Description of Consulting Services

Medical Device Academy, Inc. is a medical device consulting firm incorporated in the state of Indiana. Our company has primary offices located at 345 Lincoln Hill Rd., Shrewsbury, VT 05738 USA. Our company has 4 full-time employees and 1 part-time employee, not including the founder and President--Rob Packard.

Medical Device Academy specializes in helping small and medium-size medical device companies with quality system implementation and regulatory approval of new devices. Although Rob Packard and Mary Vater have experience with European and Canadian submissions, our focus is 510(k) submissions and De Novo applications to the US FDA. You are the ideal customer for our firm if you are an early stage company that needs help establishing a quality system, creating your first design history file (DHF) and the development of your product is still in the prototype or feasibility stage.

What we can do for you

- Provide procedures and training for design controls and risk management
- Facilitate your design reviews and act as an independent reviewer
- Identify the product classification, regulatory pathway and identify required testing requirements
- Recommend testing vendors and contract manufacturers
- Recommend world experts in software validation, electrical safety, human factors testing and clinical studies
- Prepare an application for the Breakthrough Devices Program
- Prepare a pre-submission request for the FDA, facilitate the meeting and write your meeting minutes
- Prepare a 510(k) submission - Special, Abbreviated or Traditional
- Prepare a De Novo application
- Provide you with a turn-key quality system
- Provide customized training (web-based or on-site)
- Conduct internal audits and supplier audits (remote and on-site)
- Implement and validate an electronic quality system solution

In order to contact us, please email Rob Packard: rob@13485cert.com.

Or schedule a call using the following link: https://calendly.com/13485cert/30min

Every medical device company eventually has a complaint, conducts a recall and has an FDA inspection. If you need urgent help, don't panic and text Rob's mobile @ +1.802.258.1881.

Standard Pricing Valid from August 1, 2019 until July 31, 2020

Standard Pricing Sheet

As of August 1, 2019, the standard prices for Medical Device Academy, Inc. are:

Description of Services	Amount / Rate
Rob Packard's hourly rate	$300/hour
Mary Vater's hourly rate	$250/hour
Mark Durivage's hourly rate (external subcontractor)	$200/hour
Matthew Walker's hourly rate (quality system consulting)	$200/hour
Domestic Travel Time Fee (not including expenses)	$500 each way
International Travel Time Fee (not including expenses)	$1,000 each way
510(k) submission or De Novo Request (not including FDA User Fees or FDA eCopy preparation; includes pre-submission and assisting with responses to RTA and/or AI requests)	$14,000/each
Pre-submission Meeting Request (Teleconference, not including FDA eCopy preparation)	$3,000/each
513(g) Submission Preparation (not including FDA eCopy preparation)	$3,000/each
eCopy Service (includes printed cover letter, flash drive and FedEx overnight in accordance with FDA's current policy)	$150/each
Turn-key Quality System compliant with FDA, European and Canadian Requirements - includes all required procedures, forms, logs, pre-recorded training webinars and 16x 30-minute consultations	$7,500

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