



RF Precision Implements Medical Quality Management System

Contributed by
Texas Manufacturing Assistance Center (TMAC)

The Situation

RF Precision needed to be registered to ISO 13485 to enable them to bid and work on projects for medical equipment supplies. ISO 13485 enables them to retain work from existing customers and acquire work from new customers.

The ISO 13485 Quality Management System (QMS) certifies quality control for contract manufacturers of medical and dental devices and implants. Registration opens markets to RF Precision for a wide variety of customers in North America and Europe.

The Solution

President Otis Blackwell asked their ISO 9000 registrar for an ISO 13485 referral in early 2008. He was referred to the Texas Manufacturing Assistance Center (TMAC).

TMAC is the US Department of Commerce Manufacturing Extension Partnership Center for the state of Texas.

RF Precision contracted with TMAC to design and implement a Medical Quality Management System compliant to ISO 13485. TMAC Manufacturing Specialist Mike White worked with RF Precision's management team with included the president, the lead operators and their lead inspector.

Research for a gap analysis was conducted to fully understand problems and the uncertainties of the current operating environment. White then worked with staff on flow charting the organization to determine compliance and areas for improvement. The group teamed to create the quality policy manual, procedures, work instructions, and records/forms required to meet the requirements of ISO 13485. Personnel were then trained on documentation that affects their work area.

The Results

RF Precision reports they have enhanced routing systems and inspection techniques. They now measure re-work which has led to increased capacity for more value-added activities. Their work processes are simplified, taking less steps and shorter lead times. They have also enabled their operators to have more control at the source to correct quality issues.

- 80% reduction in inspection process time
- \$160K projected annual sales impact
- \$17K investment in their workforce
- 12 jobs retained
- \$70K reduction in costs

RF Precision successfully passed their ISO 13485 audit with no non-conformances. The company is now positioned to direct-bid for work instead of contracting with other companies already ISO 13485 registered.

“TMAC has been very helpful in both obtaining and maintaining RF Precision's medical equipment ISO registration. In addition to doing a great deal of work during the initial registration process, TMAC has also been very helpful in the period following registration. Their assistance has been very valuable in keeping the company headed in the right direction and setting a new course in many ways. Our ISO registration status has opened up our available customer base to several new markets that we would not have been able to enter into without being ISO 13485 registered.



As we continue to grow our company and mature our QMS, the lessons learned from our collaboration with TMAC will long remain with this company well after their presence is no longer needed. It has been a pleasure working with TMAC; they are a very knowledgeable and professional group of people that should be proud of their many accomplishments in this area.” - *Tammy Tindal, Quality Manager*