

# DERMATOLOGY AND WOUND HEALING

## EXPERIENCE

NAMSA has extensive experience with Class I, II and III dermal and wound healing devices. Our experience ranges from wound dressings through tissue glues and dermal laser products.

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 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 systems consultants have written successful submissions and managed Quality System development, gap analysis and audits for many dermal and wound healing device companies.

## 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, or manages a completely outsourced project efficiently and effectively.

## EXPERTISE

### Dermal:

- Dermal void fillers
- Skin graft and eschar cicatrization studies
- Lasers

### Wound Healing:

- Abdominal mesh
- Adhesion prevention products
- Wound adhesives, sealants, and tissue glues
- Hydrocolloid and other wound dressing products
- Suture delivery devices
- Hemostatic agents

## 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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## NAMSA Product Development Phases



### 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

- Development and implementation
- Audits and gap analyses
- Document control process
- Design controls
- Supplier audits
- BIMO Inspection preparation and participation



### EFFICACY AND FUNCTIONAL STUDIES

NAMSA's preclinical capabilities include developing models to help clients quickly determine whether their device/product performs as intended.

- Multiple wound models including normal and delayed wound healing, partial or full thickness wounds, inflammatory, devascularized, contaminated or infected (BSL-1 and BSL-2) wounds and superficial burns
- Diabetic wound models
- Models for functional intradermal administration
- Models for hemostatic devices and materials
- Various models for anti-adhesion product evaluations
- Test products include absorbents, protective and negative pressure dressings, wound treatments with growth factors incorporated and tissue engineered products
- Abdominal repair meshes
- Dermal and general void fillers/bulking agents
- Skin closure devices, adhesives and sealants



### 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



### STERILITY ASSURANCE AND MICROBIOLOGY SERVICES

- Environmental monitoring
- Single use and reusable devices: cleaning, disinfection and sterilization validations
- Sterilization validation and monitoring
- Packaging validation
- Shelf-life testing
- Biological indicators



### 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:

- |                         |       |             |
|-------------------------|-------|-------------|
| • Physicochemical tests | • GC  | • Viscosity |
| • FTIR                  | • ICP | • SEM       |
| • HPLC                  | • GPC | • DSC       |
| • MS                    |       |             |



### CLINICAL SUPPORT

The clinical phase is commonly the most time consuming, expensive, and least predictable part of your development effort. 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 dermatology and wound healing product development process in many ways:

- Study design
- Biostatistics
- Report, manuscript and technical writing
- Study Management
- Clinical Evidence and Post Approval
- Clinical Auditing
- Data Management and EDC
- Data Monitoring and Clinical Events
- 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