ProMed Delivers Proven Expertise in Contract Medical Manufacturing for Medical Device and Pharma Companies

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ProMed, a leading contract manufacturer specializing in medical-grade silicone and plastic components, provides comprehensive support for medical device, pharmaceutical, and combination drug-device manufacturers. With more than three decades of experience, ProMed delivers reliable, regulatory-compliant contract medical manufacturing across both prototyping and commercial production.

The company?s services span the full spectrum of medical silicone molding, including Liquid Silicone Rubber (LSR) and High Consistency Rubber (HCR), micro-molding, insert molding, and multi-component molding. By integrating multiple manufacturing methods within single facilities, ProMed offers manufacturers the ability to address complex design requirements without coordinating multiple vendors. The in-house tooling and prototyping capabilities further streamline development, reducing lead times and enabling efficient scaling from low-volume clinical trials to high-volume commercial production.

Cleanroom production is a core component of ProMed?s operations. Facilities maintain ISO Class 7 cleanroom standards, ensuring tight control over environmental conditions critical to sterility, precision, and product performance. Temperature, humidity, particle counts, and differential pressure are continuously monitored, while HEPA filtration systems and validated cleaning protocols support compliance with regulatory standards. Controlled environments enable precise molding, secondary assembly, and packaging of sensitive medical components, implantable devices, and pharmaceutical products.

Material expertise is integral to the company?s manufacturing processes. ProMed offers a broad range of LSR and HCR materials with durometer values from 10 to 80 Shore A, allowing precise control of component flexibility, sealing, and durability. All materials meet USP Class VI standards and ISO 10993 biological evaluation requirements. Comprehensive traceability ensures consistency across sterilization methods, including gamma, ethylene oxide, and autoclave processes, supporting regulatory compliance for medical and pharmaceutical applications.

Quality management and regulatory oversight form the foundation of ProMed?s operations. The company maintains ISO 13485:2016 certification, ISO 9001:2015 compliance, and FDA registration under 21 CFR Parts 820, 210/211, and Part 4\. ITAR compliance supports defense and security projects, demonstrating control over sensitive manufacturing processes. Quality systems encompass Design History Files, Device Master Records, and process validation documentation (IQ/OQ/PQ), with active corrective and preventive action protocols and supplier quality management.

Advanced metrology and testing capabilities provide robust verification of part integrity. Computed tomography (CT) scanning offers non-destructive internal inspection to detect hidden voids and cavities, while chromatic white light and optical 2D inspections ensure surface accuracy. Coordinate measuring machines (CMM) verify critical dimensions, while rheometry, electrical testing, and material analysis?including FTIR and UV/VIS spectrometry?confirm material performance. Pharmaceutical components undergo specialized testing such as high-performance liquid chromatography (HPLC), drug elution assessment, and residual solvent analysis to meet stringent regulatory requirements.

ProMed?s integrated approach to contract medical manufacturing and assembly extends beyond molding. The company provides multi-material overmolding, adhesive bonding, plasma surface treatment, metal insert welding, and full subassembly production. Device assembly and primary packaging occur in controlled environments to maintain sterility and support downstream regulatory requirements. Micro-molding and precision assembly techniques enable production of small-scale medical devices, including ophthalmic implants, catheters, and guidewires, while larger components for subcutaneous or intrauterine products are produced with equal attention to quality and compliance.

Scalability is a key consideration in ProMed?s operations. Facilities spanning more than 134,000 square feet across multiple U.S. locations, including Puerto Rico, accommodate a wide range of production volumes. Single-cavity molds for clinical trial runs can transition seamlessly into high-volume, multi-cavity production for commercial launches. Geographic diversification reduces supply chain risk and allows closer collaboration with development teams during prototyping, testing, and regulatory review.

ProMed supports a variety of highly regulated sectors, including medical device, pharmaceutical, combination drug-device, defense, and security applications. The company?s experience with complex material interactions, stringent tolerances, and regulatory requirements enables manufacturers to meet development milestones while ensuring products are safe, reliable, and compliant. Documentation packages, process validation records, and sterilization compatibility information are provided to support FDA, EU MDR, and other international regulatory submissions.

Through a combination of technical expertise, integrated capabilities, and regulatory experience, ProMed

positions itself as a partner capable of bridging the gap between development and full-scale production for complex medical and pharmaceutical components. By centralizing manufacturing, tooling, assembly, and quality oversight within a single provider, the company reduces risk, simplifies communication, and helps manufacturers achieve predictable, compliant outcomes for their products.

About ProMed:

Since 1989, ProMed has been recognized as a leading Contract Manufacturer of complex, intricately designed molded silicone and plastic components and assemblies for highly regulated industries. ProMed?s expertise extends across applications for short-term and long-term implantable devices, single-use devices, drug-releasing combination devices, and specialized materials and processes for defense applications. They collaboratively work with our customers from prototype through production, providing over 30 years of experience related to design for manufacturability, material selection, tool and fixture design, process development, manufacturing, and other value-added services that result in cost-effective solutions with superior quality.

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