QUALITY ASSURANCE & REGULATORY AFFAIRS CONSULTING TEAM

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

Rob Packard - Founder & President

Rob is the founder and president of Medical Device Academy. He manages the 510(k) Consulting Team. The company was incorporated in October of 2013, but he wasn't smart enough to get some full-time help until 2017. He is constantly doing everything to extremes. That includes Zoom meetings with Austria, Sweden, the Netherlands, and Israel at 6 AM, and Skype calls with China and Australia at 10 PM. He "balances" this out with two to 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, and is responsible for scheduling meetings with the President and assisting 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, VT, 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, he 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: (802)342-1446

QUALITY ASSURANCE & REGULATORY AFFAIRS CONSULTING TEAM

Lindsey Walker - Sales Team

Lindsey studied at Castleton State College in Castleton, VT, 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, she 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, and managing our new billing clerk.

You can schedule a call with Lindsey using her Calendar app.

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

Alysha Chesser - Sales Team

Alysha (aka - 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 selects one procedure that will be eligible for the "Alysha" 50% discount.

Becca Taylor - Sales Team

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

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

Shaily Shah - Sr. Regulatory Consultant

Shaily Shah has over 10 years of experience in Quality Management System & Regulatory Submissions. She has worked at various companies ranging from corporate to medtech startups. She has prior experience in leading 510(k) submission for Artificial Intelligence in Software as a Medical Device. She holds a master's degree in Regulatory Affairs and an undergraduate degree in Pharmacy. She is passionate about helping clients bring innovative medical devices/technologies to the market.

Email: shaily@fdaestar.com