Aseptic Fill/Finish

Waisman Biomanufacturing offers Aseptic Fill manufacturing services to meet your project needs and budget. Waisman Biomanufacturing operates an Aseptic Technologies Crystal SL1 robotic fill line. Processes have been established for aseptic fill/finish in industry-standard vial sizes of liquid formulations for parenteral administration.

Waisman Services
- ISO 2R, ISO 6R, ISO 10R Type I borosilicate glass vials
- Up to 2,000 dose batch sizes; custom fill volumes
- Multiple options for cap colors
- Custom, client-approved labeling
- Prior media fill and container closure integrity studies requalified annually
- Custom, client-specific media fills available by request

CGMP Manufacturing and Testing
- Robotic fill line housed inside a barrier isolator for added sterility assurance and VHP sterilization to reduce risk of cross-contamination
- 100% visual inspection according to USP <790>
- Standard QC including sterility, endotoxins, fill volume, and particulates testing
- Product-specific QC methods can be discussed

Quality and Regulatory
- QA-audited Certificate of Analysis and batch records
- Full-support for IND filing including manufacturing summaries, CMC write-up, and letter of authorization to cross-reference Facility Master File

Waisman Biomanufacturing has over 20 years experience manufacturing hundreds of clinical grade products and has earned a reputation as a strategic partner for cost effective and timely delivery. We strive to meet these high standards with each manufacturing campaign or development program.

For More Information:
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Additional Areas of Expertise Include:
- Plasmid DNA
- Bacterial & Mammalian Protein Production
- Viral Vaccines and Gene Therapy Vectors
- Live Bacterial Therapeutics
- Cell Therapeutics

Cost-estimates available upon request!