

## Sparta Systems Success Story

### *Invacare Streamlines Complaint Management to Improve Customer Service Levels Worldwide*

*Sparta Systems' TrackWise solution enables Invacare to harmonize the complaint intake and investigation process globally, consolidating redundant systems, reducing manual operations and reducing costs*

#### The Client

Invacare Corporation

#### Situation Analysis

Invacare Corporation is the global leader in the manufacturing and distribution of innovative home and long-term care medical products that promote recovery and active lifestyles. The company sells its products to over 25,000 home health care and medical equipment providers, distributors, and government locations in the United States, Australia, Canada, Europe, New Zealand and Asia. With 5,700 associates, Invacare markets its products in 80 countries around the world.

Invacare provides a full range of home medical equipment including rehab, respiratory and standard products, and the company is the leading company for power and manual wheelchairs, home care bed systems and home oxygen systems.

#### The Challenge – Ensuring Global Quality and Accurate Reporting

Invacare faced the challenge many medical device companies face in today's global market. The company has a diverse product line that is sold in markets around the world. The complaint process differed across sites and business units and it was difficult to triage complaint event data, assess risk and escalate a complaint to a reportable event for submission to the applicable regulatory bodies. In addition, Invacare's existing complaint handling system provided little visibility into complaint data across geographies, making root cause analysis and complaint trending inefficient and reporting cumbersome. Changes to the existing complaint system required significant customization, resulting in expensive professional service engagements with their software vendor and additional re-validation efforts that made upgrading and maintaining the current system unsustainable.

As with many medical device manufacturers, Invacare had previously collected its reports via a paper-based system. This approach served the company well in years past, but the limitations of the traditional approach quickly surfaced. Every time complaints or incidents arose, Invacare was forced to search laboriously for files documenting the devices in question. Adding the risks of human error, Invacare struggled to manage their reporting and compliance efforts, as collecting the paper documents for submission became considerably more arduous as the company continued to expand its organization globally.

Invacare was tasked with finding a solution that would not only streamline the paper-based reporting process, but would also prepare for the FDA's forthcoming Electronic Medical Device Reporting (eMDR) mandate which requires medical device companies like Invacare to electronically submit their medical device reports through a specially designed Electronic Submissions Gateway (ESG). While the goal of the FDA mandate is to ultimately reduce costs while increasing the accuracy of reporting, companies must carefully plan and prepare for the changing requirements.

Ultimately, Invacare sought a scalable solution that could be implemented quickly with minimal risk as a replacement to their existing legacy complaint system. They required a solution that would not only streamline the medical device reporting process, but also increase global efficiencies, improve visibility, and reduce costs associated with lengthy complaint investigations outside of the current system – all while equipping the company for future regulatory compliance with FDA’s pending eMDR legislation.

## The Sparta Systems Solution

Invacare chose Sparta Systems’ TrackWise based on its reputation as the leading Enterprise Quality Management System (EQMS) for medical device manufacturers in the market, as well as its ease-of-use and configuration, scalability and quick potential for return on investment. After considering several vendors offering EQMS and compliance software options, Invacare selected TrackWise for its best-of-breed reporting capabilities and because it offered the most robust process management functionality to meet the company’s quality management needs. With capabilities including nonconformance management, customer complaint management, supplier quality, internal and external audits, change control, corrective and preventative (CAPA) management and a host of other processes pre-built into the software, Invacare found an out-of-box solution that allowed the company to quickly and easily manage and report its market-leading medical devices.

For Invacare, Sparta Systems’ TrackWise solution addresses quality issues across the global supply chain, allowing efficiency, accountability and, ultimately, an increase in customer satisfaction and compliance. TrackWise was chosen also due to the software’s scalability. Invacare fact that they could grow with the system – rather than the point solution they had which required lengthy customization.

## Successful Outcome

Invacare rolled out TrackWise for compliant handling to the North America Elyria, OH headquarters beginning in the summer of 2009. Leveraging Sparta Systems solution delivery team, Invacare was able to harmonize their quality processes, validate the system and go live within 6 months - on budget and ahead of schedule

## Future Plans

- Now that Invacare has a global platform in place, regulatory reporting and complaint management will next be rolled out globally
- Expand complaint system to sales force, providing more visibility, trending and reporting to a wider audience
- Implement eMDR as part of enterprise-wide complaint handing process
- Global CAPA across more than 40 all manufacturing facilities. This will provide a true global EQMS – linkage between quality issues and corrective action that results – all through a centralized system
- Audit management to manage internal audit program. Due to TrackWise’s time-to-value and scalable nature, Invacare will use TrackWise to manage the company’s e supplier quality management process



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**About Sparta Systems:** Founded in 1994, Sparta Systems, Inc. is the industry leader for Enterprise Quality Management Solutions. Its product, TrackWise®, is used by Global 500 companies around the world to ensure compliance, improve control, reduce risk, and lower costs by consolidating issues and actions, automating workflow, and facilitating trending and reporting. Additional information about Sparta Systems and TrackWise can be found at [www.spartasystems.com](http://www.spartasystems.com)