Navigating Innovation ▪ Advising Leaders, Investors & Startups ▪ Elevating Medtech

Transforming the Standard of Care

Transforming Medical Device Innovation

We are your trusted partner in turning groundbreaking medical device concepts into market-ready solutions. Our comprehensive development services combine engineering excellence with deep industry expertise to drive healthcare innovation forward.

End-to-End Development

From initial concept through market launch, we guide every step of your journey

Industry Expertise

Decades of experience in medical device innovation and regulatory compliance

Proven Success

Track record of delivering successful medical devices that improve patient care

Our Proven Process & Expertise

1

Regulatory Pathway

Navigate complex FDA requirements with confidence through our proven strategy.

2

Clinical Trials

Execute rigorous clinical studies that demonstrate your device's safety and efficacy.

3

Reimbursement Strategy

Develop comprehensive reimbursement plans that ensure financial viability.

4

Go-To Market Strategy

Launch your device successfully with data-driven market strategies.

5

Post-Market Support

Ensure long-term success through continuous monitoring and optimization.

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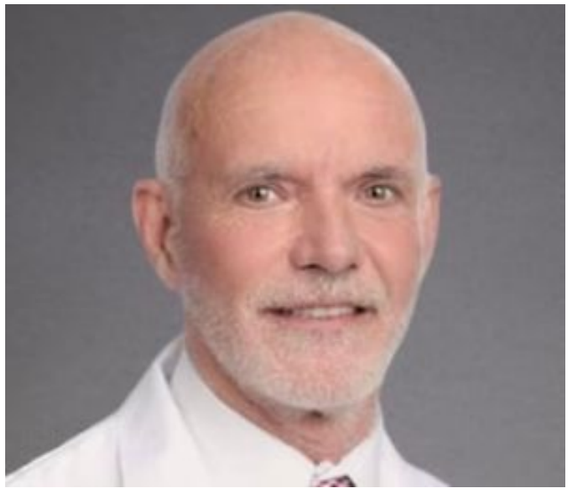
Meet Our Team

Robert Lee, MD



John Ross, MD

Terry Litchfield

Geoff Beecher

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Robert E. Lee, MD

Dr. Robert E. Lee is a distinguished vascular surgeon and regulatory expert with over 40 years of experience in clinical practice, academia, and medical device regulation. He served as a Medical Officer at the FDA's Center for Devices and Radiologic Health, where he led the evaluation and approval of innovative vascular and endovascular devices, focusing on renal and vascular access care.

Dr. Lee is a graduate of the University of Michigan Medical School and completed his general surgery residency and vascular surgery fellowship at Henry Ford Hospital. Certified in both general and vascular surgery, Dr. Lee has contributed significantly to clinical research, regulatory pathways, and best practices for vascular treatments. His work has improved safety standards and patient outcomes globally.

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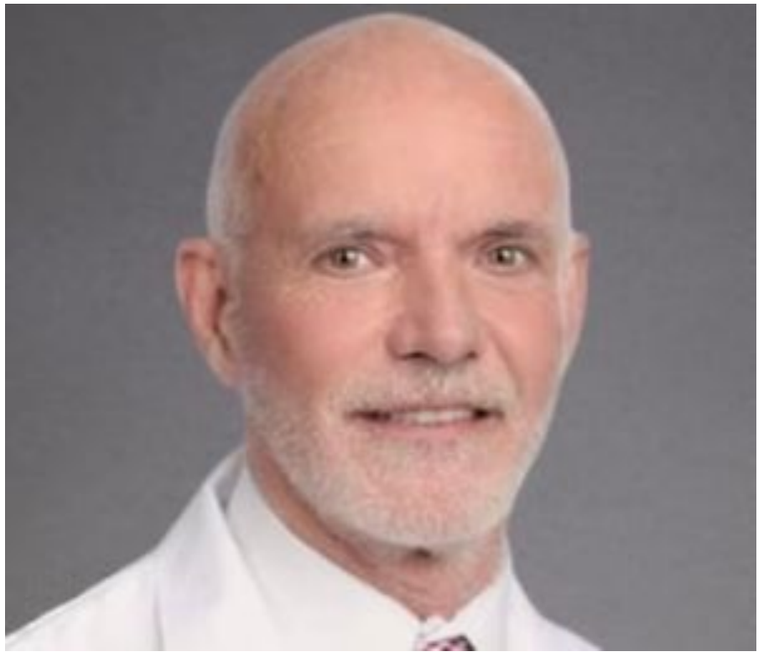
John Ross, MD

Dr. John R. Ross is a leading expert in vascular access and dialysis care, with decades of experience in clinical practice, research, and medical innovation. He founded the Dialysis Access Institute, a premier center dedicated to advancing vascular access procedures and education. Dr. Ross earned his medical degree from the Medical University of South Carolina and completed his residency and fellowship at the University of South Carolina School of Medicine.

