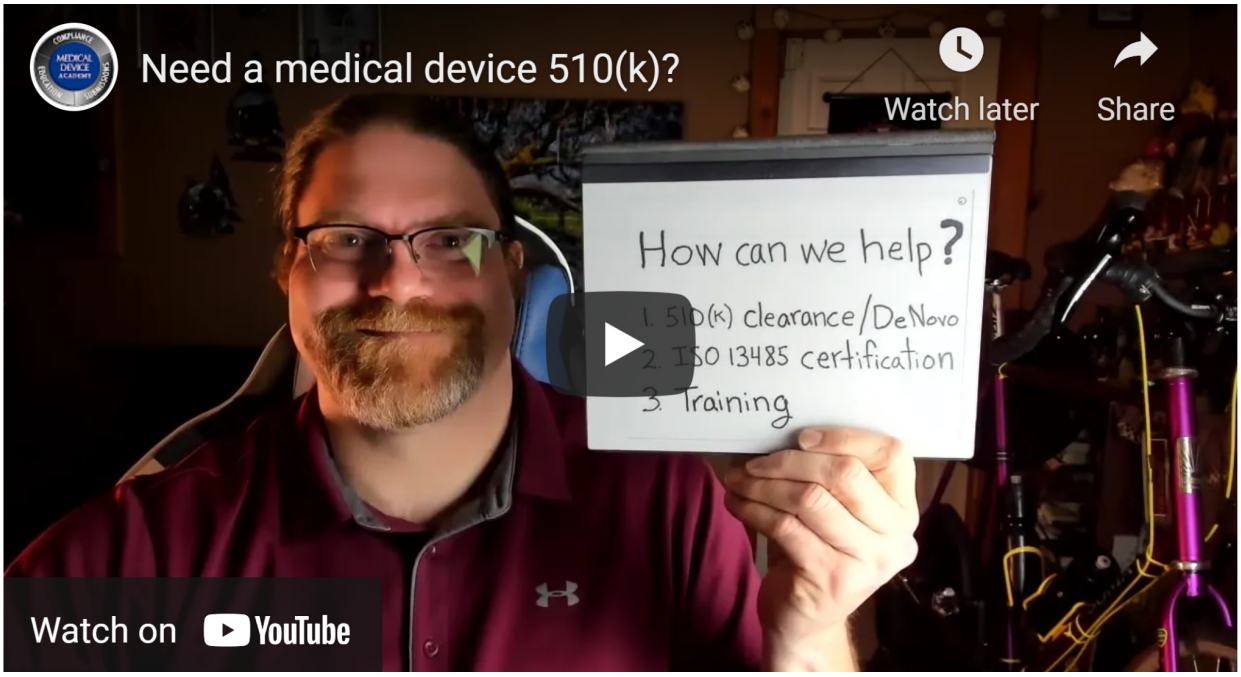
Standard Pricing of Consulting Services Offered by Medical Device Academy

https://medicaldeviceacademy.com/

Medical Device Academy, Inc. specializes in helping device companies launch in the US first. We still help companies with CE Marking and Canadian Licensing, but we help start-up companies prepare 510(k) and De Novo submissions first. As part of the process, we help clients create testing plans, write usability testing protocols, and perform cybersecurity risk assessments. In parallel with these design and risk management activities, you need to implement your quality system.



You are the ideal customer for our firm if you are an early-stage medical device 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.

Consulting Team Contact Information

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Hourly Rates for the Consulting Team:

- $350/hour - President (Rob Packard)
- $275/hour - Consulting Partner & Sr. Regulatory Consultant (Mary, Bhoomika, and Matthew)
- $200/hour - Associate Regulatory Consultants (Wonde, Becca, and Tifany)

What we can do for you

- Identify the product classification, regulatory pathway and identify required testing requirements
- Facilitate your design reviews and act as an independent reviewer
- Provide procedures and training for design controls and risk management
- 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

Medical Device Academy Incorporated is a medical device consulting firm incorporated in the state of Indiana. Our company has primary offices at 345 Lincoln Hill Rd., Shrewsbury, VT 05738 USA. Our company has nine (9) full-time employees and two (2) part-time employees.

If you need urgent help, don't panic. Text Rob at +1.802.258.1881 instead.

Initial 30-minute Phone Consultation is Free

To request a formal proposal or invoicing questions, please contact Lindsey Walker directly at sales@medicaldeviceacademy.com or by phone at +1.802.989.3939.

