AXCELLERATE

A Genericspecialties.com Company

PHARMA LLC

AXCELLERATE PHARMA LLC

# Focus

- Provide contract manufacturing and research services for New Drugs, Generics and Biologics.
- Deploy its unique combination of assets and operational capabilities to provide high quality CMO and CRO services
  - Research & Development Services
  - Early clinical supply cGMP manufacturing of NCE, API and drug product for both large and small molecules.
- Engineering, Quality, R&D and Manufacturing teams will provide regulatory compliant and innovative solutions for customer product needs.

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# Capabilities of the Piscataway, NJ facility

## Small molecule development and synthesis

- NCE, API, chemical intermediates synthesis
- Oligonucleotide synthesis and purification

## Biologics development and manufacturing

- Mammalian cell culture suite (150 L)
- Microbial fermentation suite (150 L)
- Down stream purification

## cGMP aseptic drug product manufacturing

- ISO 5,7,8 controlled environments
- Sterile filling (Flexicon filler)
- Depyrogenation, terminal sterilization
- Lyophilization (FTS)

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# Capabilities

## Scaled-up Cell Culture Upstream & Downstream Production

- **3 x10,000 liters, Production Bioreactors**
- Harvest
- Downstream Processes with Ultrafiltration/Di-filtration and Chromatography

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# Capabilities

## Analytical and microbiological laboratories

- Discovery and cGMP analytical support
- Analytical methods development

## Supportive Systems

- Reverse Osmosis DI water system
- Clean steam generation
- pH neutralization system
- Syltherm system
- Walk in Howorth fume hoods Class I Div I (x-proof)
- Walk in cold rooms

## Formulation development

## Lyophilization cycle development

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# Biologics Services and Capabilities

| | |
|---|---|
| Proteins & Peptides | Development of complex proteins and peptides with synthesis, analysis and formulation. Protein synthesizer, amino acid sequencer and analyzer |
| Mammalian Cell Culture | Process development, cell culture of monoclonal antibodies and other products with upstream and downstream capabilities including bioreactors up to 150L, chromatography and UF/DF. |
| Microbial fermentation | Process development, microbial fermentation with upstream and downstream capabilities including fermenters up to 150L, centrifugation and crystallization. |

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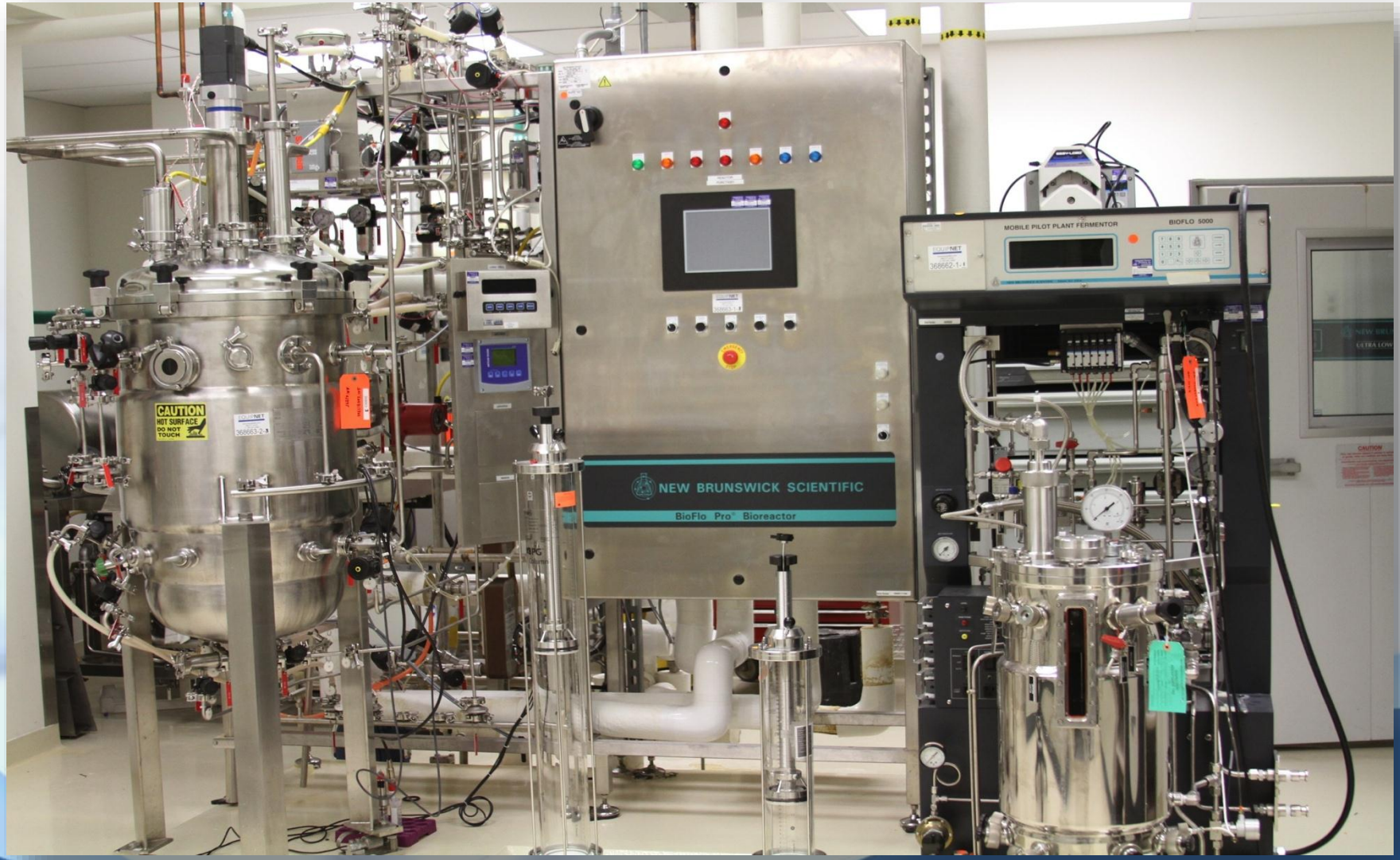
# Cell Culture



