Regulatory and Quality Systems Consulting

NAMSA®

PEOPLE › SCIENCE › SOLUTIONS

With regulatory expertise in global markets, we bring clarity and direction to your process.

Delivering a medical product to market can be a long and complicated process, even when you're familiar with the regulatory requirements. But when requirements are rapidly changing or when you're entering international markets, the process can seem insurmountable.

At NAMSA, we provide efficient, responsive regulatory and quality services across the full spectrum of product design and development—and we stay with you for post-market support as well. From high-level expertise to practical working solutions, our staff develops and implements global regulatory strategies.

WE'RE YOUR TRUSTED ADVISOR, OFFERING STRATEGIC SUPPORT AT EVERY STAGE OF THE PRODUCT DEVELOPMENT PROCESS. IN FACT, WE'VE BEEN THE WORLD LEADER IN THE SAFETY EVALUATION OF MEDICAL DEVICES FOR MORE THAN 40 YEARS.

We also prepare submissions, plan testing, and manage communications with regulatory bodies. With our approach, you maintain project control while gaining the benefit of on-demand external support—whether it's to extend your in-house capabilities or get access to the specialized expertise you need.

Regulatory Consulting

Our regulatory experts are specialized in devices and biologics across many jurisdictions, from the U.S. to Europe, Japan, Canada, Australia, and beyond. Our support ranges widely, including Notified Body selection, pre-IDE and early collaboration meetings, advisory panel meetings, pre-approval inspections, FDA District Office meetings, and more.

And when you make a submission, we support you on every level. Our consultants are available for emergency situations—if you come up against regulatory action or a product recall, we're there for you.

Global Compliance Support

Further, we can act as your Designated Agent, assisting with FDA communications with foreign establishments and responding to questions regarding your products. We've assisted in the preparation and facilitation of FDA inspections for clinical and manufacturing requirements around the world—including bioresearch monitoring (BIMO), quality system regulation (QSR), and ISO compliance.

USING OUR KNOWLEDGE AND INSIGHT, WE CAN DEVELOP AND EXECUTE SUCCESSFUL REGULATORY STRATEGIES FOR ALMOST ANY PART OF THE WORLD.

Why NAMSA?

SPEED AND RESPONSIVENESS: Our experience includes hundreds of successful submissions in virtually every therapeutic specialty. We can expedite your submission process with our creative, customized approach to your specific situation. And our regulatory staff is fully integrated with our pre-clinical, clinical and compliance staff, creating a team that can address the full scope of your project—meeting your goals with speed, efficiency, and expertise.

KNOWLEDGE: At NAMSA, we're well informed and well connected. We communicate regularly with key agency personnel and have the autonomy to explore critical questions without revealing client information. And when it comes to regulatory changes, our staff is up to date, keeping you informed and ahead of possible impacts on your product.

TAILORED SERVICES: Our staff is available on or off site, and we can rapidly supply a team to meet critical deadlines, resolve urgent situations, or even act as a virtual department. And we have offices around the world, so you'll have access to our global expertise no matter where you're located.

RECOGNIZED EXPERTISE: We've strategically networked with governing bodies and regulatory agencies in the U.S., Europe, and Japan. Our experts are regularly invited to speak at professional seminars and training courses. And our technical specialists provide reports and supporting data in ways that are both easy to understand and preferred by regulatory bodies.

With clear expertise and strategic guidance, we can help you navigate the fastest, safest way to global markets.

At NAMSA we can assist you in designing and implementing quality systems through our comprehensive service offerings.

REGULATORY STRATEGY
- Agency Interaction
- Device Classification/Predicate Device Searches
- Product Change Management
- Import/Export Licenses and Management
- Labeling/Advertising Review
- FDA Collaboration Meetings
- Real-Time Reviews
- U.S. Designated Agent/EU Authorized Representative
- Due Diligence Assessment and Support

REGULATORY SUBMISSIONS
- U.S. Pre-Market Submissions—510(k)/PMA/HDE
- Device Master Files
- International Registrations—CE Mark, Canada, Australia, Japan
- Submissions for Clinical Approval
- Device Listing and Establishment Registration
- Regulatory Letters to File
- Technical Files and File Management
- Biologic Licensing Applications

QUALITY SYSTEMS
- Development (ISO, QSR, GLP)
- Audits and Gap Analyses
- Pre-Certification Assessments
- Customized Training
- Facilitate Management Responsibility
- Corrective and Preventive Action (CAPA) Implementation
- Supplier Compliance
- Design Control and Project File Compliance

PRE- AND POST-MARKET SUPPORT
- Device Standards Assessment
- Risk/Benefit Analysis
- Statistical Sampling Plans and Analysis
- Biocompatibility/Sterilization Assessment
- Internal Audit Support
- Technical File Configuration
- Complaint Handling, Medical Device Reporting (MDR), Vigilance Reports
- Inspection Advice and Management
- Device Recall Determination and Management
- Enforcement Action Resolution—Warning Letters, Consent Decrees

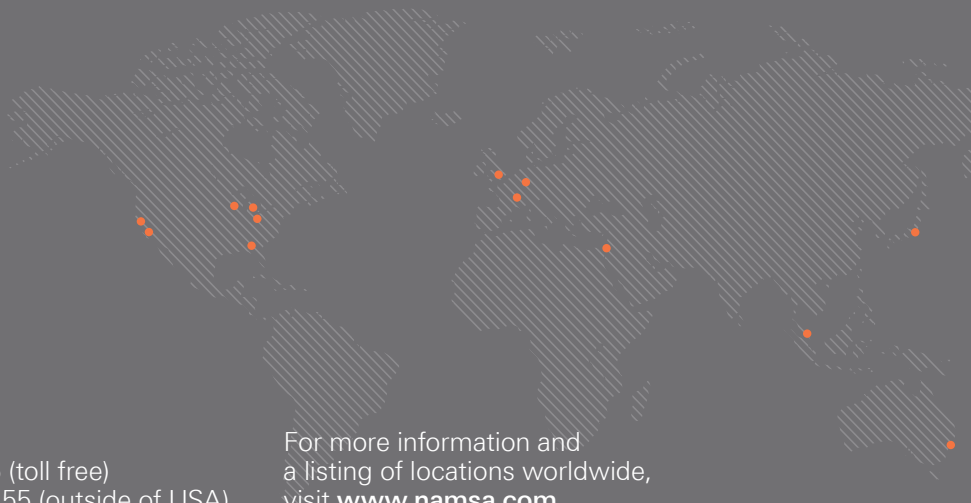
We've been the world's leading medical device research organization for over 40 years.

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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