

HemoSonics Implements Copley's FDA Extended Solution

“With Copley, HemoSonics now has the system and processes in place to address FDA regulatory mandates and CE requirements, as well as satisfying financial compliance requirements. The new system includes mission-critical features such as serial lot traceability to track all components of their products through the manufacturing lifecycle, and to meet FDA software validation requirements, thus ensuring quality control.”

-Steve Erwine, CFO at HemoSonics

About HemoSonics

HemoSonics is a medical device company offering a novel point-of-care diagnostic platform to guide the management of critical bleeding to improve outcomes and reduce healthcare costs by enabling more targeted transfusion of blood products. The Quantra® System is designed to transform the way clinicians manage coagulation dysfunctions by providing comprehensive, timely information on coagulation status at the point of care.

HemoSonics seeks to transform the way clinicians manage coagulation dysfunctions by providing comprehensive, timely information on coagulation status at the point of care. By enabling clinicians to choose the right treatment in the right time frame, this dramatically improves outcomes. Their innovative in vitro diagnostic platform characterizes hemostasis – the balance between bleeding and clotting – in a variety of acute care clinical settings.

HemoSonics is headquartered in Charlottesville, VA, with research, development and manufacturing facilities in Durham, NC.



Business Challenges

- Meet FDA regulatory requirements
- Compliance across US and Europe
- Support for mixed load manufacturing
- Automate service and product re-ordering
- Reduce regulatory risk

Benefits

- Copley Consulting implemented the FDA Extended ERP Solution system, which replaced manual systems and processes, providing all the functionality needed for HemoSonics to support their aggressive growth goals
- Implemented an ERP system that could keep up with company growth and compliance mandates, while reducing regulatory risk
- The FDA Extended Solution also allows the organization to know their service footprint, such as tracking product warranties, as well as allow their customers to reorder cartridges on an ongoing basis in order to perform critical blood tests

To find out more about Copley's FDA Extended Solution or to schedule a demo contact us at sales@copleycg.com.

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