
Precision in Every Dose,
Innovation in Every Form
bpi Labs

Pioneers in precision and innovation, dedicated to delivering excellence in every formulation.

BPI Labs is a FDA registered drug manufacturer and 503B outsourcing facility, providing the absolute highest quality medications to fill unmet needs. BPI services hospitals, clinics, and pharmacies throughout the US. As a leading drug manufacturer and 503B, we ensure the highest quality standards in every product we produce.

BPI Labs steadfast commitment to quality, is shaping the future of healthcare, one dose at a time.

503B OUTSOURCING FACILITY
FDA REGISTERED

FDA REGISTERED DRUG MANUFACTURER

cGMP CERTIFIED

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Facility Overview

BPI's is one of the most technologically advanced sterile manufacturing facilities in the country. The facility was designed with cGMP adherence in mind.

- Fully Human-Less Robotic Filling Technology
- Automated Visual Inspection
- Sterile Water for Injection Manufacturing Plant
- 500 Liter Batch Capacity
- One-Time Use, Disposable Pathways
- In-House Analytical Labs
- In-House Microbiological Labs
- In-House R&D
- In-House Validation; IQ, OQ, PQ

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About Us

BPI Labs, LLC, a subsidiary of Belcher Pharmaceuticals, a leading manufacturer of branded and generic injectable medications is proud to be one of a handful of FDA registered drug manufacturer and 503B. BPI's strong quality culture, led by experienced professionals adhering to the strictest GMP regulations, is the cornerstone of our operations. Using cutting-edge isolation and human less robotic manufacturing technologies and all in-house analytical and microbiological testing, we maintain the absolute highest quality sterile injectable production to meet market demands.

- FDA Registered
- 22 Approved Drugs
- Over 50,000 sq ft Sterile Manufacturing
- Over 100 Employees

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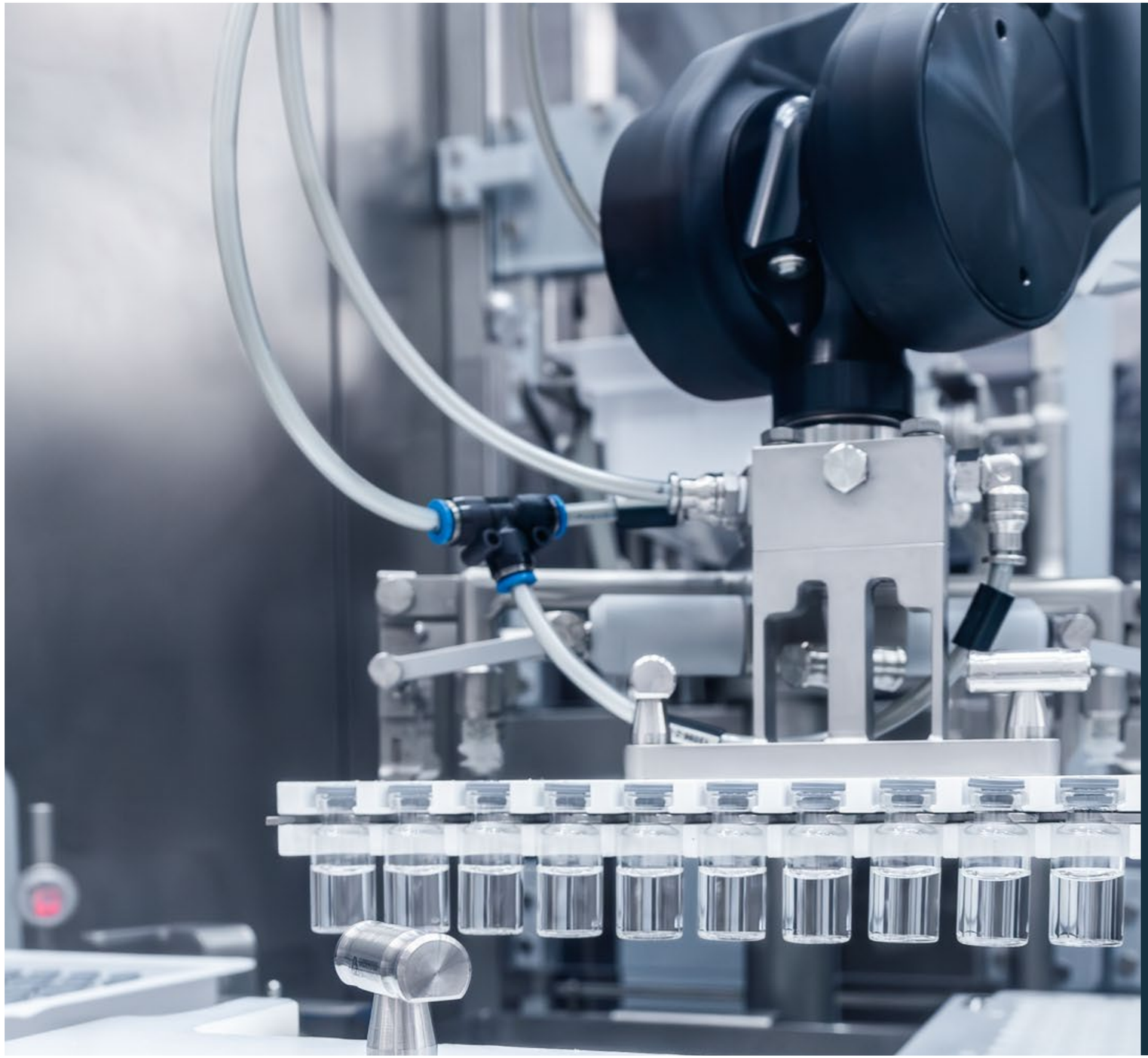
Quality

