NAMSA

PEOPLE > SCIENCE > SOLUTIONS

PEOPLE > SCIENCE > SOLUTIONS

Our difference

Our foundation

Our focus

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY (Functional testing)

BIOCOMPATIBILITY
(in vivo & in vitro toxicology)

CLINICAL TRIALS

STERILITY ASSURANCE & MICROBIOLOGY

TESTING

CONSULTING AND ADVISORY SERVICES

STERILIZATION MONITORING PRODUCTS

PEOPLE

Our difference

COMPANY HISTORY

Founded in 1967 in Perrysburg, Ohio, by Dr. Ted Gorski and his wife Lucille, NAMSA remains family owned and operated. Dr. Gorski recognized the need by medical device manufacturers for quality control testing of biomedical products and opened a new lab in Northwood, Ohio in 1971. It was his vision that NAMSA would play a vital role in helping companies bring safe products to market.

PEOPLE

Our difference

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

NAMSA TODAY

NAMSA has been serving clients for more than 35 years. Our company employs over 300 associates across the globe offering both testing services and sterilization monitoring products. We are headquartered in Northwood, Ohio with facilities throughout the world.

PEOPLE
Our difference

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

NAMSA VISION

Our vision is to be the premier global resource providing non-clinical, clinical, and advisory services to medical device, pharmaceutical, and biotechnology companies. We collaborate with our customers to bring safe, effective, and compliant products to market. We are passionate about the work we do because the technology and therapies that pass through our hands touch millions of lives.

PEOPLE
Our difference

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

NAMSA TODAY: OUR FACILITIES

NORTHWOOD, OH

IRVINE, CA

ATLANTA, GA

LYON, FRANCE

Our International locations include:
LABORATORY: Biomatech (Lyon, France)
OFFICES: Germany, Israel (MedNet), United Kingdom (MET), Japan (Senkom), Singapore (BRASS)

PEOPLE

Our difference

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

OUR EXPERTISE

NAMSA people have extensive experience working with companies of all sizes and a wide range of medical disciplines.

Cardiovascular	Dental	Drug Delivery
Gastrologic	Neurologic	Obstetrics/Gynecology
Ophthalmology	Orthopedic	Tissue Engineering
Urologic	Wound Healing	

Our clients include entrepreneurial and start-up enterprises along with global Fortune 100 companies.



PEOPLE

Our difference

COMPANY HISTORY

NAMSA TODAY

OUR EXPERTISE

NAMSA CERTIFICATIONS & ACCREDITATIONS

All NAMSA and Biomatech laboratories are fully certified and accredited according to the highest industry standards. Testing is performed in accordance with the requirements defined in 21CFR part 58, 820 (US FDA, GLP, and QS regulations). Biomatech is accredited to international quality systems standard ISO 17025 and NAMSA U.S. laboratories are certified to ISO 13485:2003 and are compliant with ISO 17025.

SCIENCE

Our foundation

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY

BIOCOMPATIBILITY

CLINICAL TRIALS

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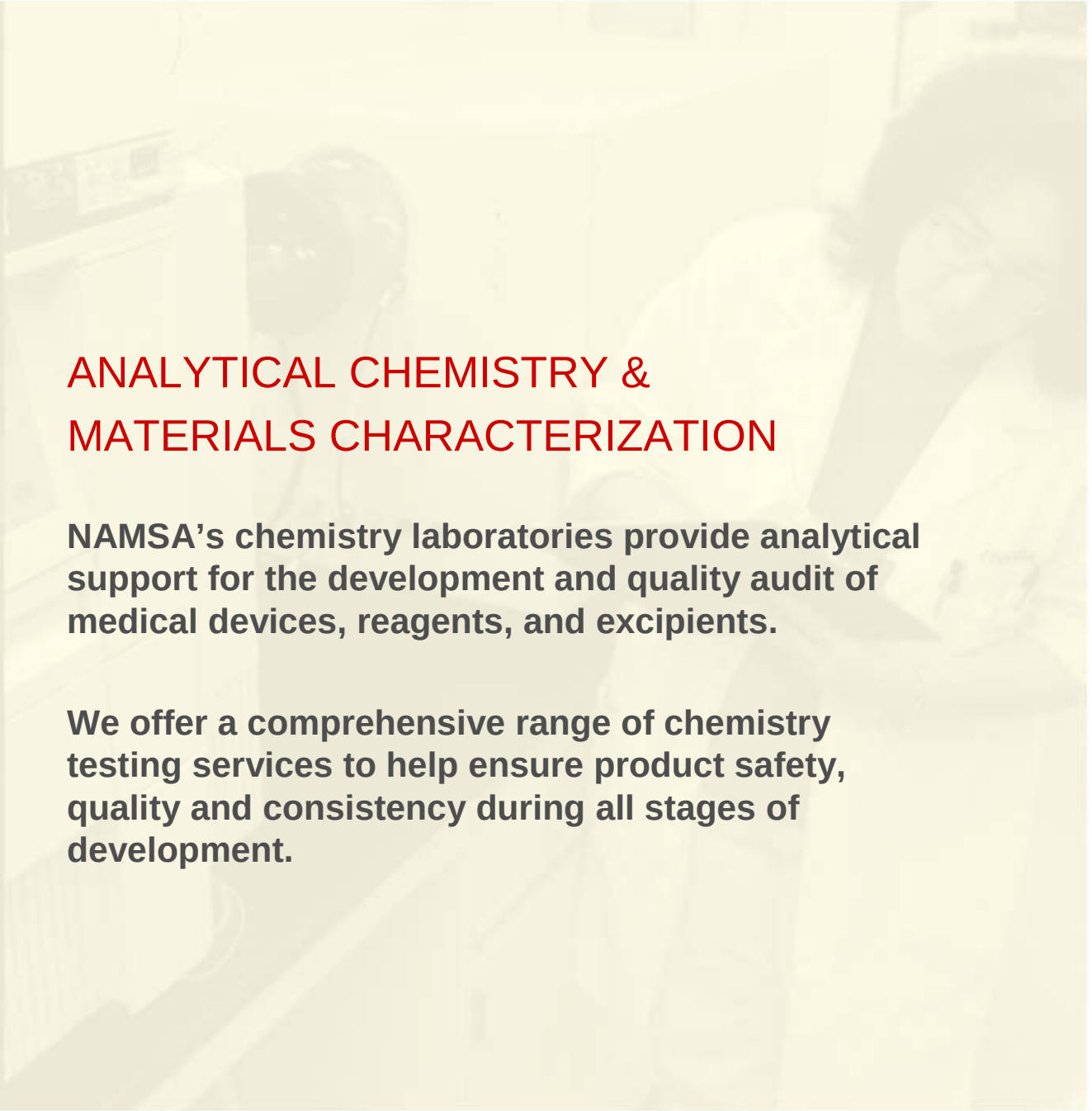

