



AVIO
Medtech Consulting

January 2025

Startups are Hard

It's lonely, failure rates are high, money is tight, fundraising is slow, finding the right vendor/partner/employee is fraught with risk.

We get it

Founded by a medtech entrepreneur, for medtech entrepreneurs, we understand your challenges. And we've built Avio to meet them.

Founder's Story

Frustrated at having to rebuild an army of independent consultants--many which have never worked together before--for each new venture, Avio's founder, Morgan Evans, saw an opportunity to consolidate fractional expertise as a cohesive team.

This team would not only support acceleration of 3 female-founded entrepreneurs in the Medical Alley, but also invest in accelerating the systems, processes and paperwork of medtech.

Others liked the idea and asked for help. And thus, Avio was born as a startup serving startups.



A better way to Increase Returns & Patient Impact



60+ Startups/Year

You benefit from the experience of working with only startups



Higher ROI

Raise less capital to reach milestones, preserving early investor ownership

Continuous Improvement

After each client we translate learnings into templates, playbooks, and best practices

We Serve You

First Time Founder / CEO



- **Have:** A market problem and a solution, may have a functional prototype.
- **Need:** To develop, document, and test your product to go to market.

Serial Entrepreneurs



- **Have:** The experience, know what you're doing.
- **Need:** Technical expertise for specific tasks.

Established Businesses



- **Have:** Seasoned team with strong leadership and solid product roadmap.
- **Need:** Extra bandwidth for technical work required for commercialization and exit.

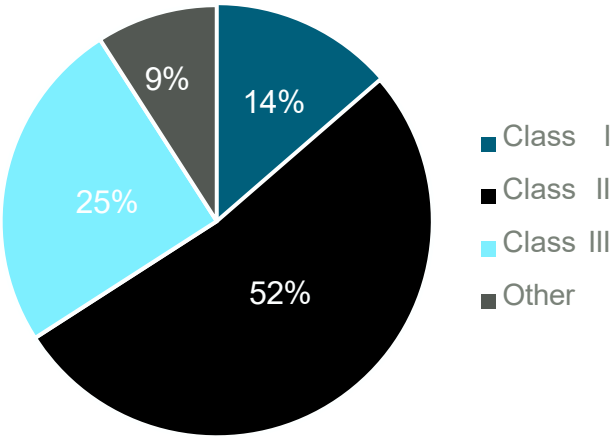
We Serve You

40%
Diverse Founders

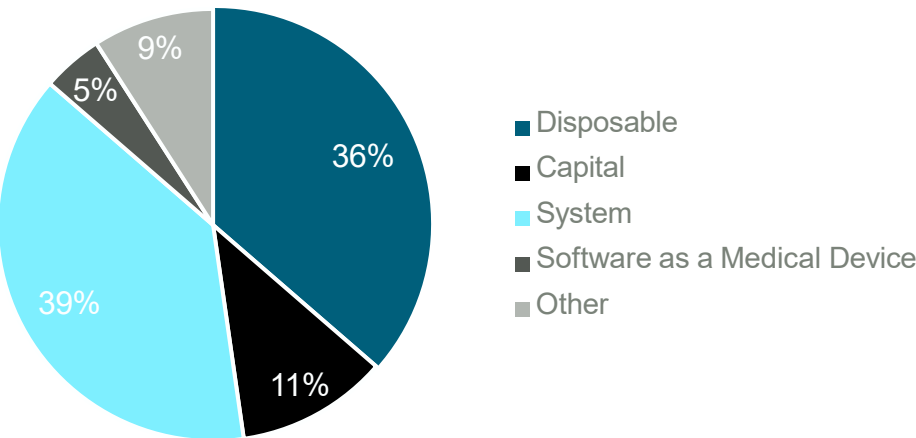
50+
Clients Served in '24

58%
First Time Founders

Regulatory Classification



Product Type

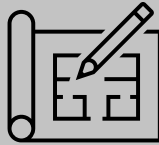


Faster to Market Less Risk



Thought Partner

Partnering with startups on strategy, go-to-market, corporate development, fundraising and more



R&D Program Management

Ensuring product development is done right from concept to commercialization



Regulatory

The right path to market to drive adoption, increase company value, and reduce risk



Quality

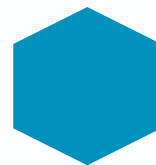
Operational excellence and compliance scaled for startups



Thought Partner 2 the CEO

Your vision, our experience

Benefit from the experience (and scars) of experienced entrepreneurs to position your company for success. Thought Partners become your co-pilot to support strategy and execution.



