RQMIS Inc.
Highlight

RQMIS helps a China-based Orthopedic Company establish German Operations and gain EN/ISO13485: 2012 Certification

Customer:
- Chinese Based Manufacturer of Medical Devices

Industry:
- Class I, IIa, IIb, and III Devices including implantable devices

Project Timeline:
- 6 months to establish and implement Quality System and 1st OEM vendor Contract.
- 2 months for audit and receipt of certification.

Customer Objectives:
- Establish Company in Europe to acquire OEM product and apply own CE mark.
- Implement Quality System compliant with EN/ISO 13485 and gain certification through Notified Body.
- Establish Technical Files and labeling to support their own CE marking of OEM product.

Methodologies:

After interviewing customer, RQMIS utilized process flowcharting to layout the overall operational processes. Once the flowcharts were finalized we developed the documents to complement the flowcharts. These included the Quality Manual, SOPS, WIs and Forms. All forms were pdf-based forms for ease of use.

Since the majority of the products were being sourced from OEMs a comprehensive Quality Agreement was established to place the appropriate controls on Supplier Quality.

After the core structure of the Quality System was established a Management Review (the 1st) was utilized to walk through each document to assure it reflected the needs of the customer.

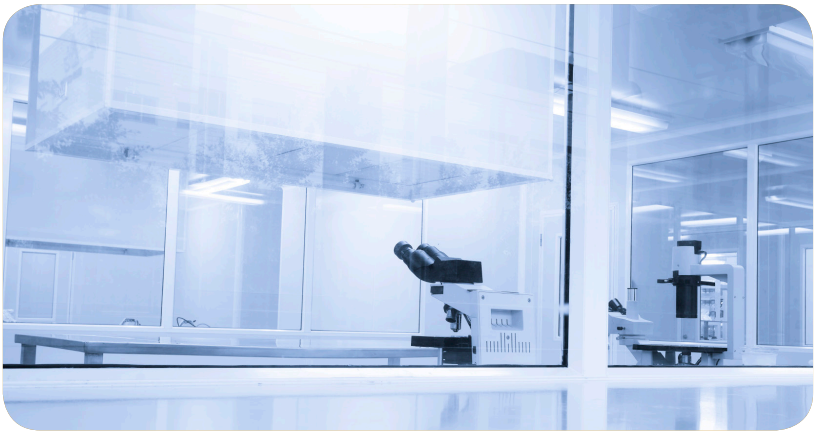
RQMIS chose and negotiated with the Notified Body to successfully pass the certification audit. We also managed the Document Control Management System during the development and implementation of the Quality System.

RQMIS Approach:

A Senior Quality Consultant and Technical Writer were assigned to the project. The Sr. Quality Consultant managed the project. Frequent teleconferences were utilized.

Over a period of 2 months a complete Quality System was designed with cooperation of the Client. The Quality Manual, SOPs, WIs and related forms were customized to the actual operations taking place at the EU facility. RQMIS does not take the approach of simply providing "canned" Quality System procedures that so many consulting companies provide. They rarely reflect the true activities that a customer wants to follow. Our approach is to understand how the customer wants the operation to perform.

Since RQMIS consultants have deep operational experience in other medical device companies they are able to provide suggestions on how an operation can be designed more efficiently while still being compliant with the standards/regulations.



Challenges And Issues:

- Develop pipeline of OEM supplied medical devices.
- Required establishment of Quality System that was particularly focused on management of suppliers.
- EN/ISO13485:2012 compliant Quality System with a Risk Management process compliant with EN/ISO14971:2012.
- Establishment of Technical File for each product family that complemented the OEM design history file.
- Design and control of own labeling to assure compliance with OEM design file.
- Customer located in China, new company located in Germany and RQMIS is located in the United States.

Benefits/ Results:

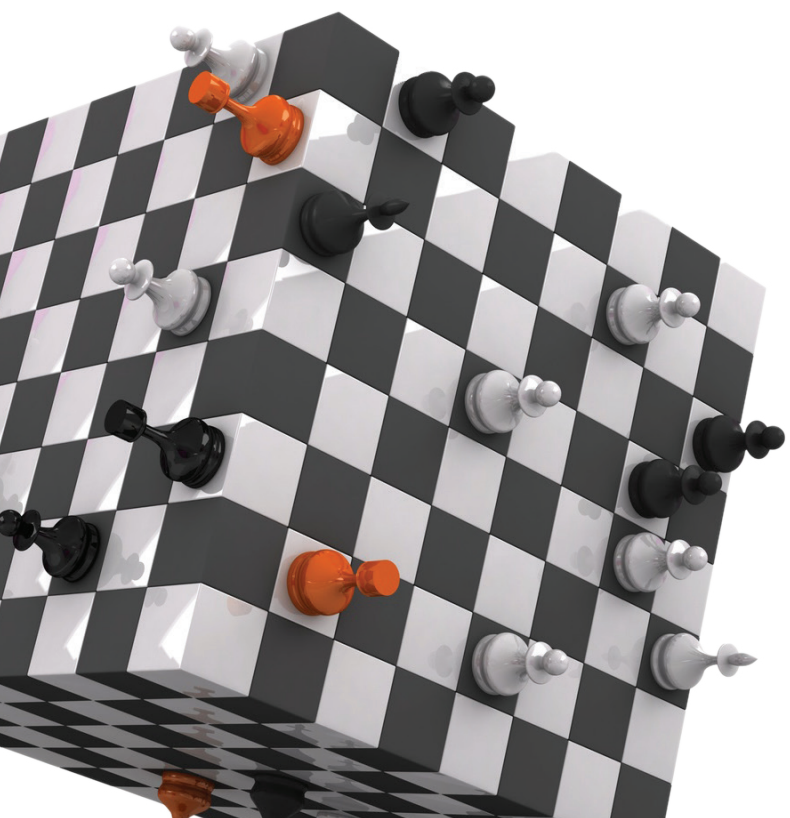
Customer now has a fully operational company in the EU, which is EN/ISO13485: 2012 Certified. By utilizing RQMIS minimal internal resources were consumed. Overall cost of project to client was less than 35k plus travel expenses.

About Us:

RQMIS, Inc. is a solutions-driven provider of therapeutically focused, comprehensive, regulatory consultation to the global medical device and the combination product industry. The regulatory consultancy is focused in three principal areas, regulatory strategy/submissions, clinical study design/management and quality systems design/compliance. We are headquartered just outside of Boston, MA.

RQMIS was established in 1996 with the specific intent to provide medical device/biotechnology manufacturers with strategic guidance on how to effectively navigate the FDA and EU regulations specific to medical devices and combination products. Sr. management has worked both at the Office of Device Evaluation/CDRH/FDA and in the field for FDA.

For further information about RQMIS, Inc., please visit www.rqmis.com or call 978-358-7307.



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