



2026
PRODUCT
CATALOG

(877) 444-1133

Advancing Healthcare Through Innovation

503B OUTSOURCING FACILITY • INJECTIONS • AND MORE

Orange County Manufacturing Facility

Our 86,000 sq. ft. FDA-registered and inspected aseptic fill-finish manufacturing facility. One of two sterile drug manufacturing sites operated by McGuff Pharmaceuticals in California.

*McGuff Outsourcing Solutions is a
Division of McGuff Pharmaceuticals, Inc.*



The McGuff Family of Companies



54+ Years
Serving Clinicians



24+ Years
Sterile Drug Manufacturing



6,000+ Clinicians
Supported Nationwide



4 Locations
to Serve



Why More Than 6,000 Clinicians Trust McGuff

Trusted by physicians, clinics, and healthcare providers for more than five decades.

For 54 years, McGuff has supported clinicians with dependable medical supplies and pharmaceutical products that enable safe, efficient patient care. Today, more than 6,000 clinicians nationwide rely on McGuff for reliable medications, trusted clinical supplies, and responsive support built on long-term relationships.

Manufacturing Expertise / Quality Products by Design

- ✓ Sterile medications produced within a regulated pharmaceutical manufacturing environment

Complete Clinical Supply Access

- ✓ Over **4,000 clinical products** for physician offices, infusion clinics, and urgent care practices
- ✓ **One account** providing 24/7 access to both sterile medications and clinical supplies

Real Support from Real People

- ✓ **U.S.-based** customer service and pharmacist support

Reliable Supply

- ✓ Structured production planning and **data-driven inventory management**
- ✓ **Reliable two-day delivery** designed to support clinical supply planning

Transparent Business Practices

- ✓ **Clear pricing. Full visibility. No surprises.** Know your total cost before ordering
- ✓ Delivered pricing—**no added shipping charges or hidden fees**
- ✓ **2-Day delivery included in price**
- ✓ Certificates of Analysis, Safety Data Sheets, and product specifications readily available

A Partner Built for Your Long-Term Clinical Success

McGuff is a **privately held, family-owned, veteran-owned** organization dedicated to supporting clinicians and their patients through **reliable products, responsible pricing, and dependable service.**

The Active Pharmaceutical Ingredient **DIFFERENCE**



Federal requirements for 503B outsourcing facilities establish baseline expectations for bulk drug substances APIs. MOS fully complies with these requirements while **voluntarily applying additional standards** modeled after pharmaceutical manufacturing programs commonly associated with FDA New Drug and Abbreviated New Drug Applications.

What 503B Minimum Standards Require vs. McGuff Standards

503B Minimum Requirement	MOS Standard
✓ FDA-registered supplier	✓ FDA-registered supplier ✓ On-site inspections of API suppliers
✓ Certificate of Analysis	✓ Certificate of Analysis ✓ Independent analytical verification
✓ Identity Testing	✓ Identity Testing ✓ Impurity & potency profiling

QUALITY PRINCIPLE

The quality of a sterile drug product cannot exceed the quality of its Active Pharmaceutical Ingredient (API).

Not all APIs are the same. Small variations in API purity, impurity profiles, or manufacturing controls can affect the consistency, stability, and performance of the finished sterile drug product. For this reason, **McGuff Outsourcing Solutions (MOS) voluntarily applies rigorous additional oversight to the sourcing, qualification, and verification of APIs**—extending well beyond baseline requirements for outsourcing facilities.

Quality oversight begins at the source—with direct verification of the API manufacturer.

MOS personnel, or qualified third-party auditors acting on our behalf, conduct recurring risk-based **on-site evaluations of API manufacturers worldwide** to assess conformance with U.S. current Good Manufacturing Practices (cGMP).

These inspections evaluate:

- Quality systems and batch documentation controls
- Impurity monitoring and control programs
- Change control and deviation management procedures
- Environmental and contamination control systems
- Controls designed to support consistent reliable batch-to-batch performance

These inspections confirm that manufacturers operate as represented and that quality systems function in practice—not only on paper.

Analytical Verification Beyond Identity Testing

All incoming APIs are quarantined and released only after approval by the MOS Quality Unit.

In addition to required identity testing, **MOS performs risk-based analytical verification in our in-house microbiology and chemistry laboratories**, which may include:

- HPLC identification and impurity profiling
- Assay or potency verification where appropriate
- Review of specified and unspecified impurities
- Endotoxin evaluation based on product risk

Internal laboratory capability allows MOS to independently verify supplier documentation rather than relying solely on external Certificates of Analysis.

Manufacturing Discipline at the Source

By combining direct cGMP inspection of API manufacturers with expanded analytical verification, **MOS applies pharmaceutical manufacturing discipline at the API level**—strengthening supply chain integrity and supporting the consistent production of reliable sterile medications.



