# Start-Up Medical Device Manufacturer Matures Quickly with an Automated Management System.

"TraTek is a start-up company, and we are building the foundation to organize workflows, processes, and procedures. By creating this foundation now, Entropy is primed to grow with us."

Luke Bulino, General Manager

## Customer Needs

- Paperless environment to streamline operations and efficiency
- Monitoring and maintenance of ISO 13485 Certification
- Well-defined and seamless workflow of processes and procedures
- Ability to demonstrate value and compliance to the organization

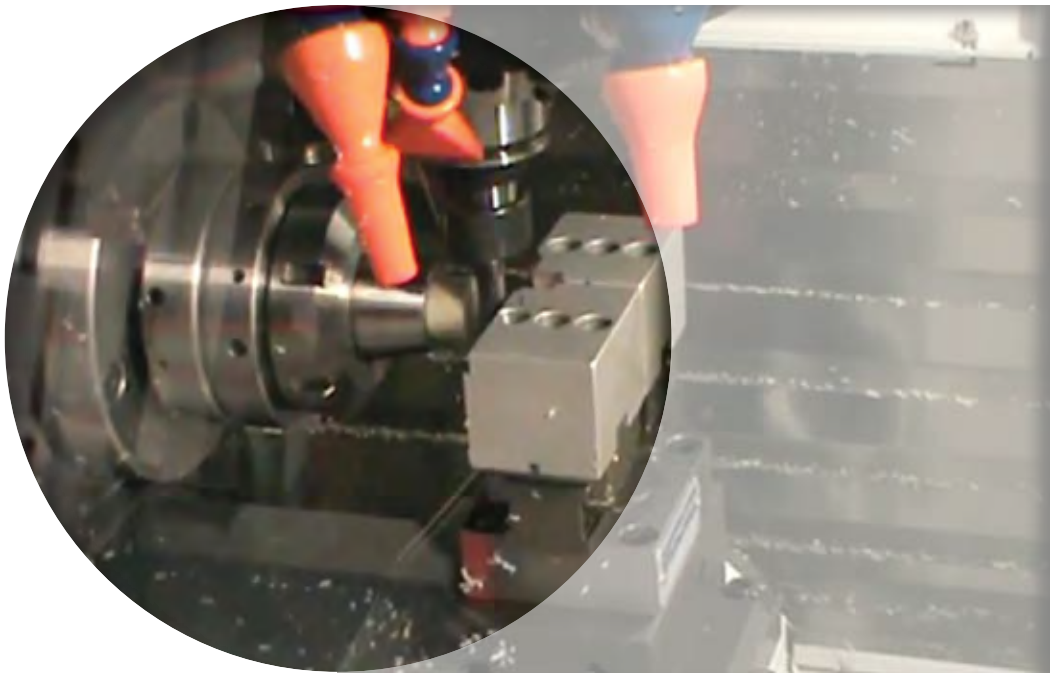
## Customer Benefits

- Automated Quality Management System
- Centralized ISO 13485-compliant storage and access to records
- Records of actionable data and information
- Task-driven system with accountability of defined roles and responsibilities
- Streamlined reporting and auditing for reporting

## Customer Background

TraTek Inc. is a start-up company that performs precision manufacturing of Class I and II medical devices for an expanding base of customers. Their products are designed for simplicity of use, and engineered to exceed the required standards of performance. TraTek's manufacturing facilities are located in Indiana (U.S.) and Costa Rica. Both facilities are ISO 13485 certified.

Currently, TraTek specializes in the precision machining of products for the orthopedic industry, including a wide variety of screws, plates, and surgical instruments. TraTek promotes its highly experienced team of professionals as being able to accommodate fast turn-around times for prototypes, short or long runs, as well as low-cost, high-volume manufacturing requirements. The company minimizes turnaround time for all jobs by performing necessary manufacturing processes onsite. According to TraTek, these capabilities, and the team's wealth of experience, creativity, and expertise, enable the company to deliver both high-quality craftsmanship and cost-competitive products to customers worldwide.



## Customer needs

Working in the medical device industry, and complying with ISO 13485, required TraTek to either maintain a large volume of paper records; or alternatively, create, and store those records electronically. TraTek made the decision to pursue a software-based quality management system (QMS) in order to reduce, and eventually eliminate, the use of paper records in its plants. TraTek was doing its best to run a paperless operation with managers and employees storing documents in Microsoft SharePoint. Control procedures were being stored in SharePoint, but the company still had paper-based engineering change forms and audit reports.

"We knew after eight months of operation that we were generating a lot of paper, and it was quickly burying us. TraTek was building a library of three-inch thick binders. We had a strong desire to get an automated system right from the beginning," said Luke Bulino, General Manager.

In addition to streamlining operations with paperless, instant availability of records, TraTek required the chosen QMS software help with the implementation and ongoing maintenance of its ISO 13485 certification. With this goal in mind, TraTek searched for a software solution that would keep the company's records in a safe place and routinely provide back-up. With two manufacturing facilities, one outside the U.S., TraTek also wanted to enable users with layers of secure, role-based access to records from anywhere in the world.

