



20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.axcelleratepharma.com

Small/Large Molecules CRO Fill/Finish Lyophilization

Executive Summary for Piscataway Plant, NJ

Summary of Capabilities

The Axcellerate facility is a one-stop location for all contract research and manufacturing needs. The facilities' unique offering of multiple technologies as well as its location in New Jersey, USA makes it the perfect contracting location for manufacturing as well as research needs. It caters to production of clinical material and research for up to phase 1 clinical trials involving:

- 1) API products**
- 2) Sterile Filling Operations**
- 3) Microbial fermentation**
- 4) Mammalian cell culture**
- 5) Oligonucleotide synthesis**
- 6) PEGylation**
- 7) Process R&D**
- 8) Peptide synthesis**

With our proven team of experts in each individual field, we can assist you in all your post discovery stages including scale-up and process development as well as running various production or stability runs. The full array of state of the art laboratory and process equipment and know how will accelerate your movement in the drug development cycle. The facility also has access to multiple vivariums in the vicinity and aims to act as a contract development organization, which will support research and development needs in all the above segments.

An Integrated Facility Under One Roof:

- Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

ACCELERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.acceleratepharma.com

Small/Large Molecules CRO Fill/Finish Lyophilization

1) API products

Axcellerate houses two identical Class 1 Div 2 suites with Class 1 Div 1 hoods for kilo-scale API synthesis. Axcellerate's state of the art Buchiglas reactors with associated filtration and drying equipment make these suites an ideal manufacturing engine for small-scale API synthesis. A number of small volume, high value products, like orphan drug API can be manufactured and tested here.

2) Sterile Filling Operations

The API division has a complimentary fill/finish area for injectable products. This area has controlled environment clean rooms from ISO 8 to ISO 5 and is completely validated for cGMP drug product manufacture, up to Phase 1 product. This suite is regularly monitored with routine sampling and fully validated. Multiple cGMP Phase 1 and preclinical toxicology batches have been successfully manufactured in this space.

3) Microbial Fermentation

Axcellerate's uniqueness stems from expertise both in small and large molecules. We boast of a complete set of upstream fermenters and downstream purification equipment for microbial fermentation. Axcellerate offers multiple services in fermentation including scale-up, characterization as well as production up to 150L fermenter scale.

4) Mammalian cell-culture

Axcellerate's expertise encompasses all facets of biological manufacture including mammalian cell culture. With upstream and downstream equipment capable of manufacturing in up to 150 L scale bioreactor, we offer a great opportunity for product development and scale up studies.

An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

ACCELERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.acceleratepharma.com

Small/Large Molecules CRO Fill/Finish Lyophilization

5) PEGylation

Axcellerate's location at 20 Kingsbridge road in Piscataway NJ is an original Enzon facility. Enzon Pharmaceuticals was founded on PEGylation. Axcellerate has retained the original scientists and chemists who developed a number of patents for Enzon in linker technology, permanent and releasable PEG linkers. Axcellerate offers its client formulation development opportunities to take advantage of this expertise in PEGylation.

6) Oligonucleotide Synthesis

As with PEGylation Axcellerate has inherited assets for oligonucleotide synthesis. Axcellerate can provide custom oligonucleotide synthesis and product development research for oligonucleotide products.

7) Process R&D

One of the strongest capabilities of Axcellerate is process R&D and scale up. Axcellerate can offer scale up and custom synthesis of products from milligram to gram scale and further into kilo scale. One of Axcellerate's main advantages is the partnership with one of the biggest CRO's in India, the TCG Lifesciences division. With innovative collaborative approaches we have been able to deliver our clients the best of both worlds with the Indian cost advantage and the American reliability.

8) Peptide Synthesis

Axcellerate specializes in the production and custom synthesis of peptides. With our state of the art Discovery and Liberty microwave peptide synthesizers, we can provide a range of peptide solutions. Axcellerate has the entire array of peptide equipment from synthesizers to amino acid sequencers as well as DNA analyzers and the expertise to give you quality peptide synthesis.

An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

ACCELERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.acceleratepharma.com

Small/Large Molecules CRO/CDMO

Path Forward

Our goal is to provide seamless service from development to commercial manufacturing.

