

<https://www.medicaldeviceacademy.com/>

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 6 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

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.

Initial Phone Consultation is Free



Standard Pricing of Consulting Services Offered by Medical Device Academy



<https://www.medicaldeviceacademy.com/>

Description of Submission Services	Amount / Rate
510(k) submission or De Novo Request (not including FDA User Fees; includes assisting with responses to RTA holds, AI requests, and two FDA eCopy fees) - bundled submissions or submissions with multiple predicates will cost more	\$12,300/each
Pre-submission Meeting Request (preparation, teleconference, and meeting minutes and two FDA eCopy fees)	\$3,300/each
513(g) Submission Preparation (preparation and one eCopy fee)	\$2,150/each
FDA eCopy Service (includes printed cover letter, USB flash drive, validation of eCopy, and FedEx overnight in accordance with FDA's current policy)	\$150/each
Preparation of a CE Marking Technical Documentation in accordance with MDD, AIMD, IVDD, MDR, or IVDR	Request Quote
Preparation of a Literature Review, State of the Art Review, and Clinical Evaluation Report	Request Quote
Clinical Study Protocol Development & PMCF Study Protocol Development	Request Quote
Canadian Class I MDEL Application Preparation (not including Health Canada fee for an Establishment license application) - Available with quality system for Canadian Importers	\$2,000 w/o QMS \$3,300 with QMS
Canadian Class II MDAL Application Preparation (not including Health Canada fee for Class II license application)	\$3,000
Canadian Class III MDAL Application Preparation (not including Health Canada fee for Class III license application)	\$10,000
Canadian Class IV MDAL Application Preparation	Request Quote

<https://www.medicaldeviceacademy.com/>

Description of Other Consulting Services	Amount / Rate
Rob Packard's hourly rate (quality & regulatory consulting)	\$300/hour
Mary Vater's hourly rate (quality & regulatory consulting)	\$250/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
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
US Agent Services, including initial FDA registration (not including FDA User Fee for establishment) - we will provide you with a video showing you how to pay the fee	\$600 - initial \$450 - renewal
Initial FDA registration for 1 product (not including FDA User Fee for establishment) - we will provide you with a video showing you how to pay the fee	\$300 - initial Changes are hourly at \$200/hour

Note: <https://FDAeCopy.com> is a website owned by Medical Device Academy, Inc. that was created when we first began offering FDA eCopy printing and shipping services to clients and other independent consultants. The website is now being rebuilt as a podcasting site for hosting recorded audio content.

Note: <http://13485cert.com> is a URL owned by Rob Packard, the owner/founder of Medical Device Academy, Inc. THE URL pre-dates the company by approximately 5 years.

<https://www.medicaldeviceacademy.com/>

Description of Services EUA Preparation Services	Amount / Rate
Preparation of In Vitro Diagnostic EUAs - March 16, 2020 policy update (includes FDA notification, pre-EUA request, EUA request, and FDA eCopy fees)	\$6,000
Preparation of EUA for: 1) not-NIOSH approved respirators, 2) face masks with liquid barrier protection, and 3) face mask without liquid barrier protection. - April 24, 2020 policy update	\$1,500
Preparation of other EUA Requests	Request Quote

Note: EUA request pricing is only validity based upon the date of the EUA Policy.

Payment Terms

Quotes are valid for 90 days. Payments due 15 calendar days from submission. A 2% discount is offered for payments received on-time. Discounts are not available for credit card payments or wire transfers due to additional banking fees. PayPal payments can be made to rob@13485cert.com. A 5% penalty is charged for payments received later than 30 calendar days. All invoices will be payable to Medical Device Academy, Inc.

Refunds

If you purchase digital products from our website, in order to receive a refund you must provide a written explanation of why the product did not meet your needs. For consulting services, if you terminate a project before it is completed the hourly consulting time for the project will be estimated and you will be refunded any remaining balance.

Contact Rob Packard, President

rob@13485cert.com

Schedule a call: <https://calendly.com/13485cert/30min>

Tel | +1.802.281.4381

Contact Mary Vater, Regulatory Consultant

mary@fdaecopy.com

Schedule a call: <https://calendly.com/maryvater>

Tel | +1.913.274.9899