Advanced Aseptic Fill–Finish Technology Used in Pharmaceutical Manufacturing

McGuff's sterile manufacturing facilities utilize advanced pharmaceutical production systems, including the VarioSys® aseptic fill–finish platform from Bausch+Ströbel, one of the world's leading manufacturers of sterile pharmaceutical production equipment.

Operating within a **sealed isolator environment** designed to maintain exceptional sterility assurance, systems of this class perform the complete sterile production sequence—from vial washing and depyrogenation to aseptic filling, stoppering, and capping.

This equipment reflects the pharmaceutical manufacturing technology and sterile processing capabilities within the McGuff organization.

The Advantage of Using McGuff Outsourcing Solutions (MOS)

A 503B Facility Built Inside a Commercial Pharmaceutical Manufacturer

MOS operates as the 503B outsourcing division of McGuff Pharmaceuticals, Inc. (MPI), a commercial pharmaceutical manufacturer with more than two decades of continuous FDA registration and state licensure.

MOS was built within a pharmaceutical manufacturing organization — not as an extension of a compounding pharmacy. MOS was established within an organization built on regulated drug manufacturing, including successful New Drug Applications, human clinical trials, and Abbreviated New Drug Application products. This manufacturing foundation and FDA-regulated experience define how MOS governs quality, risk, and production.

Manufacturing-Level Governance

MOS operates within quality systems developed for commercial pharmaceutical manufacturing, including:

- Independent Quality Unit authority
- Structured change control, deviation management, and CAPA processes
- Extended oversight of Active Pharmaceutical Ingredients
- Validation and qualification of facilities, equipment, utilities, and processes
- Executive oversight shaped by real-world FDA inspection and regulatory experience

These controls are integral to operations, not supplemental.

Proven Infrastructure

MOS functions within facilities and utility systems designed for long-term, regulated pharmaceutical manufacturing, including:

- Established cleanroom environments with extended operating history
- Qualified HVAC, water, and critical utility systems
- Preventive maintenance and environmental monitoring programs built for sustained reliability

Mature infrastructure supports controlled aseptic performance and process consistency.

Operational Discipline

Production planning, batch controls, personnel training, and documentation systems are structured for controlled, repeatable manufacturing.

Why This Matters

All 503B outsourcing facilities operate under the same statutory framework—but how they are built, governed, and operated differs.

MOS delivers sterile medications within a pharmaceutical manufacturing environment defined by regulatory experience, disciplined quality systems, and established infrastructure—supporting consistent product performance and long-term clinical reliability.



Methycobalamin Injection

NDC# 67157-006-30

Strength	5,000 mcg/mL
Size	30 mL Multi-Dose Vial
Expiration Date	9 months from manufacturing date
Storage	20°–25°C (68°–77°F)



Glutathione Injection

NDC# 67157-135-30

Strength	200 mg/mL
Size	30 mL Multi-Dose Vial
Expiration Date	6 months from manufacturing date
Storage	2°–8°C (35.6°–46.4°F)



Procaine HCL Injection

NDC# 67157-005-30

Strength	20 mg/mL
Size	30 mL Multi-Dose Vial
Expiration Date	12 months from manufacturing date
Storage	20°–25°C (68°–77°F)



Lipoic Acid Injection

NDC# 67157-002-15

Strength	40 mg/mL
Size	15 mL Single Dose Vial
Expiration Date	9 months from manufacturing date
Storage	20°–25°C (68°–77°F)



Taurine Injection

NDC# 67157-013-30

Strength	100 mg/mL
Size	30 mL Multi-Dose Vial
Expiration Date	Under Development
Storage	20°–25°C (68°–77°F)



Dexpanthenol Injection

NDC# 67157-014-30

Strength	250 mg/mL
Size	30 mL Multi-Dose Vial
Expiration Date	Under Development
Storage	20°–25°C (68°–77°F)



NAD+ Injection

NDC# TBD

Strength	50 mg/mL
Size	10 mL Single Dose Vial
Expiration Date	Under Development
Storage	2°–8°C (35.6°–46.4°F)



DMPS Injection

NDC# TBD

Strength	50 mg/mL
Size	5 mL Single Dose Vial
Expiration Date	Under Development
Storage	20°–25°C (68°–77°F)



Built for Pharmaceutical Manufacturing— Not Traditional Compounding

Hot Water for Injection generation
and storage systems in operation at
McGuff Pharmaceuticals

BWT
BEST WATER TECHNOLOGY



PSG2500+MS900-4

PUREtec MIXED BED FLÖMAX

Who We Are

Behind every MOS sterile medication is a pharmaceutical manufacturing organization built for regulated drug production, not traditional compounding.

McGuff is a privately-held, family-owned and veteran-owned organization. Ownership continuity and long-term leadership support a governance structure focused on regulatory discipline, operational stability, and sustained investment in pharmaceutical manufacturing infrastructure.

