We provide proof of concept, R&D, clinical and commercial manufacturing that includes liquid-filled capsules, band/sealing technologies, powder and over-encapsulated capsules, topical formulations, and clinical and blister packaging, manufactured in our purpose-built facility including state-of-the-art ISO 7 and ISO 8 cleanrooms. We have a DEA license for controlled substances, a full analytical laboratory, ICH stability chambers, cGMP warehouse, and shipping capabilities to help you in every aspect of your project.

Manufacturing Services Offering

Product Development and Manufacturing Capabilities
• Formulation and development
• Process optimization
• GMP clinical supply manufacturing (Phases I-IV)
• Scale-up and engineering batch manufacturing
• Validation batch manufacturing
• Commercial batch manufacturing

Controlled Substance Manufacturing Capabilities
• DEA Manufacturing License (Schedules I-V)

Additional Client Support Services
Facility expansion capabilities, including dedicated space and equipment, as required to meet project demands.
• Man-in-plant
• Perform supplier audits

Dosage Type and Process Capabilities
• Liquid-filled hard shell capsules
• Capsule banding
• Particle size reduction (wet milling/nanomilling)
• Powder blending
• Powder-filled capsules
• Over-encapsulation
• Injectable vial filling (pre-sterilized)
• Solutions and suspensions
• Gels and creams
• Clinical packaging (bottles and blisters)
• Potent product handling
Analytical Services Offering

Development and Validation of Critical Methodologies
• Cleaning methods for the detection of API on manufacturing equipment
• API methods for assay/related substance
• Finished dosage products (assay/degradation, dissolution)

Stability Testing
• ICH environment stability chambers

Controlled Substance Testing
• DEA analytical license (Schedules I-V)

Drug Product Release Testing
• High Performance Liquid Chromatography (HPLC) and Ultra Performance Liquid Chromatography (UPLC)
• Dissolution and disintegration
• Moisture analysis (Gravimetric and Karl Fischer [KF] Titratron)
• Spectroscopy (Ultraviolet/Visible [UV/VIS] and Infrared [FTIR])
• Total Organic Carbon (TOC)
• Viscosity
• Particle size analysis
  - Malvern
  - Horiba
  - AccuSizer (USP<788>)

Quality Assurance Services

Quality Systems
• Product release
• Standard Operating Procedures (SOPs)
• Equipment and facility qualification documentation
• GMP audits
• Regulatory inspections

Data Management Systems
Agilent enterprise content management (OpenLab ECM) and chromatography data system (CDS)
• Secured client portal for 24-hour off-site access to data and documentation