https://www.medicaldeviceacademy.com/

Medical Device Academy Incorporated 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 9 full-time employees and 2 part-time employees.

Medical Device Academy specializes in helping start-up medical device companies with quality system implementation and regulatory approval of new devices. Although Rob Packard, Mary Vater, and Sharon Morrow 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 (including 3rd party submissions)
- 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 30-Minute Phone Consultation is Free

Standard Pricing of Consulting Services Offered by Medical Device Academy

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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	$14,410/each
Pre-submission Meeting Request (preparation, teleconference, and meeting minutes and two FDA eCopy fees)	$3,850/each
513(g) Submission Preparation (preparation and one eCopy fee)	$2,750/each
Regulatory Pathway with Draft Testing Plan for FDA Submissions	$1,000/each
FDA eCopy Service (includes printed cover letter, USB flash drive, validation of eCopy, and FedEx overnight in accordance with FDA's current policy)	$99/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	$2,200 w/o QMS $3,630 with QMS
Canadian Class II MDAL Application Preparation (not including Health Canada fee for Class II license application)	$3,850/each
Canadian Class III, III POC & IV MDAL Application Preparation	Request Quote

Description of Other Consulting Services	Amount / Rate
Hourly rates for our consulting team: • $350/hour - President • $275/hour - Sr. Regulatory Consultants • $200/hour - Associate Regulatory Consultants	See bullets to left
Turn-key Quality System compliant with FDA, European and Canadian Requirements - includes all required procedures, forms, logs, 17 pre-recorded training webinars and up to 8 hours of consultation (US-only is $6,000 and includes 6 hours)	$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 several years.

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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 consulting work will stop if payments are not received within 45 calendar days from the date of the invoice and additional late fees may be charged. 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, Founder/President

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

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Contact Mary Vater, Sr. Regulatory Consultant

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Contact Sharon Morrow, Sr. Regulatory Consultant

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