Description of FDA Submission Services	Amount / Rate
510(k) submission or De Novo Request using the new FDA eSTAR template (includes assisting with responses AI requests) - Bundled submissions or submissions with multiple predicates will cost more *FDA User Fee is extra	$17,500/each
513(g) Submission - We recommend the following content to be included if you believe your device requires a De Novo: ● device description ● draft instructions for use ● draft labeling ● classification rationale as Class 1 or 2 ● a proposed regulation name and number ● proposed special controls ● draft benefit/risk analysis ● risk mitigation table ● alternative procedures and techniques to the subject device's technology ● your efforts to identify a potential predicate device *FDA User Fee is extra	$6,000/each
Breakthrough Device Designation (BDD) & STeP Application - Since the submission content is nearly identical for a Breakthrough and a STeP, if a BDD is denied we are willing to revised your submission to a STeP and resubmit at no additional charge. *No FDA User Fee	$3,000/each
Pre-submission Meeting Request using the new FDA PreSTAR template (preparation, teleconference, and meeting minutes) - Determination of the regulatory pathway, predicate selection, or developing a testing plan may require additional hourly consulting if an FDA Special Controls Guidance is not obvious or your device is significantly different from cleared devices *No FDA User Fee	$3,500/each

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Description of FDA Registration Services	Amount / Rate
Regulatory Pathway, Predicate Selection & Draft Testing Plan for FDA Submissions - this is typically needed only when there is no FDA Special Controls Guidance is not obvious or your device is significantly different from cleared devices	$1,250/each
Human Factors Documentation: • Define user group, use environment, and the user interface • Identification of Use Errors (including task analysis) • Creation of a User-Related Risk Analysis (URRA) • Critical Task Analysis • Creation of Summative Usability Test Protocol Note: may require additional time for product classifications with many use errors reported and for devices with multiple user groups	Hourly Consulting Only

Description of FDA Registration Services	Amount / Rate
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 *FDA User Fee is extra	$600 - initial $450 - renewal

Make sure that you apply for small business status every year for any regulatory submissions to the FDA. Small business discounts do not apply to the FDA registration/listing user fee:

https://medicaldeviceacademy.com/small-business-qualification/

Description of Quality System Services	Amount / Rate
Al a carte (you buy procedures individually as needed); purchases are via PayPal or Stripe using a credit card, but wire transfers are possible for quotes	$299/each (unless noted otherwise)
US Only turnkey quality system - $5,000 (four monthly payments of $1,250), but no consulting time is included	$5,000
US Only turnkey quality system - $6,000 (four monthly payments of $1,500) including 6 hours of consulting time	$6,000
Global turnkey quality system - $6,000 (four monthly payments of $1,500), but no consulting time is included	$6,000
Global turnkey quality system - $7,500 (four monthly payments of $1,875) including 8 hours of consulting time	$7,500

Description of Canadian Licensing Services	Amount / Rate
Canadian Class I MDEL Application Preparation - Available with 4 required QMS procedures *Health Canada Fees are extra	$2,750 w/o QMS $3,700 with QMS
Canadian Class II MDAL Application Preparation *Health Canada Fees are extra	$4,950/each
Canadian Class III, III POC & IV MDAL Application Preparation *Health Canada Fees are extra	Request Quote

CE Marking Services (EU MDR & IVDR)

In 2014, when Medical Device Academy was first incorporated, we did more consulting projects for CE Marking than FDA 510(k) submissions. However, we focused on 510(k) submissions between 2017 and 2021 because changes to the European Regulations increased the costs of the CE Marking process and delayed the issuance of CE Certificates. Now that the MDR and IVDR have both come into force, we are gradually increasing the number of CE Marking projects we are quoting. If you would like a quote for a CE Marking project, please contact us.

Payment Terms

Quotes are valid for 90 days. Payments are due 15 calendar days from submission. A 2% discount is offered for payments received on time. Discounts are unavailable for credit card payments (Stripe or PayPal) 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 after 30 calendar days. All consulting work will stop if payments are not received within 45 calendar days from the invoice date, 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, to request a refund, you must provide a written explanation of why the product did not meet your needs. We **do not** offer refunds for turnkey quality systems. We recommend that companies evaluate our sample procedure (SYS-003) and purchase individual procedures initially if you are unsure if the complete quality system will 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.

Note: https://fdaestar.com, https://fda-us-agent.com/, https://fdaecopy.com are domains owned by Medical Device Academy, Inc. We will be launching the new FDAeSTAR website in late 2023 due to the FDA's mandatory transition to the FDA eSTAR templates.

Note: http://13485cert.com is a URL owned by Rob Packard, the owner/founder of Medical Device Academy, Inc. This domain is used by Rob Packard and our AWeber email hosting. The website is now redirected to https://medicaldeviceacademy.com/.