EXPERIENCE
NAMSA has extensive experience with Class II and Class III, cardiac, cardiovascular, peripheral vascular, and neurovascular devices, such as ventricular assist devices, circulatory support, pacing devices, aneurysm stents and fillers, IVDs (cardiac markers), combination products, and tissue/biologics. NAMSA also has expertise with diagnostics, electrophysiology and interventional devices for other cardiology and cardio/neurovascular indications.

NAMSA’s testing, pre-clinical, consulting and clinical research staff includes experienced professionals who are knowledgeable in the field of clinical research and the medical device industry. Many have professional certifications (e.g., CCRA) and have worked in healthcare and/or the industry as RNs, medical technologists, biologists, toxicologists, chemists, microbiologists, statisticians, field clinical engineers, veterinary surgeons, pathologists and other health professions.

In addition, NAMSA’s highly skilled and experienced regulatory and quality consultants have a long history of successful submissions and practical, effective quality system development. We’ve conducted beneficial gap analyses and audits for many cardiac, cardio/peripheral vascular and neurovascular companies as well.

MRO™ APPROACH
NAMSA is a medical research organization applying our regulatory and quality system consulting, testing services, preclinical efficacy studies, clinical research, and sterilization products to support every phase of medical product development. With NAMSA’s MRO™ approach to testing and consulting, you maintain project control while gaining a partner who extends your in-house capabilities, provides specialized expertise at exactly the right time, and manages a completely outsourced project efficiently and effectively.

EXPERTISE
Cardiac, Cardiovascular, and Peripheral Vascular Devices
- Metal and self-expanding stents
- Drug eluting stents
- Carotid embolic filter and stent
- Distal protection device with stent
- Angioplasty and drug coated balloon catheters
- Atherectomy catheter systems
- Thrombectomy and thrombolytic infusion catheters
- Aspiration systems
- EP mapping and ablation systems
- IVUS systems
- Percutaneously placed cardiac implants
- Adult and pediatric LVADs
- Counter pulsation pumps
- Aneurysm coils and fillers
- Left atrial appendage occlusion devices
- PFO occluder
- Heart failure and CHF devices
- Leads, pacers and ICDs

Neurovascular Devices
- Stents
- Aneurysm coils and fillers
- IVUS catheters - neuro
- Thrombolytic infusion catheters

NAMSA CERTIFICATIONS
NAMSA laboratories are registered with and inspected by one or more of the following:
- United States Food and Drug Administration (FDA)
- Department of Agriculture (USDA)
- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

NAMSA’s quality system complies with:
- 21 CFR Part 820
- 21 CFR Part 58
- 21 CFR Part 210/211
- 21 CFR Part 11
- ISO 13485:2003
- ISO 17025:2005
- Registered with FDA as a HCT/P establishment (21 CFR 1271)
- NAMSA Clinical and Consulting is certified to ISO 9001:2008

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REGULATORY
• Regulatory strategies
• Pre-Submission meeting preparation and attendance
• U.S. Regulatory submissions (IDE, 510(k), PMA, HUD, HDE, BLA, Device Master File)
• FDA panel preparation and participation
• International Submissions (Ethics Committee, Technical File, Dossier, STED) and Registrations (EU, Canada, Australia, Japan, BRIC and more)

QUALITY SYSTEMS
• Quality system development and implementation
• Audits and gap analyses
• Document control process
• Design controls
• Supplier audits
• BIMO Inspection preparation and participation

EFFECTIVENESS AND FUNCTIONAL STUDIES
• Blood/material interface evaluation, including comprehensive pathology capabilities
• Disease Models (atherosclerosis, aneurysm, heart failure, hypertension, flow, and other models as requested)
• Cardiac rhythm management/electrophysiology
• Vascular repair
• Cardiac bypass, left ventricular assist device (LVAD), valve replacement and transplant procedures
• Hemostasis
• Angioplasty, stenting, atherectomy, thrombectomy, inferior vena (IVC) filters, embolic protection and combination devices
• Imaging (angiography, intravenous ultrasound (IVUS), Echo (ICE, TTE), CT/MRI/PET)
• Cadaveric studies

BIOCOMPATIBILITY EVALUATION AND TESTING
• Biological and toxicological risk assessments
• In vitro and in vivo toxicology
• GLP and GMP regulated testing
• Safety programs (in vitro and in vivo) follow:
  • ISO 10993
  • U.S. Food and Drug Administration Guidance Documents
  • Japanese MHLW Regulations
  • Chinese CFDA Regulations
  • Board Certified Pathologists and Toxicologists
  • Complete histopathological services
  • State-of-the-art Histology Laboratories

MATERIAL CHARACTERIZATION AND ANALYTICAL CHEMISTRY
Analysis of polymers, metals, and other components for purity, uniformity, composition, processing residues, and extractable profiles
Examples of testing performed at NAMSA include:
• Physiochemical tests
• FTIR
• HPLC
• MS
• ICP
• GC
• Viscosity
• SEM
• DSC

STERILITY ASSURANCE AND MICROBIOLOGY SERVICES
• Environmental monitoring
• Reusable devices: cleaning, disinfection and sterilization validations
• Single use devices: sterilization validation and monitoring
• Packaging validation
• Shelf-life testing
• Biological indicators

CLINICAL SUPPORT
The clinical phase is commonly the most time consuming, expensive, and least predictable part of your development effort. It is essential that you work smart from the start to avoid costly do-overs. NAMSA has designed and conducted clinical trials to obtain market approvals, improve reimbursement, or generate publications on a global scale.
NAMSA has supported the clinical phase of the cardiac, cardiovascular, peripheral vascular and neurovascular product development process in many ways:
• Study design
• Biostatistics
• Study Management
• Data Management and EDC
• Data Monitoring and Clinical Events
• Report, manuscript and technical writing
• Clinical Evidence and Post Approval
• Clinical Auditing
• Field Clinical Engineers

POST-MARKET STUDIES / SURVEILLANCE
The need for post-market data is on the rise in today’s global markets. This data is critical to your marketing, payor coverage and reimbursement levels, and often your ongoing ability to stay in the market. We understand these market pressures and the regulatory rigors required to conduct a successful post-market or non-traditional study.
• FDA mandated post-market studies
• Registries and retrospective studies
• Health Economics studies
• Post-market surveillance
• Literature based meta-analysis