Reliable. Tailored. Focused.

Ophthalmic Testing Services
Industry Leading Expertise Embodies NAMSA’s Reputation

For over 40 years NAMSA has been the leading contract research organization helping medical device companies bring safe and effective products to market.

NAMSA’s comprehensive offering of toxicological (in vitro and in vivo), analytical chemistry, microbiology testing services, regulatory and clinical trial support provide our clients all the global reach and service they need, while working with one single source.

OPHTHALMIC TESTING
At NAMSA, we understand the process of bringing innovative ophthalmic medical devices to market can be a time-consuming and difficult process. The need for absolute certainty in your entire testing program is critical. That is why it is essential to partner with a CRO that not only knows the process, but one that helped develop it as well.

Whether you’re developing contact lenses, intraocular lenses, solutions or drug delivery devices, our industry leading expertise and experience will show you the ultimate path to market. Our Technical Specialists and Scientists are adept at developing non-clinical and clinical testing programs for these devices and other ocular products with proven methods based on international requirements.

BIOCOMPATIBILITY
Safety evaluation studies, in vitro and in vivo, are conducted on a variety of ophthalmic products as well as biomaterials, medical devices and combination products.

Testing ranges from the initial screening of new materials to product release testing, periodic audit testing and non-clinical or pre-market safety evaluations to meet current FDA and international standards. Studies performed include:
- Contact Lenses
- Intraocular Implants
- Drug Delivery Devices
- Topical Therapies and Solutions

EFFECTIVE FUNCTIONAL TESTING
NAMSA’s team of in-house veterinary surgeons and scientists offer years of experience in developing and overseeing unique studies designed to demonstrate proof of concept, efficacy and biocompatibility. For more complicated studies, NAMSA uses board certified veterinary ophthalmologists for the procedures and consultation.

Our team offers a broad range of in vivo models and analysis tools that will provide data in support of a specific application of a device. NAMSA specializes in a wide variety of ophthalmic models for the anterior segment, posterior segment and intraocular pressure and including:
- Corneal Healing Studies
- Vitreal Procedures & Replacements
- Conjunctival Implants
- Aqueous Shunts
- Intraocular Implant Studies

NON-CLINICAL PATHOLOGIC OCULAR EVALUATION
In addition to the standard test offering, NAMSA also offers more specialized ophthalmic services. Led by the renowned ocular pathological specialist, Dr. Jim Render, NAMSA offers:
- Peer Review Services
- Internal & External Study Review
- Consulting Services

HISTOPATHOLOGICAL CAPABILITIES
In addition to the full line of histopathology services, NAMSA has multiple full-time board certified pathologists in-house, including ocular specialist Dr. Jim Render. NAMSA provides Advanced Histological Technology for the testing and evaluation of implanted medical devices. Valuable tissues can be collected and processed on site under the supervision of a board certified pathologist.

MATERIALS CHARACTERIZATION AND ANALYTICAL CHEMISTRY
In addition to the tests outlined in the NAMSA Characterization Matrix®, we offer a comprehensive range of chemistry testing services to ensure product quality and consistency during all stages of development. Our Technical Specialists are prepared to design and implement special studies for medical devices, pharmaceutical container/closure systems and other innovative products. Examples include:
- ISO 11979 IOL Testing
- Exhaustive Extractions
- Photostability
- Hydrolytic Stability
- Leachables Testing
- Nd. Yag Laser Exposure

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:
- Cleaning Studies
- Antimicrobial Studies
- Disinfection Studies
- Product Sterility
- Sterilization Validation
- Bioburden
- Microbial Identification
- Product/Packaging Aging & Stability
- Environmental Monitoring

NAMSA CERTIFICATIONS
NAMSA laboratories are registered with and inspected by the United States Food and Drug Administration (FDA), Department of Agriculture (USDA), the American Society for Testing and Materials (ASTM), the International Organization for Standardization (ISO), the British Standards Institute (BSI), the American Association for Laboratory Accreditation (A2LA), the American Society for the Prevention of Cruelty to Animals (ASPCA), the American Association for Laboratory Accreditation (A2LA) and the American Society for Testing and Materials (ASTM). NAMSA’s quality system complies with ISO 13485:2003 and ISO 17025:2005.

For a more detailed listing of our specific offerings in non-clinical testing services, please visit our website at www.namsa.com.
We’ve been the world’s leading medical device research organization for over 45 years.

You want sound advice and action from a partner who can quickly move your product into a global market. So we’ve made a science out of service, identifying challenges and solving them with the right advice at exactly the right time. We can guide and support you through the most complex submissions and the most rigorous testing programs. We do the work that moves things forward quickly without ever compromising quality. And our passion for scientific integrity gives you the security that you’re on the optimal path to market, anywhere in the world.

We’ve worked with thousands of companies to date—bringing safe, effective, and compliant medical products to market. We are passionate about our people, our scientific integrity, and the breadth of solutions we offer our clients globally. And we’re ready. Ready to take you to market.

OUR SERVICES

Regulatory and Quality Systems Consulting
Research and Development Support
Non-Clinical Testing
Clinical Research
Post-Market Support

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