

CONTRACT MANUFACTURING Start-Up Medical Equipment Company

EXECUTIVE SUMMARY

Industry: MEDICAL/ HEALTHCARE

Company Type: START-UP

Location: OHIO

Production Stats:

- 1-100 yearly
- 2-3 Month Production Lead Time

Capabilities Utilized:

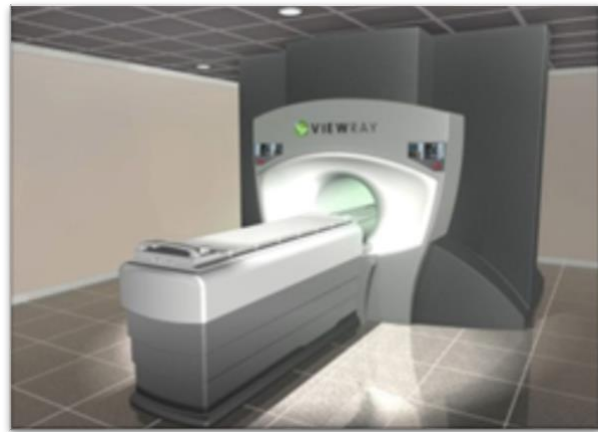
- Program Management
- Supply Chain
- Quality Management System
- Production Planning
- CNC Machining, Welding, Metal Fabrication
- Manufacturing and Assembly
- Final Testing, Packaging and Logistics

Results:

- Near 100% Quality and Delivery
- Increased Sales for end customer

CHALLENGE:

A medical start-up utilized PEKO's Product Development Engineering capabilities to solidify a working and manufacturable MRI-Radiation Therapy device ([Development Case Study](#)). Once PEKO solved the challenge of design, the customer knew the next hurdle would be to get the design to market to meet their increasing customer demand. This meant finding a skilled ISO 13485 certified Contract Manufacturer capable of large scale and repeatable manufacturing of complex equipment. Of course, the customer need not look any further than PEKO's own Contract Manufacturing division.



SOLUTION:

PEKO sprung to action by putting together a tenured Program Management team to kick-off the manufacturing program. The Program Manager assembled a team that included Manufacturing Engineers, Production Planners, Assembly



Supervisor, Quality Personnel and Purchasing. The Bill of Materials along with all component parts were reviewed to ensure accuracy and Rev level. Manufactured component parts were released to PEKO's in-

house machining and fabrication centers. Fixture design/manufacture was implemented by its respective engineering and tool making teams. Procurement staff handled the acquisition of off-the-shelf items. Hundreds of Proprietary work instructions were created by engineering and loaded into PEKO's secure intranet systems. Quality created corresponding documentation



Contract Manufacturing Case Study

to support regulatory, customer, FAI and Critical to Function requirements. The production team configured a 5,000 sq foot assembly area and trained in-house technicians on the new processes. Testing procedures were created and validated to ensure the product was in working order at time of shipment. All the while, regular customer visits and web meetings were held to update status. In a few short months, the first production units were coming off the line nearly perfect. With some lessons learned, internal documentation and technician training was updated. The next units finalized the production process to ensure repeatable product is manufactured and ready for shipment to the world's top cancer centers.

SUCCESS:

The customer has successfully delivered working units to customers and sales are exploding. By utilizing PEKO's contract manufacturing expertise, the customer is not only able to meet customer demand, but will utilize PEKO for forecasted future demand due to our ability to grow with the customer. The customer is delivering excellent product, receiving huge investments and profits are steadily increasing. The world of cancer treatment has been forever changed by the customer's brilliant technology and partnering with a Contract Manufacturing like PEKO that made this medical equipment a reality.

