ORTHOPEDIC, SPINE AND ORTHOBIOLOGICS

EXPERIENCE
NAMSA has extensive experience with Class II and Class III orthopedic, spinal and orthobiologic devices, as well as cell and tissue products regulated under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. NAMSA projects have included large and small joint replacement devices, cartilage repair systems, spinal stabilization and fixation devices, disc and vertebral body replacement devices, and biologics including bone morphogenic proteins (BMP), allografts and demineralized bone matrix products.

NAMSA’s testing, pre-clinical, consulting and clinical research Associates include experienced scientists and professionals with deep knowledge of 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.

NAMSA’s highly skilled and experienced regulatory and quality consultants have a long history of successful submissions and practical, effective quality system development. In addition, we have conducted gap analyses along with clinical and quality system audits for numerous orthopedic, spinal and orthobiologic 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
- Small bone implants (wrist-hand-finger)
- Large joint replacement (hip-knee)
- Cartilage repair systems
- Orthotics and prosthetics
- Hip resurfacing product
- Biologic fusion devices (spine & dental)
- Injectable devices to treat arthritic shoulders and knees
- Bone growth products for spine surgery including: liquid based products, synthetic carriers of calcium products, autologous bone grafts, combinations mixed with stem cells
- Annulus repair devices
- Lumbar and cervical cage devices
- Disc replacement device – lumbar/cervical
- Vertebral body replacement (VBR) devices
- Stabilization devices – screws/plates
- Disc nucleus replacement
- Biocompatible polymers to resurface joint cartilage
- Scaffolds
- Xenografts
- Allografts
- DBM

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. Ortho, spinal and orthobiologic models include:
- Joint replacement
- Bone fracture and defect repair
- Bone reconstruction implantations
- Articular cartilage repair
- Ligament and tendon fixation/repair
- Intervertebral disc reconstruction/replacement
- Anterior and posterolateral spinal fusion
- Osteoinduction

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
- Orthobiologics and tissue testing:
  - Antimicrobial efficacy
  - Residual moisture analysis
  - Residual lipid analysis
  - Microbial outgrowth study
  - Cleaning/disinfectant effectiveness
  - Residual calcium analysis
  - Bone void filler analysis

DEMINERALIZED BONE MATRIX (DBM) – LOT RELEASE TESTING
- Lot release Osteoinduction testing
- Lot release testing includes:
  - Alkaline Phosphatase Assay (ALP)
  - Athymic mouse and rat models
  - Bone Morphogenic Protein (BMP)
  - Limulus Amebocyte Lysate (LAL)

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
  - Specialized tissue-implant processing using the Exakt Histological System

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
  - GC
  - ICP
  - GPC
  - Viscosity
  - SEM
  - DSC

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. We have supported the clinical phase of numerous orthopedic and spinal devices as well as orthobiologic products in many ways:
  - Study design
  - Biostatistics
  - Study Management
  - Data Management and EDC
  - Data Monitoring and Clinical Events
  - 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