IntraOp Medical Corporation is the pioneer in portable electron-beam Intraoperative Radiation Therapy (IORT). The IntraOp® Mobetron® has transformed cancer treatment by bringing radiation technology into the operating room, uniting radiation oncology and surgery. For patients and their families, this means markedly shorter treatment and recovery times, improved outcomes, greater comfort, and quality of life. To ensure the teams execute on product realization at the highest levels of quality and adhere to regulations, IntraOp uses Arena Solutions for their critical product and quality management processes.

IntraOp®

At a Glance

Mission:
Accelerating the cure of cancer

Requirement:
Support regulatory compliance

Must Have:
Integrated product and quality management

Bottom-Line Impact:
Analytics for better decisions

Daily Benefit:
Up-to-date process progress

As an FDA-regulated company, IntraOp must not only design and produce a complex product with electro, mechanical, and software components, but do so while meeting all FDA 21 CFR 820, EU Medical Device Directive (MDD), ISO 13485, Health Canada, and other regulations requirements. So IntraOp needed more than a system to manage all the product details, changes to product, and collaboration efforts with the teams. They also needed a quality management solution to ensure absolute regulatory compliance. IntraOp chose the Arena Solutions platform for both product and quality management.

After IntraOp implemented Arena to manage the product and quality processes, the team took the next step to business analytics with Arena Analytics. They wanted Analytics to provide critical day-to-day insights into quality process progress as well as provide confidence that they can meet regulatory requirements. As An Nguyen, director of regulatory affairs and quality assurance, shares, "Information from the Arena Quality module, such as CAPA and non-conformances visualized through the Arena Analytics dashboard, allows us to monitor the up-to-date performance of our product process, see the areas and suppliers which have unfavorable quality trends, and plan for our improvements or preventive actions."

Before implementing Arena Analytics, IntraOp depended on lengthy, labor-intensive manual data crunching to see what was happening with quality processes. "Before Arena Analytics, we had to export quality process information to Excel, then use pivot tables and charts to manually create dashboards. Now, with Analytics we monitor quality performance and see our up-to-date progress automatically. The value of Arena Analytics is very high," explains An.

IntraOp continues to expand the processes managed through the Arena platform. IntraOp's next focus is on gaining business insights into customer complaint processes and more detailed CAPA analysis to optimize supplier management. On Arena as a solution vendor, An comments, "Arena continues to push the product and add new functionality quickly—we like seeing that growth."

" Monitoring and measuring product and process performance are key requirements of medical device regulations. "

An Nguyen
Director of Regulatory Affairs
& Quality Assurance