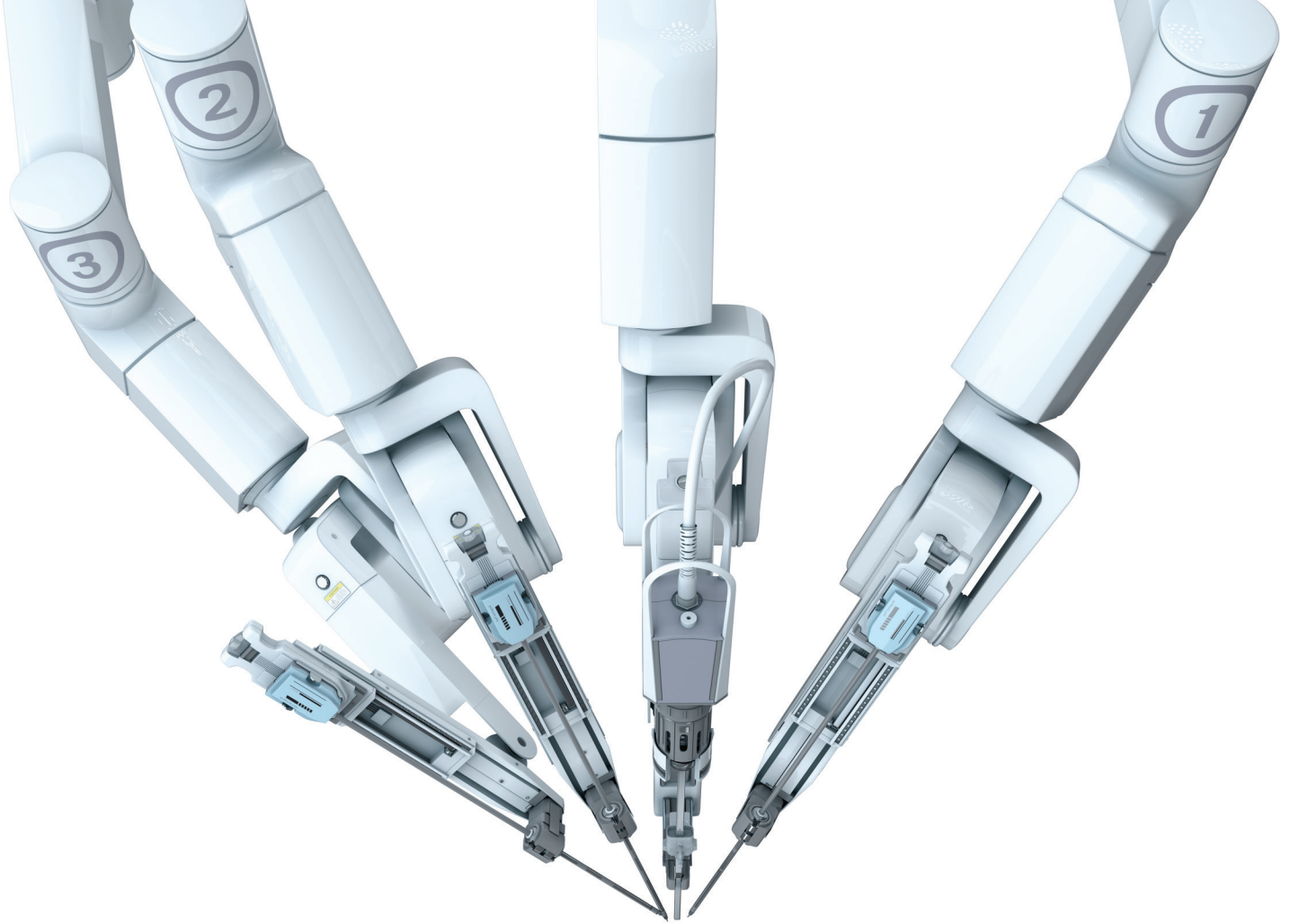
Unfortunately, medical device product liability lawsuits are a stark reality in the manufacturing industry. The nearly doubling of medical device recalls in the past decade proves that even with the FDA working to ensure that only “safe” products are made and manufacturers making a dedicated effort to keep harmful devices out of the marketplace, faulty products still fall into the hands of consumers.

- Medical device product liability can occur at one of these three phases:
- Design (A design portion of the product is proven to be inherently unsafe)
- Manufacturing (A product is proven to be flawed as a result of machinery problems, unintended human error or faulty components)
- Marketing (A failure to market a product adequately is proven, including improper labeling, insufficient instructions or inadequate safety warnings)

To add fuel to the fire, manufacturing defects are often the easiest to prove. So how can a manufacturer mitigate their product liability risk? In the battle against device liability, the best defense is a good (automated) offense. With a comprehensive ERP solution, you can prove, without a doubt, that you manufactured the part correctly. By automating the collection process so there is no human entry error, tracking every production detail (including temperature, cycle time and other process parameters) and tracing the entire lifecycle of every finished product and component from start to finish, you can greatly reduce your product liability risk. The key words here are “comprehensive” and “automated.”

