

ISOGEN

Advanced Sterile Processing

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Who We Are

ISOGEN, LLC IS THE FIRST of a new breed on sterile filling contractors. Isogen is dedicated to providing GMP sterile filling for clinical and transitional scale commercial supplies.

Founded by Les Edwards (CEO) and Austin McDonald (COO) in 2007, the phase I Isogen facility, based in Newark, DE comes on line in Q1 2009. Sterile processing is conducted exclusively within barrier isolators in a facility designed and built to meet global regulatory compliance.

Isogen offers European compliant GMP clinical manufacturing for even the smallest batches. Isogen combines the application of Advanced Sterile Processing concepts and "OpenSource™" business practices – Isogen's commitment to complete openness and data sharing with our partners.

Major Markets

ISOGEN IS FOCUSED ON providing contract GMP Sterile Clinical Filling. Our advanced sterile processing facility provides complete segregation, isolation and containment of the manufacturing processes creating a secure multi-product facility, capable of handling a wide range of therapeutic products from monoclonal antibodies and vaccines to small molecules, including potent and BSL2 category products.

With fully integrated pharmaceutical sciences laboratories Isogen can offer an integrated contract filling service from process development, and technology transfer to filling, analytical testing and packaging – we call this Molecule to Market™.

Ultimately Isogen will offer transitional scale contract filling using common advanced sterile processing platforms. Isogen's approach to transitional scale contract filling will enable us to take clients through clinical scale manufacturing to launch and early commercial scale with easy scale up and tech transfer.

Services Offered

- GMP Clinical & Small Scale Commercial Filling:**
- Vials, Syringes, Ampoules, Specialty Containers
 - Lyophilized Products
 - Potent & BSL2 Products

Sterile Process Development, Technology Transfer and Analytical Laboratory Services Including:

- Process Development
- Criteria and Specification Setting

Quality Assurance

- Incoming Materials Testing
- Product Release Testing

Technology Transfer

- Formulation Optimization
- Product Analytical Chemistry
 - Profile Development
 - Characterization
- Cleaning Studies
- Leachables and Extractables Studies
- Stability Studies
- Container Closure Qualification and Testing
- Filling Studies
- Process Optimization
- Disposable Fluid Paths for Product Pathways

Pharmaceutical Engineering Consultancy

- GMP project management, design, procurement and validation

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