About Our Company

Our company is a quality and regulatory consulting firm. We have eight (8) employees, and everyone works virtually from home. We specialize in helping small device companies prepare FDA 510(k) submissions using the eSTAR template, preparing FDA pre-submissions using the PreSTAR template, implementing new quality systems for compliance with the FDA, ISO 13485, and MDSAP, and conducting quality system **audits**. We also help with **FDA US Agent services**, CE Marking preparation, and Canadian License applications. Clients with urgent needs where time to market is critical turn to us. Our passion is teaching medical device professionals how to prepare for future regulations. For more information, please visit our website or our **YouTube channel**. We even wrote a 510(k) book, **"How to prepare your 510(k) in 100 days**," because 100 days is how long your testing will take. It is only available as part of our 510(k) course series, and you can find all the details on our **510(k) course** webpage.

What do our quality and regulatory consultants do?

Most of our work is preparing regulatory submissions, but 20% of our work involves helping you implement your quality system. We can help you with your **medical device regulatory submissions.** We specialize in medical device 510(k) submissions, preparation of CE Marking Technical Files, and Canadian device license submissions. We also created a business unit that specializes in preparing and validating FDA eCopies for pre-submissions, 510(k) submissions, and De Novo Applications. Due to changes in the FDA eCopy policies, we no longer offer FDA eCopy services except to active medical device consulting clients. If you need to upload your own FDA eCopy, you can **register for a Customer Collaboration Portal Account** with the FDA so that you can upload your own submission documents electronically.

Most of our clients are small and mid-size medical device companies that need **continuing education training** and **quality System Auditing for compliance**. Clients with urgent needs where time to market is critical turn to us. Our passion is teaching medical device professionals how to prepare for future regulations and self-monitor compliance to avoid compliance remediation.

How is our company different from other quality and regulatory consultants?

Most medical device consultants work by the hour, while our firm has flat-fee pricing. We can do this because we specialize in a narrow niche–primarily medical device 510(k) submissions and De Novo requests. We also differ from independent consultants and law firms because we have designed and built medical devices. Rob Packard was CEO and co-founder of a medical device start-up in 2004.

Who is our ideal medical device consulting client?

We are a full-service medical device **regulatory consulting firm**. The name "academy" emphasizes our love for training. We specialize in helping entrepreneurs get their first product to market–regardless of whether that is a medical device 510(k) clearance or a De Novo Classification Request. Ideally, you are located in another country, and you need help understanding the requirements of the US FDA. The best time for you to contact us is at the early stages when you have a proof-of-concept prototype but are unsure what to do next. You also might be under-capitalized, and you need advice on how much to budget and how to use your limited funding most efficiently.

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Quality Assurance & Regulatory Affairs Consulting Team

Our permanent, full-time employees are listed below in the order that they joined our team. The titles for our FDA 510k consultants are based upon the number of 510k submissions that they have submitted and were successfully cleared–not the years of experience. Consultants with five (5) or more cleared 510k submissions are Sr. Regulatory Consultants and consultants with less than five (5) cleared 510k submissions are Associate Regulatory Consultants.

Rob Packard – Founder & President

Rob is the founder and President of Medical Device Academy. He manages the FDA 510(k) Consulting Team. The company was incorporated in October 2013, but he wasn't smart enough to get some full-time help until 2017. Rob is constantly doing everything to extremes. That includes Zoom meetings with Austria, Sweden, Netherlands, and Israel at 6 a.m.; and Skype calls with China and Australia at 10 p.m.. He "balances" this out with two and three daily workouts and a good novel until midnight. You can schedule a call with Rob using his **Calendar** app.

Email | rob@fdaestar.com **Tel |** (802) 258-1881

Tifany Chesser – Human Factors Team

Tifany is an Executive Admin for Medical Device Academy. She reports to Matthew Walker on the Human Factors Team, she is responsible for scheduling meetings with the President, and she assists the sales team with data entry. She also helps with the preparation of 510(k) submissions and pre-submissions.