BPI's 503B drugs are made under the strictest cGMP guidelines, uses the same commercial manufacturing equipment and follows the same quality systems and procedural standards as its other FDA approved drugs. BPI's quality is far beyond reproach and is unequivocally the most reliable compounded drugs on the market. Our most recent FDA audit of our 503B resulted in approvals with no 483 observations.



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Exceptional Testing

Every batch is fully tested in our full chemistry and microbiology labs within the facility to meet more strict, self generated guidelines and parameters. This provides full confidence in producing industry best results for our consumers through strict compliance with cGMP regulations. We do not rely on third-party manufacturers' C of A to assure quality. All ingredients are tested in-house, upon arrival and must meet our strict standards and methods developed with our in-house QC chemistry lab and microbiology labs.

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Unparalleled Safety Standards

BPI Labs only uses DMF active ingredients along with validated inactive ingredients to assure the purest materials are incorporated.

Robotic Automation

BPI Labs proudly adopts robotic technology and system into sterile pharmaceutical manufacturing and testing process, making its products unmatched in the generic injectable industry.

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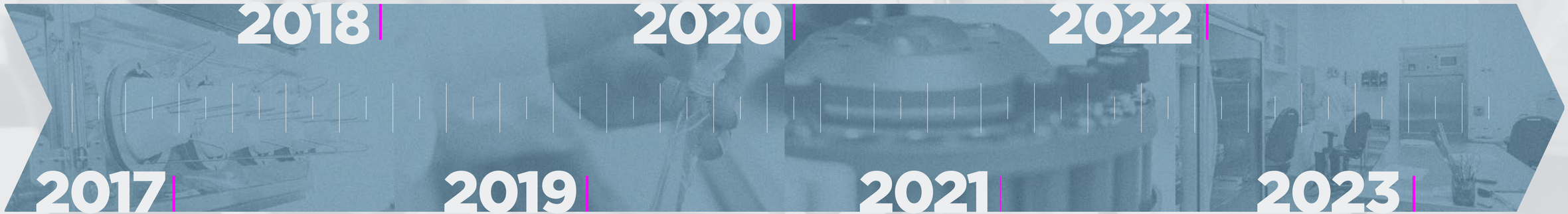
Our Journey



2017 — New Facility Concepts

2018 — Facility Construction Completed

2019 — Validation and cGMP Manufacturing Activities

2020 — NDA Filing

2021 — FDA, 503B and State Authorities Audit

2022 — 1st NDA Approval

2023 — 10 Products Commercially Launched

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Capacities

Batch sizes are 40,000 units and current production capacity is in excess of 100,000 vials a week. Additional expansion is underway, which will increase capacities in excess of 1 million vials per month.

