REGENERATIVE MEDICINE, CELLULAR THERAPY and TISSUE ENGINEERING

EXPERIENCE
NAMSA has extensive experience with combination products, tissue/biologics, regenerative medicine, cellular therapy and tissue engineering therapies.

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 regenerative medicine, cellular therapy and tissue engineering 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
- Extra Cellular Matrix
- Regenerative Medicine
  - Cardiovascular
  - Urologic
  - Renal
  - Neurological
  - Orthopedic
    - Chondrocytes
    - Bone Healing
    - BMP
  - Pancreatic
  - Ophthalmologic
  - Dermal
  - Tissue Engineering
  - Xenotransplantation
  - Cellular Therapies

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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For more information, visit www.namsa.com
NAMSA Product Development Phases

01 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)

02 EFFICACY AND FUNCTIONAL STUDIES
NAMSA's preclinical capabilities include developing models to help clients quickly determine whether their device/product performs as intended.
- Feasibility/Efficacy
- Tumorigenicity (in vivo)
- Biodistribution (in vivo)
- General Safety (in vivo)

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

04 CELLULAR TESTING SERVICES
- Molecular Biology
  - PCR, RTPCR, qPCR
  - Gene Expression
  - DNA Damage Analysis
  - Trans Gene Analysis
  - Genotox
- Immunogenetics
  - Flow Cytometry
  - Stem Cell Characterization
- Cell Biology
  - Cell Culture
  - Cell Viability
  - Cellular Differentiation

05 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

06 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
  - HPLC
  - MS
  - GC

07 MICROBIOLOGY SERVICES, STERILITY ASSURANCE & PACKAGING VALIDATION
Our well-equipped facilities contain laboratories for bacteriology and sterility testing, clean rooms, aging chambers and media preparation areas. We perform custom and routine studies such as:
- Environmental monitoring
- Single use devices: sterilization validation and monitoring
- Packaging validation
- Shelf-life testing
- Biological indicators

08 CLINICAL SUPPORT
NAMSA has designed and conducted clinical trials to obtain market approvals, improve reimbursement, or generate publications on a global scale.
- Study design
- Biostatistics
- Database development
  - Electronic data capture (EDC) platforms
- Data management
- Study management
- Data Monitoring Committees (DMC)
- Clinical Events Committees (CEC)
- Reports, manuscripts and technical writing
- Clinical audits
- Field Clinical Engineers

09 POST-MARKET STUDIES / SURVEILLANCE
Post-Market 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