Email | tifoncomp@msn.com **Tel |** (802) 779-4897

Matthew Walker – Human Factors Team

Matthew came to us with a regulatory background focused on OSHA and NFPA regulations when he was a Firefighter/EMT. Since we kidnapped him from his other career, he was recently promoted to manage our human factors team as Branch Chief of the Human Factors Division. He is a Junior at Champlain College in Burlington, Vermont, where he specializes in Computer Forensics and Cybersecurity. Matthew participates as a member of our audit team and is passionate about risk management, human factors engineering, and cybersecurity. Always the mad scientist, Matthew pairs his professional life in regulatory affairs with hobbies in the culinary arts, as he also holds a Butchers/Meat Cutters certificate from Vermont Technical College.

Email | matthew@fdaestar.com **Tel |** +1.802.342.1446

Lindsey Walker – Sales Team

Lindsey Walker studied at Castleton University, way back when it was just a little old Castleton State College in Castleton, Vermont, where she received her BS in Business Marketing. She also studied at North Country Community College, where she received her Certificate in Practical Nursing. Besides preparing proposals and sending out invoices, Lindsey was recently promoted to Director of Sales. In this new position, she is responsible for managing the sales team, coordinating introductory calls with our clients, creating proposals, and managing our new billing clerk. You can schedule a call with Lindsey using our **Calendly** app.

Email | lindsey@medicaldeviceacademy.com **Tel |** (802) 989-3939

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Quality Assurance & Regulatory Affairs Consulting Team

Alysha Chesser – Sales Team

Alysha (a.k.a. – Assassin Sylvia) is our social media marketing expert and gamer extraordinaire. She makes sure we deliver helpful new content every week to our blog and YouTube subscribers. She helps our team announce new live webinar training courses and the release of new and updated procedures via email. Each month Alysha also selects one procedure that will be eligible for the "Alysha" 50% discount.

Bhoomika Joyappa – FDA 510k Consultant Team

Bhoomika Joyappa is a Senior Regulatory Consultant who joined MDA in April 2021. She is responsible strategizing regulatory submissions for the US, including 510(k)s, DeNovo, Breakthrough designation requests, 513(g), and the pre-submissions. Furthermore, she specializes in Software & Cybersecurity Regulations, conducting gap analyses, reviewing submissions, and help regulating various medical devices in cardiovascular, orthopedic, remote patient monitoring, physical medicine, radiology, imaging, IVD, dental, and more. MDA has had about ten clearances under her oversight since 2021.
Before joining Medical Device Academy, she interned in regulatory affairs at Duke University School of Medicine and completed a regulatory affairs training program. She has worked as a SAS programmer and technical writer prior to switching to Regulatory Affairs.
She earned her Master of Science degrees at City University of New York and Coventry University with a concentration in biomedical engineering and advanced medical electronics, respectively.

You can schedule a call with Bhoomika using our Calendly app.
Email | bhoomika@fdaecopy.com **Tel |** (201) 290-2613

Becca Taylor – Sales Team

Becca joined Medical Device Academy as a Billing Clerk in September 2022, and she was promoted to Sales and Marketing Executive Assistant. Becca should be your primary contact for any billing issues, questions about proposals, help with registration and listing updates, and FDA US Agent services.

Email | becca@medicaldeviceacademy.com **Tel |** (253) 329-1492

Wonde Tekolla – FDA 510k Consultant Team

Wonde joined Medical Device Academy as an Associate Regulatory Consultant in January 2023 and currently serves as a Senior Regulatory Consultant. He holds a Master's Degree in Microbial Biotechnology from North Carolina State University and a Bachelor's Degree with a double major in Business Management and Health Science, focusing on Chemistry, from Guilford College.
Prior to his role at Medical Device Academy, Wonde spent two years at Mehtra, LLC, as a Regulatory Affairs Specialist. He has extensive experience in regulatory processes, including pre-submissions, 510(k) submissions, de novos, 513(g)s and CE Marking Technical Files. Additionally, Wonde has experience in implementing quality systems compliant with 21 CFR 820 and ISO 13485.
You can schedule a call with Wonde using our Calendly app.

Email | wonde@fdaestar.com **Tel |** (919) 903-0194

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