Our Difference

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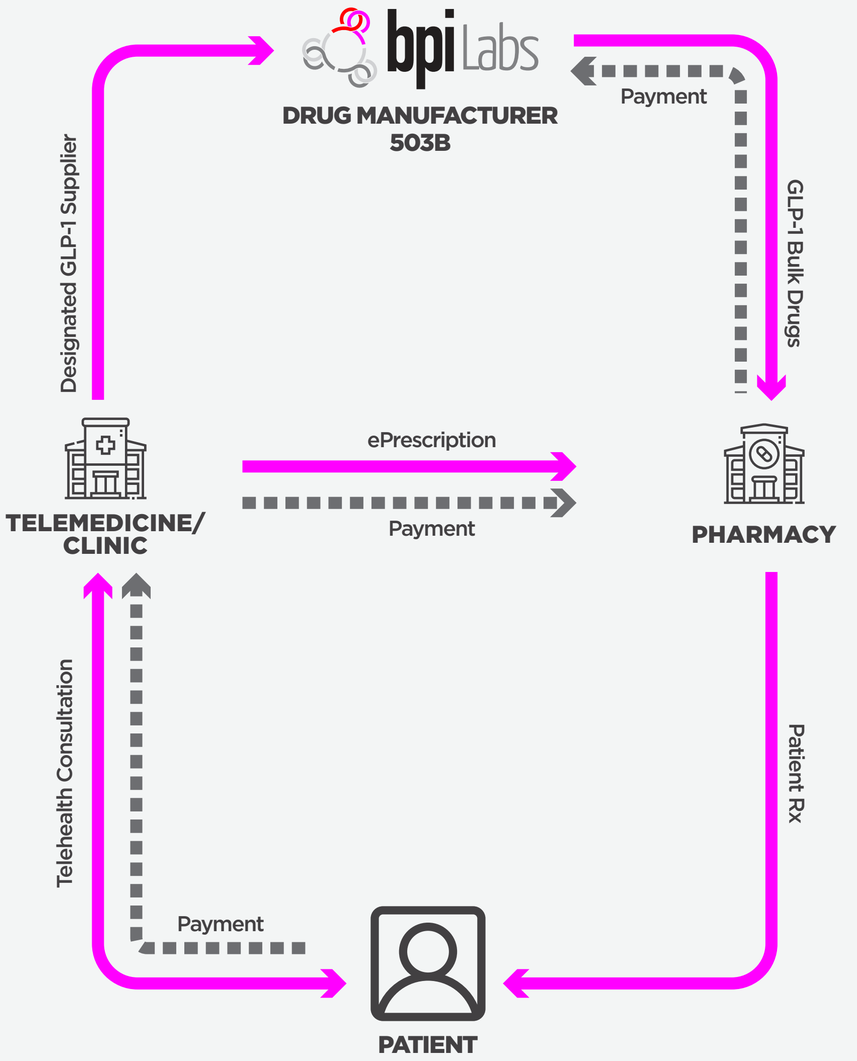
	503A (Compound Pharmacy)	**503B** (Outsourcing Facility)	**BPI Labs** (503B + FDA Drug Manufacturer)
Regulatory Agency	State (State Board of Pharmacy)	Federal (FDA) and State (SBOP)	Federal (FDA) and State (SBOP)
Regulations	USP <795>, <797>, <800>, SBOP	FDA 21 CFR Part 210 and 211 (cGMP)	FDA 21 CFR Part 210 and 211 (cGMP)
Distribution	Patient Specific Only	May or may not be. Can be sold to pharmacies or Office Use	May or may not be. Can be sold to pharmacies or Office Use
Batch Size	250 units	Limited; usually up to 25 liters	Unlimited; up to 500 liters
Raw Material	Need C of A	Require C of A and Manufacture with FDA registration	Only use DMF Material, validate, qualify and create STMs
Quality Systems	Pharmacist review their own work	Quality department in place	Full quality assurance department, independent of operations
Batch Testing	No Analytical Testing	Minimal; Outsourced	Full in process testing; All in house
Stability Dating / Beyond Use Date (BUD)	Literature Only	Minimal; Outsourced	Full stability protocol to establish BUD and expiration dates
Validation (Methods)	Literature	Outsourced; Minimal	Full validation
Environmental Monitoring	Every 6 Months	Per production batch	Exceed cGMP Requirements
Endotoxin	Required; Outsourced	Required; Outsourced	Required; In House
Impurities Testing	Not Required	Not Required	Required; In House
Release Testing; Potency	Not Required	Every batch; Outsourced	Every batch, including In Process; In House
Visual Inspection	Manual	Manual	Fully Automated; High Speed AI Equipment
Sterile Filling	Laminar Flow Hood	Laminar Flow Hood	ISO5 Robotic Aseptic Filling (Commercial)

Process Flow

Since BPI is a 503B, we do not ship patient specific prescriptions, however, we ship our product to pharmacies that cans provide direct to patient fulfillment.

BPI can ship directly to your pharmacy partner of choice or introduce you to a possible provider. BPI works with several large scale mail order pharmacies that are licensed in all 50 states and possess Legit certification. These pharmacies have technology to seamlessly integrate into virtually any platform and have capacities to pick, pack and ship in thousands of prescriptions per day. Order usually ships within 24 – 48 hours, however, most orders ship the same day if received by noon EST.