Comprehensive ERP offers an end-to-end solution that covers every aspect of your business, from ERP to MES, MRP, financials, order management, WMS, CRM and more. This single source system is what makes every aspect of your business visible, traceable and efficient. Rather than silos of quality and supply chain data, a comprehensive system offers complete traceability of all lots, batches and units, spanning multiple plants or suppliers.





Automated ERP eliminates many once manual processes. The more manual your operations are, the more errors, omissions and delays. If you were to find a manufacturing error this minute, could you easily narrow it down to which batch and parts, and then trace it to a specific device or component lot? If you don't have a modern, comprehensive ERP system, then your answer is likely no. Most legacy ERP systems do not have the ability to track shipment and inventory details at the level required to reduce exposure and quickly remove product from the marketplace.

Now that you understand the importance of a comprehensive ERP system, let's take a look at the more specific features in ERP software that can help mitigate product liability:

Process Monitoring: A process monitoring system links directly to your work centers and high value production equipment at the PLC/sensor level and collects every important variable that relates to production: Temperature, pressure, dimensions, weight, thickness, fill rate, date, time, operator, lot numbers, etc. If you are using a comprehensive ERP solution, then this detailed information is automatically populated on a historian database where it is easily accessed by your ERP solution for tracking and analysis. This two-way communication between the ERP solution and your work center eliminates breaks in the product genealogy. The real-time, automated benefits of the process monitoring package ensure that there is no need to manually rekey in data and production details are uploaded as they occur, with no delays or batch transfers.

Product Genealogy: If you are being evaluated for medical device product liability, you must be able to completely trace product genealogy, forward and backward. From the raw materials in your warehouse, to the work center they were processed on, all the way to the shipping truck, comprehensive serial and lot tracking allows you to follow the lifecycle of every piece, part, box and pallet in your company automatically. Comprehensive product genealogy functionality can be found at every step in the supply chain:

- Assign lot/batch numbers upon receipt of material.
- Implement multi-level BOMs
- Track components and use batch records to determine where the part was used based on the lot and serial number of the medical device
- Collect and analyze process parameters of the work center at the time of part creation.
- Automatically drill down from the packing slip

In the event of a recall, a comprehensive ERP solution can also offer reverse lot lookup so you know exactly where a product was used and if any other products are at risk.





Product Lifecycle Management (PLM): A medical device traveler contains important details such as materials consumed, processes and equipment utilized, quality data collected, exceptions, rework and electronic signatures. Without a comprehensive ERP solution with a medical-specific PLM module, collecting all that information can be a pain. With bolted together, best of breed ERP, you have to go to each different system, run individual reports and then try to collate and analyze the data. Comprehensive ERP offers that information all in one central location, for detailed analysis, risk capability and improved decision making.

It is time for the ultimate test. Can your ERP software help you in the example below?

The unmentionable has occurred: A lawsuit has landed on your doorstep for one of your largest customers. Litigation is pending and the prosecution is unsure if the liability lies with the design from the company that contracted the project or with your manufacturing business. The burden is on you to prove that you manufactured the part exactly as instructed. Let the investigation begin.

First, you access the sale in your comprehensive ERP system. Pulling up the packing slip, you begin drilling down through the lifecycle of the device. Down through the quality tests you performed before shipping. Down through the exact process parameters that particular part was made with, the work center it was made on (and the machine's certifications) and the operator that worked that shift the part was made. Down to the exact components that came from your suppliers. Down to the raw materials pulled from your warehouse. Every single step in the process in one glance and a comprehensive way to prove without a doubt that you are not at fault.

While the possibility of being involved in a medical device product lawsuit is a reality, a comprehensive, automated ERP solution with the features above can help you rest easier knowing that you have the tools to mitigate medical device product liability risk. Stop worrying and instead focus more on what you do best: making a perfect part every time.

About IQMS

Since 1989, IQMS has been designing and developing ERP software for the repetitive, process and discrete manufacturing industries. Today, IQMS provides a comprehensive real-time MES and manufacturing ERP software solution to the automotive, medical, packing, consumer goods and other manufacturing markets. The innovative, single database enterprise software solution, EnterpriseIQ, offers a scalable system designed to adeptly grow with the client and complete business functionality, including accounting, quality control, supply chain, CRM and eBusiness. With offices across North America, Europe and Asia, IQMS serves manufacturers around the world. If you would like to learn more about IQMS' comprehensive ERP solution, please visit www.iqms.com.