Go to Market



Fundraising and
Partnering



Strategy AND Execution



R&D Program Management

Invent the future, not the process

Comprehensive support including strategic project management, rigorous validation and verification testing, and seamless manufacturing transfer.



You do the fun, we do the documentation

Great program managers and great design engineers are different types. Our team, proven processes, and templates save you time, cost, and risk.



Recommended by CDMOs

Design and manufacturing firms regularly recommend Avio services to their clients because it makes the final product better.





Regulatory

Regulatory the startup way

From assessments to submission, we deliver regulatory services fit for startup purpose, so you get to market the right way.



Modular to fit your stage

Work with Avio, work with others, do it yourself. We adjust our services to fit your stage, budget, and strategy.



Experience = Efficiency

Our team has worked across dozens of technologies, regulatory pathways, and all levels of complexity. You benefit from our experience.





Quality

Quality scaled to startups

Quality always cost less. In the long run. With Avio, you can implement QMS earlier to speed time to market and boost exit value.



Compliance w/o the cost

Using templates, the right tools, and top people you can implement and maintain a QMS without breaking the bank.



Scale up as you grow

Avio's QMS program scales with the business so you maintain quality and compliance throughout the total product lifecycle.



What We Do. . .

Thought Partner to the CEO

- C-Suite Expertise from Leadership to Exit
 - Pitch Decks & Storytelling
 - Commercialization Strategy
 - Business Development
- Fundraising Guidance & Preparation



Quality

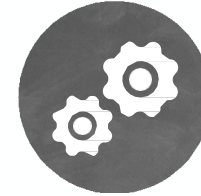
- Quality Management System Implementation
 - Supplier Audits
 - Management Review
- Design & Documentation Control
- Standard Operating Procedures
 - Quality Systems Training



AVIO

R&D PM

- Project Management
- Technical & Design History File Writing
- Validation & Verification Testing
- Cybersecurity (FDA regulation)
- Usability & Human factors
- Vendor Sourcing



Regulatory

- Regulatory Pathway Strategy
- Guidance & Support for FDA Submissions
- FDA Site Registration
- Manual/Label Creation
- 510(k) Creation and Submission



AVIO MedTech Consulting

*We help Medtech Innovators **take flight**.
Championing, Accelerating and Navigating the journey to market.*

Thought Partner to the CEO



Trusted Advisor – Board Level Experience

We believe trust is the cornerstone of our relationships with our clients. Valuable advice that is consistently in the best interest of our client is imperative as we support and guide you and your leadership team.



C-Suite Expertise – Leadership to Exit

When you need to make high-stakes decisions that impact the entire company, we are here to partner with you to build your strategic vision, your industry knowledge and provide you a national and global perspective.



Fundraising Guidance and Preparation

Finding the right investors and lenders is a top priority for start-ups. We will walk you through how to identify your funding need, select your investors and prepare you for your investment meetings, with pitch decks and storytelling.



Commercialization and Market Strategy

Clearly identifying the right value proposition and target audience for a new product is critical for market acceptance and adoption. We can determine your position in the market, emphasizing your strengths and differentiators, as well as your distribution channels.

Business Acumen and Growth

Ensuring your capital spend is appropriately allocated takes financial expertise. Our fractional CFO service provides financial strategy, financial planning and analysis, cash flow management, reporting, risk management and growth funding advice.

Radically advancing the Medtech development process.



Our Mission

Mission: We help Medtech innovators **take flight**. Championing, Accelerating, and Navigating the journey to market.

Vision: Radically advancing the Medtech development process.

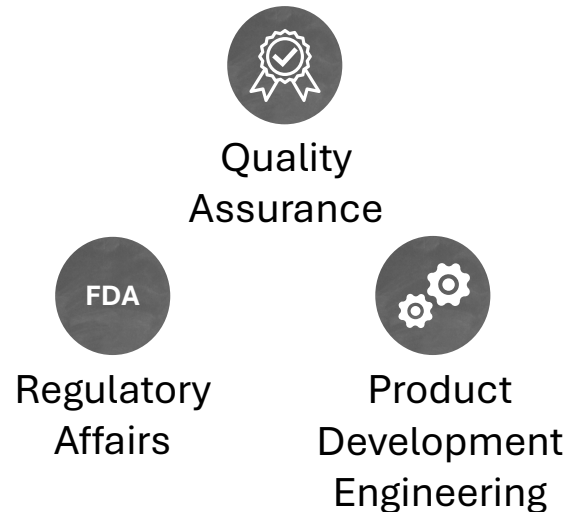


Case Study: Ampa Health



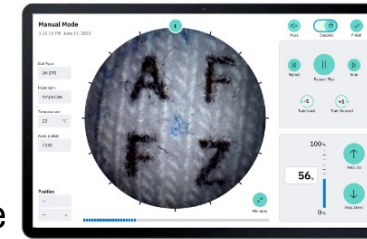
Program Description: Development of a repetitive transcranial magnetic stimulation (rTMS) system