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GLP-1 Products

- FDA Registered Drug Manufacturer & 503B Outsourcing Facility License
- DMF (Drug Master File) Semaglutide Listed with FDA
- Ready to use Formulation
- Base Form of Semaglutide, Similar to Brand (No Acetate or Sodium)
- No Additives or Adulterants
- 360 Days Beyond Use Date (BUD)
- Up to 45 Days Ambient Temperature Stable

Launching Tirzepatide in Q3 2024

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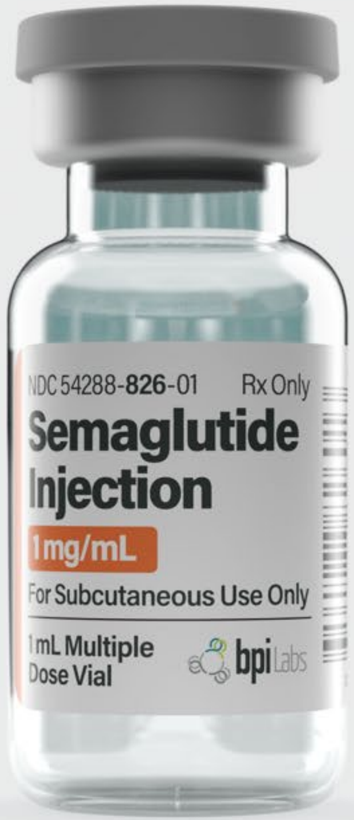
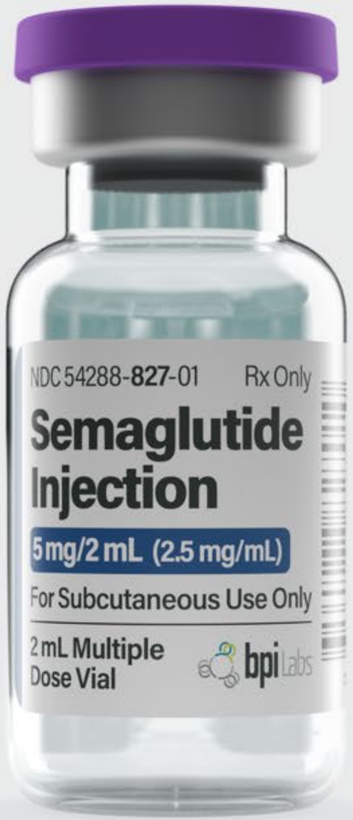
Semaglutide Injection

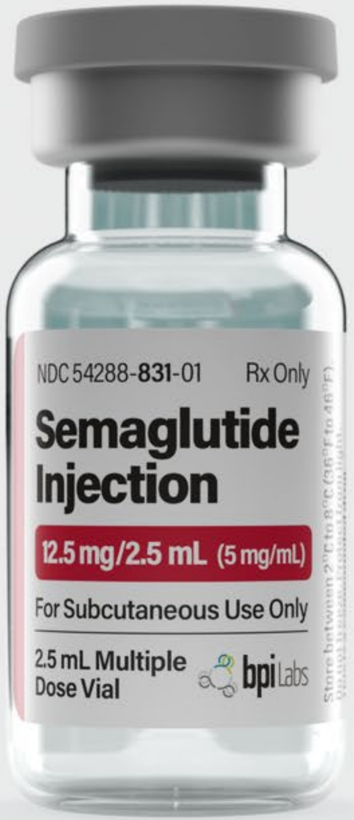


1 mg/mL

2.5 mg/mL

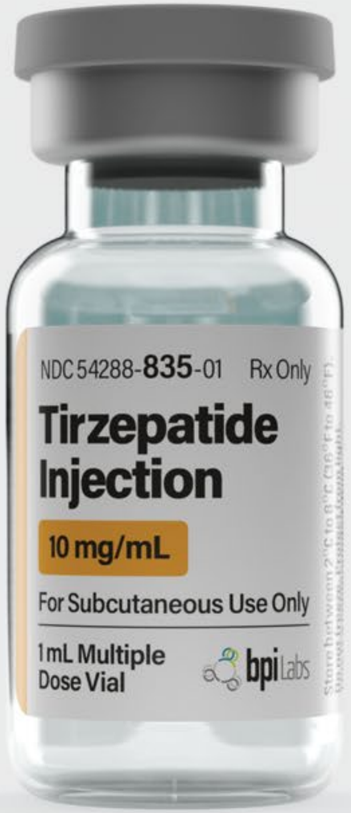


5 mg/2 mL
(2.5 mg/mL)



12.5 mg/2.5 mL
(5 mg/mL)

Tirzepatide Injection



10 mg/mL

30 mg/3 mL
(10 mg/mL)

60 mg/3 mL
(20 mg/mL)

Conclusion

BPI is confident, it can supply your entire GLP-1 requirements from a single source, with the highest service level imaginable. We remove the logistical headaches from the equation, which allows clients to focus on non supply chain related matters. This means, no more working with numerous compounding pharmacies and juggling state licenses and pharmacy capacities.

BPI's Semaglutide is ambient temperature stable for up to 15 days and has a BUD of 12 months in refrigeration, meaning we can ship directly to your patient without the need of a cold pack, saving on costly shipping.

Quality. Reliability. Competitive

bpi Labs

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