

# Plasmid DNA



## cGMP Injectable, cGMP Ex Vivo, and Bioprocess Grades

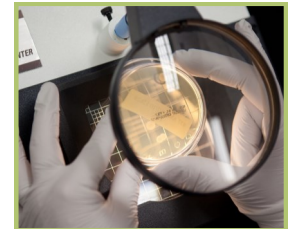
**Waisman Biomanufacturing now offers three grades of plasmid DNA to meet your project needs and budget.**

Waisman Biomanufacturing is successful in manufacturing challenging plasmids and working closely with clients to tailor project specifications to client needs from initial project planning through final product delivery.

### Waisman Process Advantages Across All Grades

- Animal-free and solvent-free manufacturing process
- Scalable manufacturing process
- Superior QC methods
- Custom formulation by TFF

Cost-estimates  
available upon  
request!



### cGMP Injectable

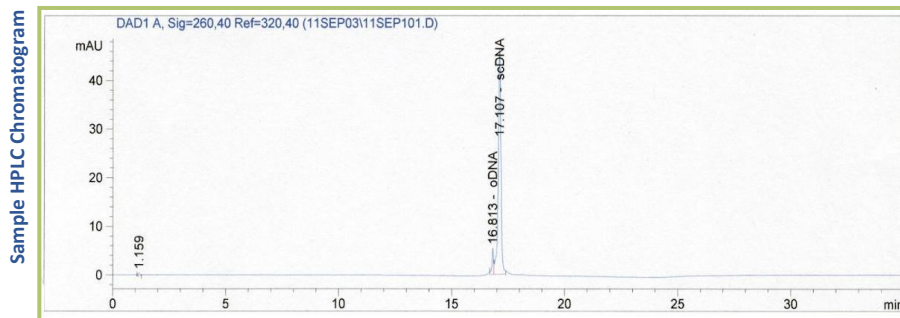
- For use in direct injection gene therapy and vaccine applications
- Scalable manufacturing process includes cGMP documentation and testing
  - Master/Working Cell Bank (MCB/WCB) with sequencing
  - In-house development of custom potency assays
  - Access to plasmid backbones and fermentation methods to enhance process yield for challenging plasmids
- QA-audited Certificate of Analysis and batch records
- Full-support for IND filing including CMC write-up and access to Facility Master File

### cGMP Ex Vivo

- For use in *ex vivo* gene therapy applications (e.g., modified T-Cells) and viral vector transgene projects
- Optional production and testing of a Master Cell Bank (MCB) with sequencing
- Full-support for IND filing including CMC write-up and access to Facility Master File

### Bioprocess Grade

- For use in manufacturing processes (such as reprogramming iPS cells) and viral vector production (non- transgene vectors)
- QA-reviewed Certificate of Analysis



*Since opening its cGMP facility in 2001, Waisman Biomanufacturing has manufactured over 320 clinical grade products and has earned a reputation as a strategic partner for cost effective and timely manufacture of quality products. We strive to meet these high standards with each product campaign.*

### Additional areas of expertise include:

Bacterial & Mammalian Protein Production  
Viral Vectors & Vaccines  
Aseptic Filling  
Cell Therapeutics

### For More Information:

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