

ENZON

PHARMACEUTICALS

Enzon Pharmaceuticals, Inc.
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Vital Statistics

Year Founded: 1981

Key Personnel: Thomas J. Puskar, associate director business development, contract manufacturing; Jan Spitael, vice president operations; Chris Dreyer, vice president quality operations.

Who We Are

ENZON PHARMACEUTICALS, INC. is a biopharmaceutical company dedicated to the development and commercialization of therapeutics to treat patients with cancer and adjacent diseases including Abelcet[®], Oncaspar[®], Adagen[®] and Depocyt[®].

Enzon also provides contract manufacturing of liquid parenteral products. Our Indianapolis manufacturing facility was commissioned in 1997. The facility received FDA and NCA approvals in early 1997. Our facility is situated on more than 26 acres of prime industrial space. The plant offers the convenience of a central location in the heart of Midwestern pharmaceutical belt which is a short plane ride from virtually anywhere in the continental United States.

Major Markets

ENZON PHARMACEUTICALS provides manufacturing, formulation, fill and finish and packaging of parenteral products, specializing in complex formulations including liposomal products. High-speed vial filling and packaging lines are complemented by dual chamber vial filling and packaging capabilities. From clinical to commercial products we provide the services you require. Our relevant experience in complex manufacturing, including PEGylation of proteins, chromatography, diafiltration and formulation development and scale up ensures we can apply a wealth of expertise to address challenging projects.

Services Offered

Manufacturing

Our specialized processes include the latest technologies:

- Liposomal and Complex Manufacturing
- Extrusion techniques
- PEGylation of proteins
- Chromatography
- Diafiltration
- Sterile filtration
- Formulation to scale up
- Small volume parenterals
- Dual chamber vial filling
- High speed vial filling
- Integrated capping

- Large scale aseptic bulk manufacturing
- Small scale bulk manufacturing
- Integrated vial washing/sterilization/fill

Analytical Quality Control

Enzon maintains fully equipped analytical chemistry laboratories for the analysis and testing of all incoming raw materials, in-process testing throughout the formulation and manufacturing processes and final product testing. Equipment and techniques include:

- HPLC
- GC
- Thin Layer Chromatography
- Laser Diffraction Particle Size Analysis
- FT-IR
- UV/Visual Spectrophotometry
- Full ICH stability studies

Microbiology Laboratories

Using the latest in isolator technology, our fully equipped microbiology laboratory conducts all sterility and endotoxin testing including:

- Bioburden
- Sterility
- Endotoxin
- Environmental monitoring



Validation Services

Enzon maintains a dedicated validation staff for routine validation activities as well as installation and qualification of client supplied equipment and processes.

Our analytical laboratories support our internal validation efforts and will develop and validate methods specific for your active pharmaceutical ingredients, excipients or stabilizers.

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