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

NAMSA's chemistry laboratories provide analytical support for the development and quality audit of medical devices, reagents, and excipients.

We offer a comprehensive range of chemistry testing services to help ensure product safety, quality and consistency during all stages of development.

SCIENCE

Our foundation

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY

BIOCOMPATIBILITY

CLINICAL TRIALS

STERILITY ASSURANCE & MICROBIOLOGY

EFFICACY (Functional Testing)

We help medical device manufacturers verify that their products perform according to their intended function.

Our scientists offer a broad range of *in vivo* models and analysis tools to provide data in support of a specific application of a device.

SCIENCE

Our foundation

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY

BIOCOMPATIBILITY

CLINICAL TRIALS

STERILITY ASSURANCE & MICROBIOLOGY

BIOCOMPATIBILITY

Safety evaluation studies *in vitro* and *in vivo* are conducted on a variety of biomaterials, medical devices and related products to identify the presence of toxins or any potentially harmful effects of the product.

In addition to the full range of ISO safety testing, NAMSA will customize test programs and protocols to accommodate the characteristics of unique devices and materials.

SCIENCE

Our foundation

ANALYTICAL CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY

BIOCOMPATIBILITY

CLINICAL TRIALS

STERILITY ASSURANCE & MICROBIOLOGY

CLINICAL TRIALS

Clinical trials in compliance with EN540 regulations and ISO 14155 standards are performed to assess device performance, possible secondary effects and risk acceptability.

These studies are required for implantables, Class III and some Class 2b devices.

Studies may be conducted according to Good Clinical Practices (GCP) and International Conference of Harmonization (ICH).

SCIENCE
Our foundation

CHEMISTRY & MATERIALS CHARACTERIZATION

EFFICACY

BIOCOMPATIBILITY

CLINICAL TRIALS

STERILITY ASSURANCE & MICROBIOLOGY

STERILITY ASSURANCE & MICROBIOLOGY

NAMSA offers a complete sterility assurance program - sterilization and packaging validation, environmental monitoring and shelf life studies. Our facilities contain laboratories for bacteriology and sterility testing, clean rooms, aging chambers, and media preparation.

Beyond sterility assurance programs we perform:

- **Antimicrobial Testing**
- **Bacterial Endotoxin (LAL)**
- **Microbial Limits**
- **Reusable Device Studies**
- **Biological Indicator Performance Studies**

SOLUTIONS
Our focus

TESTING

TESTING

Our goal is to use our expertise and reputation at each juncture in the product development process. We work to help move from concept to production quickly.

Adapted from NAMSA's Device Development Process and Testing Guide™

SOLUTIONS
Our focus

TESTING

CONSULTING

PRODUCTS

CONSULTING – NAMSA Advisory Services

With over 35 years in the medical device industry, we offer more than just testing. We partner with you to create customized solutions.

Services we offer beyond testing:

- **Regulatory Interface & Meeting Preparation**
- **Quality Assurance Auditing**
- **On-Site Seminars & Training**
- **On-site Consultation & Investigational Pathology**
- **Risk Assessment**
- **Packaging Services**
- **Bone/Tissue Interface**
- **Histopathology Services**

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