He has held leadership positions, including Medical Director of the Dialysis Access Institute and Chief of Surgery at Bamberg County Hospital. As a principal investigator for numerous clinical trials, Dr. Ross has significantly influenced the development of medical devices and best practices for dialysis access, earning recognition such as the Lifetime Achievement Award from the American Society of Diagnostic and Interventional Nephrology.



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Terry Litchfield, MPA, CPC

Terry Foust Litchfield is a recognized leader in dialysis access innovation, with over three decades of experience in healthcare management, clinical operations, and patient advocacy. She co-founded Lifeline Vascular Access, spearheading the development of over 100 office-based labs and ambulatory surgery centers to improve vascular access care for dialysis patients.

As President of Access Solutions, Terry focuses on advancing patient engagement, clinical quality, and strategic healthcare solutions. She has worked extensively with CMS and FDA to influence regulatory policies for medical devices and endovascular treatments. Her contributions to vascular access research have been widely published, and she is a recipient of the American Society of Diagnostic and Interventional Nephrology's Lifetime Achievement Award.

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Geoffrey Beecher, B.Sc., MBA

Geoffrey Beecher is an accomplished medical device executive specializing in commercializing disruptive healthcare technologies. As Chief Commercial Officer at Phraxis, he has been instrumental in advancing the EndoForce™ Endovascular Anastomotic Connector toward FDA approval, implementing a strategic commercialization roadmap, and positioning the company for acquisition.

With a career spanning over 40 years, Geoffrey has led successful market expansions and product launches at companies including Avenu Medical (now Medtronic), Agendia, and Focal Therapeutics (now Hologic). His expertise in commercialization has guided numerous startups in navigating complex medical device pathways. Geoffrey also shares his insights through advisory roles, including serving on Virginia Commonwealth University's Commercialization Advisory Board.

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Our Comprehensive Expertise

Regulatory Compliance

Accelerating FDA approvals while ensuring complete regulatory alignment.

Clinical Acumen

Orchestrating powerful clinical trials that validate device effectiveness.

Reimbursement Strategies

Securing optimal payment pathways and coverage determination.

Commercialization

Crafting data-driven strategies for successful market penetration.

Lifecycle Support

Managing post-market requirements and continuous product optimization.

Patient-Centric Approach

Integrating user feedback to enhance clinical outcomes and adoption.

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Regulatory Expertise

FDA Submissions

Masterful development and strategic management of 510(k), PMA, and De Novo applications, backed by our exceptional approval success rate and deep regulatory insights.

Regulatory Pathway Guidance

Data-driven pathway optimization that minimizes regulatory hurdles, reduces development costs, and accelerates your product's journey to market approval.

Compliance Management

Proactive oversight of FDA and CMS regulations, featuring comprehensive quality system implementation and meticulous documentation management.

Post-Market Support

Robust maintenance of your regulatory standing through strategic labeling updates, thorough audit preparation, and sophisticated compliance monitoring systems that safeguard your market position.

Clinical Knowledge

With decades of clinical research experience, Echelon Development Group transforms innovative medical concepts into proven therapeutic solutions. Our comprehensive clinical trial expertise ensures rigorous evidence generation that validates both safety and efficacy while accelerating your path to market approval.

Trial Design & Management

Developing strategically focused protocols and comprehensive trial frameworks optimized for your specific device characteristics and target patient populations.

Site Selection & Oversight

Strategically identifying and qualifying high-performing research sites with proven track records in your therapeutic area.

Patient Recruitment

Implementing multi-channel recruitment strategies through established clinical networks and innovative outreach methods to meet enrollment targets.

Data Collection & Analysis

Employing rigorous data management processes and advanced analytics to generate compelling clinical evidence.

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Reimbursement Strategy

CMS Pathways

Expert navigation of Medicare and Medicaid reimbursement processes, including NCDs, LCDs, and payment determinations. We develop targeted strategies to achieve optimal coverage classification and payment rates.

Coding & Coverage Strategy

Strategic development of CPT, HCPCS, and ICD-10 coding pathways. We build compelling coverage narratives backed by clinical evidence and create comprehensive strategies for both government and commercial payers.

Health Economics

Robust economic modeling and value analysis to demonstrate cost-effectiveness. We create compelling ROI models, budget impact analyses, and comparative cost studies that resonate with payer requirements.

Stakeholder Engagement

Proactive outreach to key payer decision-makers, medical policy committees, and technology assessment groups. We orchestrate strategic discussions that highlight your device's clinical and economic value proposition.

Accelerating Market Success

Transform your innovative medical device into a market-leading solution. Our commercialization experts provide end-to-end guidance to optimize your launch strategy, maximize market adoption, and drive sustainable growth.

Go-to-Market Strategy

Data-driven launch plans that optimize pricing, distribution channels, and sales approaches to capture your target market segment effectively.

Branding & Messaging

Evidence-based value propositions and compelling brand stories that showcase your device's unique benefits to clinicians, administrators, and payers.