McGuff Outsourcing Solutions (MOS) is an FDA-registered 503B outsourcing facility operating under Section 503B of the Federal Food, Drug, and Cosmetic Act.

MOS operates as a division of McGuff Pharmaceuticals, Inc. (MPI), a commercial pharmaceutical manufacturer established in 2002 with continuous FDA registration and state licensure. MPI has longstanding experience operating within FDA-regulated drug manufacturing environments.

MOS compounds sterile drug products in accordance with current good manufacturing practice (cGMP) requirements applicable to outsourcing facilities and operates under routine FDA and California Board of Pharmacy inspection and oversight. Products are prepared for healthcare facilities and licensed practitioners to support office-based and clinical care.

Who We Serve

McGuff supports a wide range of healthcare providers through MOS sterile medications and McGuff Medical clinical supplies—providing consistent specialty injections and essential medical products for patient care.



Physician Offices



Hydration & Wellness Clinics



Urgent Care Centers



Ambulatory Surgery Centers



Hospitals & Health Systems

McGuff Outsourcing Solutions...

Built for Long-Term Clinical Partnerships



YOUR MOS ACCOUNT IN MINUTES

Two Simple Ways to Get Started

Speak With Our Team

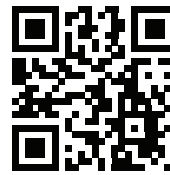
We would be happy to assist you personally with account setup and answer any questions.

 **1 (877) 444-1133**

Speak directly with our U.S.-based team

Open an Account Online

Visit: mcguff503b.com/register



Complete a short application and begin ordering once approved.

What You Gain Immediately

Once your account is active, you will have access to:

-  Secure online ordering
-  Order history for quick reordering
-  Automatic refill option
-  Product documentation and specifications

24/7 Account Access. Order anytime, from anywhere.

Real Support - From Real People - When You Need It

Our **U.S.-based customer service and pharmacist teams** are available to support your practice.

Open your account today...
And enjoy your benefits



McGuff Medical Products (MCI) supplies a comprehensive range of pharmaceuticals, IV solutions, and clinical supplies used in physician offices, clinics, and infusion practices—**supporting everyday patient care with reliable, readily available products and transparent, predictable pricing.**



Pharmaceuticals



IV Solutions



IV Sets and Access Devices



Hypodermic Supplies



Clinical Supplies



Patient Treatment Supplies



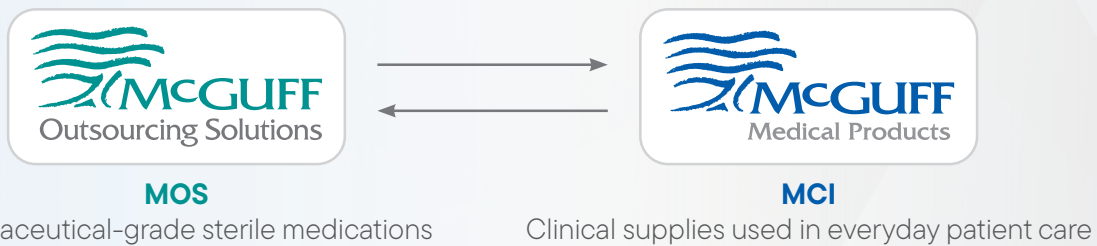
Come visit us for a tour!

We are ½ way between Disneyland and the Pacific Ocean.

WORKING TOGETHER TO SIMPLIFY YOUR PRACTICE

Two Specialized Platforms. One Coordinated Experience.

MOS and McGuff Medical Products (MCI) provide seamless, one-click access to sterile medications and clinical supplies used to administer them.



Coordinated Access—No Extra Steps

- Single sign-on access across both platforms
- Move between MOS and MCI with a single click
- Account information, order history, and ordering tools available immediately

Designed for Clinical Efficiency

- Pharmaceutical-grade sterile medications
- Clinical supplies used alongside injectable and infusion therapies
- A streamlined ordering experience across both platforms

Delivered Pricing—No Surprises

Delivered pricing across both MOS and MCI.

- No separate shipping charges
- No hidden fees
- Transparent, predictable pricing

Specialized Fulfillment—Designed for Clinical Reliability

Orders are fulfilled from dedicated McGuff facilities to ensure proper handling, regulatory compliance, and dependable delivery.

- MOS sterile medications ship via 2-Day delivery from sterile manufacturing facilities
- MCI clinical supplies ship via 3-Day delivery from distribution centers

Each order is processed and billed separately in accordance with regulatory requirements.



McGuff Outsourcing Solutions – Sterile 503B Medications Launching 2026 – Establish Your Account Today

Supporting clinicians with reliable sterile medications and trusted clinical supplies— **backed by 54+ years of clinical supply experience and 24+ years of pharmaceutical manufacturing expertise**

Scan below to establish your account today. Be ready to order at launch.

