RQMIS Inc.
Highlight

RQMIS Helps Biotech Company Fill Interim Resource Gap and Assures Success of EN/ISO 13485 Recertification Audit

Customer:
- US Based In-vitro Diagnostic and Medical Device Manufacturer

Industry:
- Class IIb Medical Device and IVD

Project Timeline:
- 9 months to perform baseline QSR/13485 audit, gap analysis and major overhaul of Design Control, CAPA system and reconstruct Technical Files.
- Manage internal audit program for 12 months.

Customer Objectives:
- Prepare company for anticipated FDA QSR audit and pass next ISO recertification audit.
- Design and Implement improved Design Control and CAPA processes.
- Reconstruct Technical Files for Medical Device and IVD.
- Manage Internal Audit Function for entire year due to staffing shortage.

Methodologies:

After interviewing customer, RQMIS conducted a system wide baseline audit using 21 CFR 820 and EN/ISO 13485 as the reference regulation/ standard. The audit results were utilized to develop a gap analysis for all major processes.

To address the redesign of the Design Control and CAPA process flow-charting was used to layout the overall operational processes. Once the flowcharts were finalized we developed the documents to complement the flowcharts. These included the SOPS, WIs and Forms. All forms were pdf-based forms for ease of use. Special attention was given to the previous NB audit in which the company's certification was called into question.

Technical File reconstrution required extensive review of existing design control documentation for a medical device and IVD. In addition, inter-views and audit source documentation were utilized.

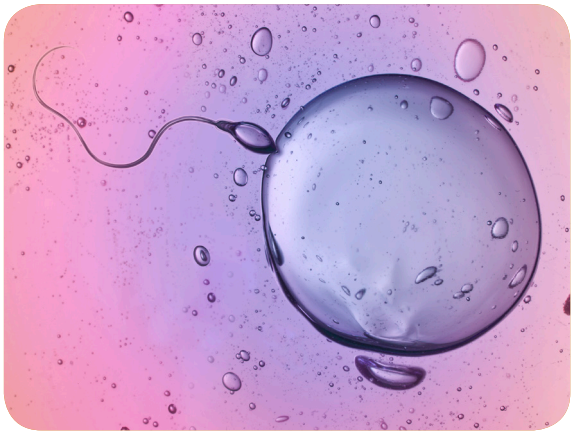
In managing the internal audit program, RQMIS conducted four audit visits to address all aspects of the Quality System. Corrective Actions were identified with consultation from company management. These corrective actions were monitored for completion.

RQMIS Approach:

A Senior Quality Consultant and Technical Writer were assigned to the project. The Sr. Quality Consultant managed the project. Frequent tele-conferences and several visits onsite were utilized.

RQMIS recommended a strategy of using a full base-line audit, Gap Analysis, and C/A Plan to get the Quality System in place and help assure future certification and to provide a comprehensive, effective Quality System.

Our base-line audit was the foundation. Continued auditing via manage-metn of the internal audit program provided ongoing oversight into the improvements being made to the Quality System. All audits were accom-panied by agendas, audit reports and corrective actions. The NB provided very positive feedback on this process and the reconstructed Technical Files.



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:

- To start – we needed to obtain and decipher the client "Source Documents" and for some companies this can be challenging. For example: is there a true DHF, is there supporting data, should certain documents be removed, does the DHF need to be rebuilt? RQMIS resources know what to look for and help the client work through this sometimes challenging and messy task.
- If a Notified Body (NB) Auditor is expecting a comprehensive "Technical File" to be available, and it's currently a mixture of assorted and sometimes non-applicable or outdated information – this can also be an issue and challenge. So – we apply our proven, Standard Technical File (STF) template to walk through necessary inclusions and assemble the file accordingly. This was done during this client project and we actually received feedback that the NB Auditor was impressed.
- Nice to have vs. Need to have? Where do you draw the line? This requires thorough knowledge of the FDA Regulations and ISO Standards. Finding the right mix of Design Control procedures, templates, forms, and requirements can be tricky. You can't overwhelm the client but yet you need to help assure compliance. We feel we found a good balance.

Benefits/ Results:

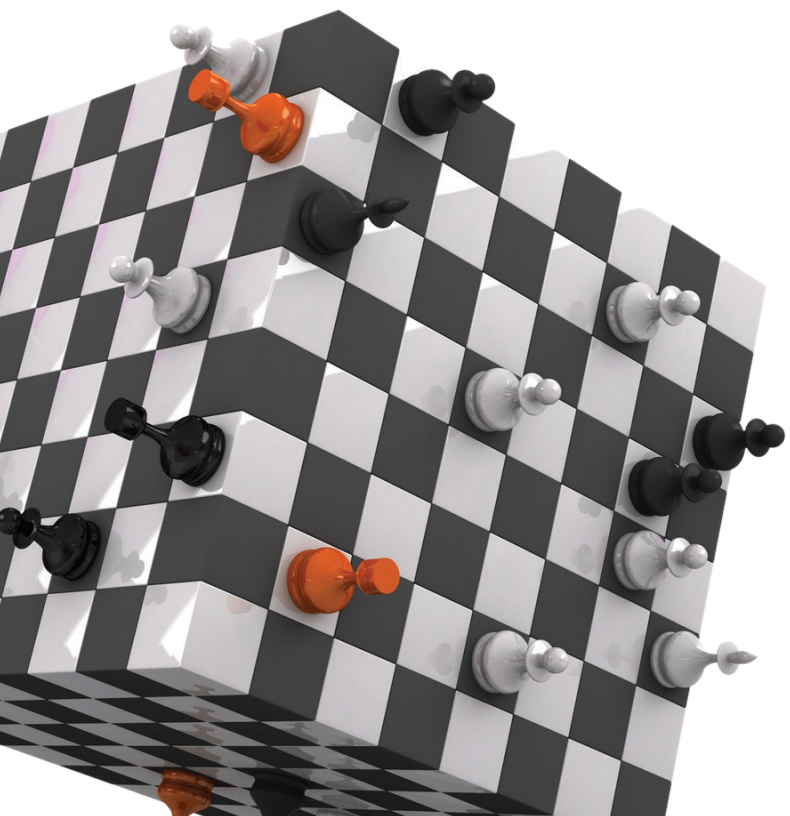
The client NB audit was completed in February 2013 – and passed. NB provided very positive feedback on the improvements. Overall cost of project to client was less than the cost of a full time senior quality engineer.

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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