YOU CAN EITHER DEVELOP YOUR PRODUCTS AND FILE YOUR ANDA'S FROM OUR FACILITY or YOU ONLY TECH TRANSFER ONCE, & WE'LL TAKE YOU THROUGH TO COMMERCIAL MANUFACTURING !!!

Commercial Sterile Manufacturing

Please see our Executive Summary for ex-Pfizer facility, acquired.

Summary of Capabilities

- Commercial Manufacturing
- High Speed Vial lines
- High Speed Syringes lines
- Lyophilization
- Separate Cytotoxic building with isolated Filling lines
- Separate Hormones & Steroids building with isolated filling lines
- Separate Antibiotics building for Cephalosporins
- Formulations Development
- Inspections, Packing and Labeling lines
- Fully automated, cGMP Warehouse for Central Distributions Facility for Raw-materials and Finished products.



An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

ACCELERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.acceleratepharma.com

Small/Large Molecules CRO/CDMO

Our core team:

- Ashwin A. Mehta, B.E. (Bio-Pharma), MMS -Director
- Dilip Mehta, M.Eng. Chemical – COO
- Maulik Patel – Process Engineer & Business Operations
- V. Rajasekar, PhD. Bio-technology, Chief of Bio-tech Operations
- IK Patel - Sterile Operations Manager
- Rabih Gabriel, Phd. Organic Chemistry, Chief Process Developer
- Dr. Mrs. Hema Dakoria, M.D., Biotechnology, MS Regulatory
- Dr. A. B. Panja –M.D. AGAF, Medical Adviser

Axcellerate Pharma provides contract manufacturing (CMO) and research

An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

AXCELLERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.axcelleratepharma.com

Small/Large Molecules CRO/CDMO

services (CRO) for the biopharmaceutical Industry and is conveniently located in Piscataway, NJ. Axcellerate Pharma deploys a unique combination of assets and operational capabilities to provide high quality CMO and CRO services. It is ideally positioned to accommodate drug product development activities as well as the manufacture of early cGMP clinical supplies of sterile drug product for both large and small molecules. If your company should require next step CMO/CRO services beyond your current capabilities **please contact us at 732.853.8866**. We encourage you to take a tour of the Axcellerate Pharma facility and experience our capabilities.

Axcellerate's capabilities include a full complement of organic synthesis, analytical methods development and biological services. In addition, Axcellerate Pharma has dedicated process areas for biologics development, chemical development and aseptic manufacturing of drug product including lyophilization. These multifunctional areas accommodate the following pharmaceutical processing capabilities, equipment and systems.

- Separate microbial fermentation and mammalian cell culture suites, ideally suited for biologics development and scale up to 150 liter capacity. (5, 12, 50 liters, downstream purification area, CIP/SIP available).
- cGMP clean room, ideally suited for preclinical and phase 1 drug product manufacturing (certified ISO8, ISO7 and ISO5 controlled environments)
- cGMP lyophilization capability as well as lyophilization cycle development
- Two multipurpose process areas with Howorth walk-in fume hoods with Hazardous Area Classification (internal = Class I Div I CD, T3 and external = Class I Div II CD, T3) along with Buchi Reactor and Filter Dryer
- Clean steam autoclave and depyrogenation systems
- Automatic Flexicon filler for sterile filling operations accommodating a wide range of vial sizes

An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*

ACCELERATE

PHARMA LLC

20 Kingsbridge Road, Piscataway, NJ 08854 Phone: 732.853.8866

www.acceleratepharma.com

Small/Large Molecules CRO/CDMO

- Fully automated Bosch filling lines with production capacities of upto 600 vials and syringes per minute.
- Organic chemistry labs, Analytical Labs and Biological labs equipped with BSC class II/TypeA/B3 (Biosafety level 2)
- Oligonucleotide synthesis

An Integrated Facility Under One Roof:

- *Small & Large Molecules CRO/CDMO • Sterile Filling & Lyophilization*
- *Complete Biotech Plant Processing, Mammalian Cell Culture & Microbial Fermentation*