Bulino preferred a hosted system to an on-premise deployment to reduce cost and overhead on maintenance and IT support. "I previously worked for a company that had a good QMS, but its efficiency was greatly hindered by the software we used," Bulino explained. "It [the software] was bulky, and slow, and required a lot of extra work to make the data helpful to us."

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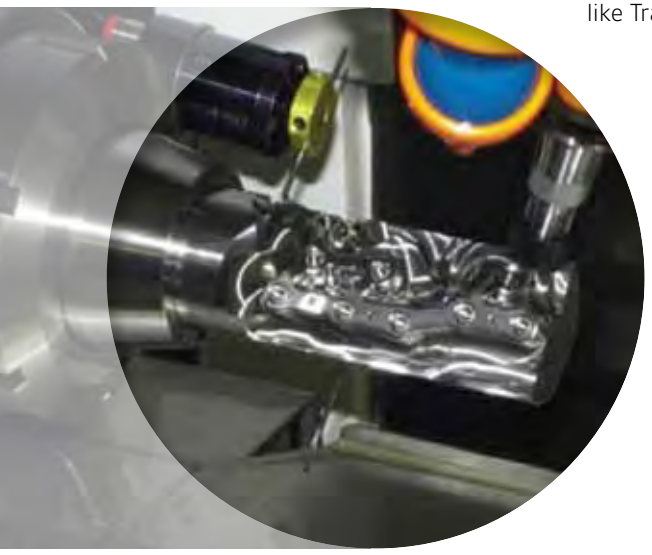
TraTek needed a solution that would facilitate a streamlined, process-based approach to quality and compliance management by first creating an action, and then notifying the proper people, tracking due dates, allocating responsibility, defining task dependencies, performing root-cause analysis, and ultimately escalating results or issues to management, as needed. The desired QMS software would make it easy for users to search and retrieve documents, as well as upload any documents for instant access.

"TraTek was looking for an affordable QMS software that would continue to provide the company with value as it grows. Since Entropy is designed and developed by BSI, a leading authority on medical device management systems, we were confident it was a good fit and built the foundation to help achieve our long-term goals," says Bulino.



## Customer Success

Since Entropy Software was installed, it serves as the company's main repository for documents and records associated with ISO 13485 at facilities in both Costa Rica and the U.S. Also, as a web-based system, users at each plant can gain access to records for which they have been assigned the proper authorization. Essentially, with configurable access, approval, and reporting privileges, all employees have what they need – at their fingertips – to do their job.

"Convenience" and "security" are just two words that Bulino uses to describe what Entropy Software offers TraTek since implementation. The software enables TraTek to use electronic signatures, and also ensures a clear definition of business process where the system recognizes each role is different. The entire application of Entropy Software revolves around the organizational structure so that policy and procedures are limited to the appropriate person(s).

"One of the major tenets of ISO 13485 is providing everyone with access to the records, procedures, and QMS documents that are part of their jobs. Entropy Software provides unlimited access, albeit role-based responsibilities. It is able to grow with the company, and therefore a good fit for a young, maturing company like TraTek," concludes Bulino.

## Reporting and Validation

Entropy Software's reporting feature makes it easy for Bulino and his managers to quickly provide auditors with reports on-demand, such as control procedures, audit schedules, management reviews, or internal audit score cards.

"Entropy's reporting capabilities really streamline the auditing process. If an auditor wants a particular document or specific report, we can retrieve it from our Entropy system as quickly as it takes to pull up a search box and enter a couple of key words," said Bulino. "It definitely improves my ability to access data, systems, documents, and records."

In addition, most of TraTek's goals are process-based, so the ability to quickly and easily make revisions to control documents has helped the company achieve those targets, he added. Other objectives for using the system include improving and adding to records that the company maintains. For instance, now TraTek is uploading raw materials certificates as control documents, and device history records are next.

Software validation is an increasingly important topic with companies in the medical device manufacturing sector. To be compliant to FDA regulations, medical device manufacturers must consider validation of software that is employed by their organizations.

"If we determine that there are risks involved in any module within Entropy, we perform a user test, document it, and accept or reject it," said Bulino. "Then we tie everything together with Entropy's traceability matrix, which shows each module, the function within the module, the risk associated with that function, and the steps we took to reduce the risk. All of those things are displayed as a table that our auditors can view to see what we did and how we did it. It is a completely transparent process."

## Future Opportunities

ISO 13485 certification affords TraTek a competitive advantage in the U.S. but even more in Costa Rica. In Costa Rica where the medical device industry is growing, TraTek's certification has boosted business potential. And the business benefits of Entropy – speed to market and reduced compliance costs – should be of interest to many companies expanding operations.

"It is quite the ecosystem developing in Costa Rica," Bolino said. "TraTek is hoping to be at the forefront of the industry that is growing here, and our certification - managed by Entropy - helps us a great deal."

Meanwhile, TraTek will continue to benefit from the speed with which it can create and maintain changes in Entropy Software. Bulino plans to expand and improve the company's current use of the system and intends to add training records and notifications to its Entropy Software infrastructure going forward.

"Entropy has definitely improved our audit experiences and made us a more efficient organization," exudes Bulino. " I would say it definitely has brought us a positive return on our investment to date."

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Your business could benefit from Entropy Software just like TraTek, Inc.
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