Avio's Engagement:



Value to our partners:

- **Nimble partnership** navigating the medical device environment, including **regulatory submission strategy** and **design control compliance**
- Navigation of the MDSAP audit process resulting in **MDSAP certification**
- Development of **V&V strategy**, including IEC 60601 Compliance, Software & Cybersecurity, Transit and Environmental Conditioning



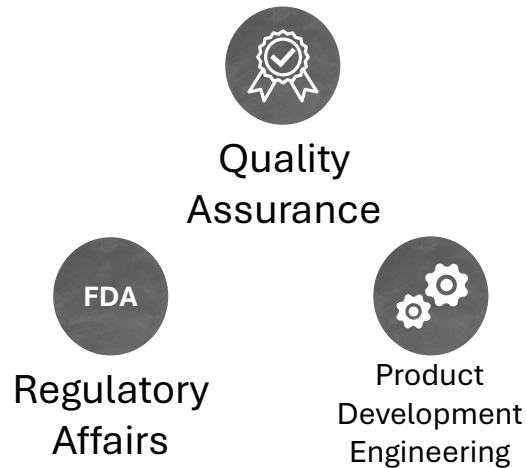
Client Testimonial: "Thanks to Avio, we not only gained a comprehensive understanding of the regulatory landscape but also successfully navigated through the rigorous process of MDSAP certification. This major milestone wouldn't have been possible without their support and expertise. Their tailored approach, attention to detail, and guidance have been instrumental in ensuring compliance at every stage."

Case Study: Fistula Solution



Program Description: Development of a single-use device intended for effluent management and promotion of healing of intact and injured skin surrounding enterocutaneous fistulae and ostomies.

Avio's Engagement:



Value to our partners:

- Collaboratively developed regulatory strategy leading to **Breakthrough Device designation**
- Responsible for guiding team through **development lifecycle**
- Generation of **Design History File, Risk Management File, and Quality Management System**
- Development of **V&V strategy**, including Human Factors, Transit and Environmental Conditioning



Client Testimonial: "Avio has been an amazing force multiplier to my company. Their team embodies collaboration and expertise, guiding us through the process of obtaining FDA Breakthrough Device Designation which was a major achievement. I've appreciated their support and insights through my product journey. I definitely recommend them to other entrepreneurs!"

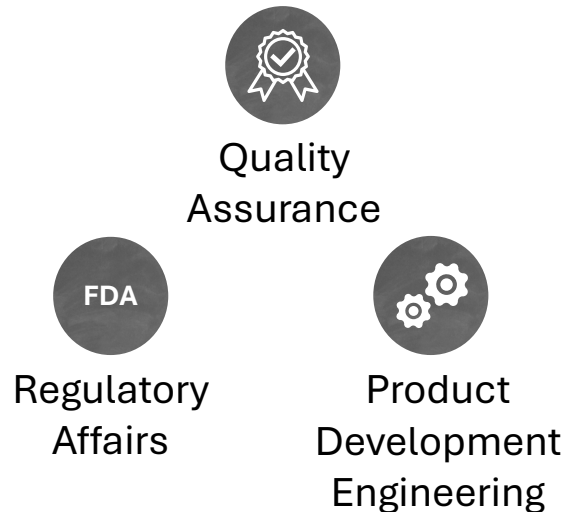


Case Study: Agitated Solutions



Program Description: Development of ultrasound contrast generating device

Avio's Engagement:

