

# Oso BIO™

an injectables cmo



Uniquely  
qualified to  
meet your  
injectable  
manufacturing  
needs.

# OsoBio delivers the sterile contract manufacturing and drug development services you require— regardless of the scale or complexity of your sterile injectable.

That's because of OsoBio's unique combination of operational size and broad spectrum of capabilities—including potent compounds. OsoBio's name may be new, but our experience is deep and familiar. For close to three decades, our professional staff and technologically advanced manufacturing facilities have handled almost every category\* of biological or pharmaceutical product from clinical to commercial scale. Today, with a renewed commitment to customer service and a solid foundation for growth, OsoBio is poised to exceed your expectations on every level.

*\*does not include beta-lactams or vaccines derived from live organisms*

## Our facilities offer flexibility and capacity.

As a mid-sized manufacturing facility, OsoBio offers flexibility in meeting a range of unique product demands for sterile liquid, suspension and lyophilized formulations—including clinical to commercial batch sizes and complex potent compounds. With the capability of providing round-the-clock production services, OsoBio is committed to meeting your timeline.

### With approximately 215,000 square feet, our facilities include:

Two Compounding / Formulation areas (4 suites)	Approximately 1,230 square feet of lyophilization capacity (Lyos: 410, 410, 300, 108 square feet)
Three Grade A aseptic filling suites	
2 cc to 100 cc vial filling	130,000 square feet warehouse space
Two TL 8 head filling machines (continuous glass supply)	2 – 8° C Cold Storage (7,000 square feet)
A TL 4 head filling machine (batched glass supply)	10,000 square feet Ambient Storage
Three vial labeling and packaging lines	-20° C Storage

### In addition, you'll find the following inspection, labeling and packaging equipment:

Inspection: Two Pace + Two Seidenater + 100% Inspection
Labeling machines: Four (2 Weiler + CCL + Newman)
Cartoners: Two Bosch



## Why Choose OsoBio?

### OsoBio possesses attributes that work for you:

- Wide range of sterile filling capabilities
- Strong compliance record
- Experienced, veteran work force
- Flexibility to meet size, scale and complexity
- Customer-focused

## Comprehensive Product Capabilities

OsoBio has demonstrated ability to support clinical (Phase I - III) and commercial scale manufacturing of virtually any category of biological or pharmaceutical product including potent compounds and DEA scheduled substances.

- Fungicides
- Vaccines
- Infertility
- Ophthalmic
- Oncology
- Cardiovascular

## Commitment to Quality

OsoBio has an impressive track record of cGMP compliance and a strong inspection history. Our intensive quality assurance support and project management methodology are second-to-none—assuring you of ongoing, thorough communication and strict attention to timelines and budgets.

## Excellent Compliance History

### OsoBio has received the approval of the following agencies:

- Australia
- Canadian Authorities
- CBER
- CDER
- CVM
- EMA
- FDA
- Gulf Cooperation Council
- IMB
- Mexican Ministry of Health
- MHRA
- NM Board of Pharmacy





#### **OSO BIOPHARMACEUTICALS MANUFACTURING**

OSO BioPharmaceuticals Manufacturing, LLC is a contract manufacturing organization focused on providing a superior level of service to customers. With an emphasis on cGMP production of injectable pharmaceutical products that require special or complex handling, OsoBio understands that attention to detail and service levels are a priority for its clients.

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