

Case Study 41:

Regulatory support for QMS Set Up for US-FDA



Client

An India based medical devices manufacturer.

Products

Radiology and Pathological Imaging solutions

Product Categories

Medical Devices Class II

Country of Interest

USA

Services Provided

- ✓ Writing the applicable Standard Operating Procedures.
- ✓ Writing the quality manual for the company
- ✓ Training on SoPs

Key Highlights:

- ✓ Client benefited from GRP's strong regulatory audit and compliance experience on authoring SoPs which helped the client in getting ISO certification.

Key Phrases:

SoP writing, SoP management, Quality Manual, Quality Management System, QMS, USFDA, India, Audit and Compliance, ISO Certified, ISO 13585.

Client Situation

The Client is a medical device company that is planning to get ISO 13485 certification in January 2018. The company designs, manufactures, sales, and services its imaging devices that are classified as class 2 in US. The client was looking to set up the quality management system (QMS). They wanted GRP to write the applicable SOPs and quality manual and provide training to their team on it as well.

GRP Solution

GRP brings decades of experience in writing SOPs for companies all across the globe. GRP's presence in USA and successful track record of obtaining 100% approval for diverse SOPs enabled Client to select GRP as partner of choice for writing of the SOPs for ISO 13485.

1 Writing Quality System SOPs

- ✓ GRP Authored set of SoPs Cross referencing ISO 13485 and FDA 21CFR 820 Respective Sections
- ✓ SoPs within the following sections were worked on:
 - Quality Management System
 - Management Responsibility
 - Resource Management
 - Product Realization
 - Measurement, Analysis and Improvement

2 Writing the Quality Manual

- ✓ GRP created the Quality Manual which would summarize all the quality activities that will be performed by client in line with the SOPs

3 Training on SOPs

- ✓ GRP worked along with the client's team to provide training on all SOPs



For additional information, please contact us at info@globalregulatorypartners.com