Market Analysis

Comprehensive market intelligence combining quantitative data and qualitative insights to identify growth opportunities, assess competitive dynamics, and anticipate industry shifts.

Adoption Support

Multi-channel engagement strategies featuring clinical training programs, thought leader partnerships, and performance monitoring to ensure sustained market success.

Lifecycle Support

Post-Market Surveillance

Comprehensive real-world data collection and analysis to ensure device safety and effectiveness in clinical settings.

Regulatory Updates

Proactive monitoring and implementation of changing regulatory requirements across global markets to maintain compliance.

Market Expansion

Strategic evaluation and execution of market penetration opportunities, including geographic expansion and new therapeutic applications.

Product Iteration

Continuous product enhancement through systematic collection of user feedback, clinical outcomes, and technological advancements.

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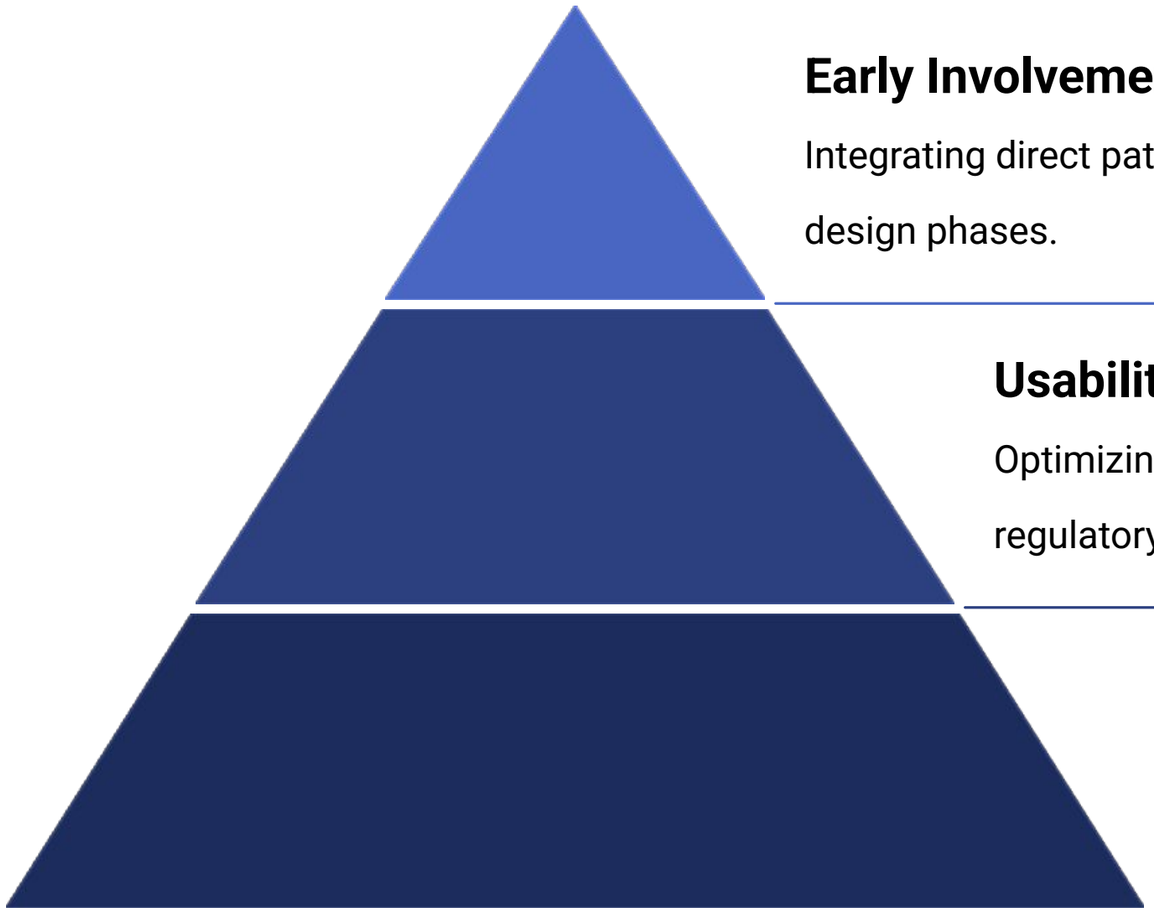
Patient Engagement



Early Involvement

Integrating direct patient feedback and experiences from initial concept through design phases.

Usability and Compliance

Optimizing device design for intuitive use while meeting stringent regulatory requirements.

Active Engagement

Conducting comprehensive patient journey mapping and continuous feedback loops.

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Key Differentiators

1

Unmatched Renal Excellence

30+ years of specialized expertise in pioneering dialysis access and innovative renal care solutions that improve patient outcomes.

2

Complete Development Partner

Seamless support throughout your product journey, from initial concept validation through successful market launch and beyond.

3

Integrated Strategic Excellence

Unified team of clinical, regulatory, reimbursement, and commercial experts working together to accelerate your path to market success.

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