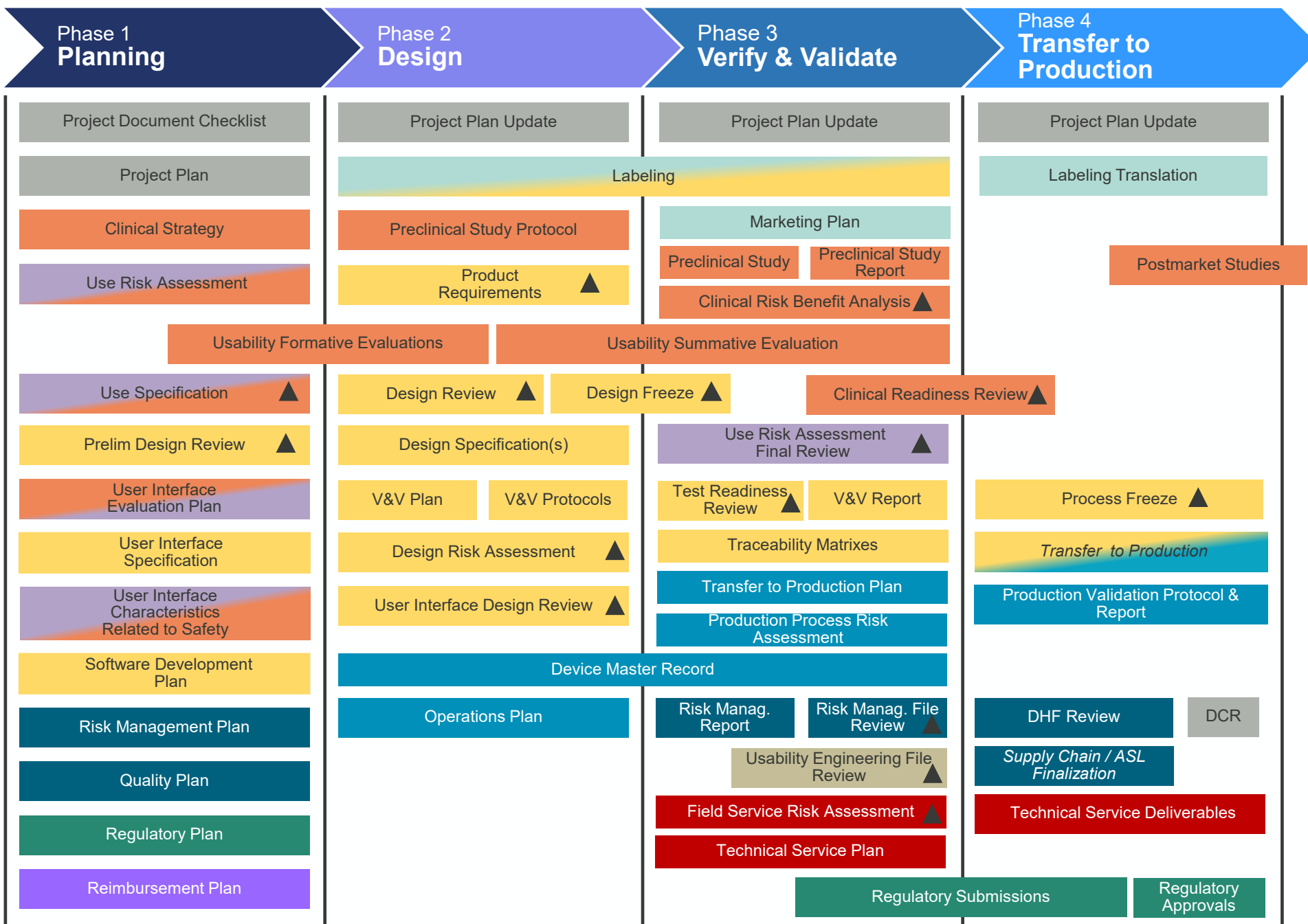


Value to our partners:

- **Navigation of unique regulatory landscape** of medical device under Health Canada and pharmaceutical-led combination product under FDA
- Achievement of MDSAP certification and **medical license in Canada**
- **Management of supply chain**, contract manufacturers and 3rd party testing houses

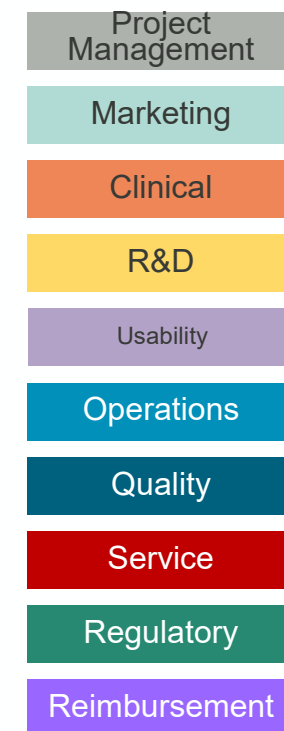


Client Testimonial: “The Avio team has been instrumental in Agitated Solutions’ success. They integrated seamlessly with my full-time team and have enabled me to reach our milestones more cost effectively. We have loved their positivity and expertise!”



The Startup Journey

Responsibility Color Coding



▲ Review meeting that requires a controlled meeting summary



Learn more:

<https://www.aviomedtech.com>

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