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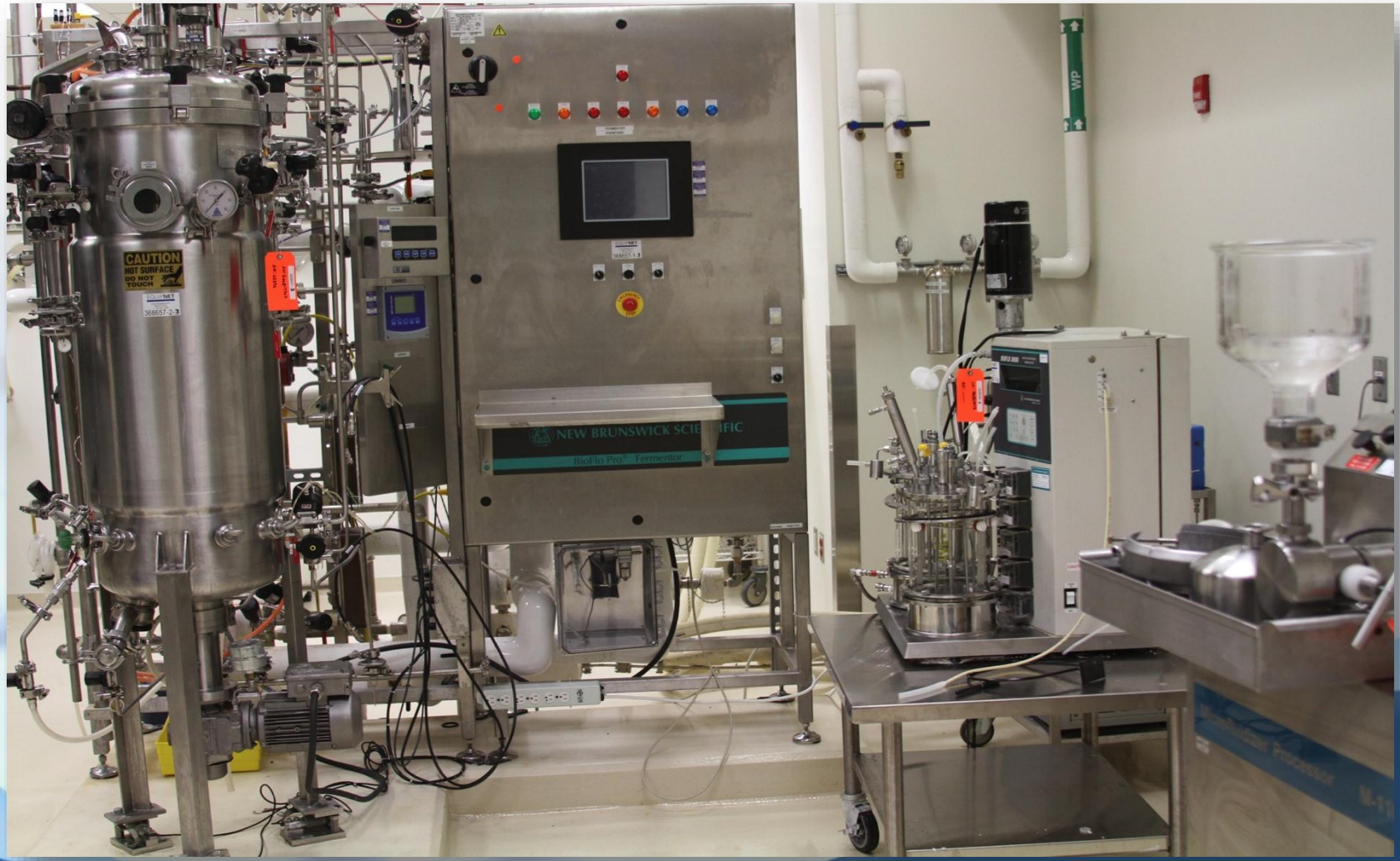
# Microbial Fermentation



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# cGMP Aseptic Processing Capabilities

| | |
|---|---|
| Sterile Filling | cGMP sterile filling operations for early phase clinical material. Flexicon FP50 automatic filler capping and over seal. Certified ISO 5,7,8 controlled areas |
| Terminal Sterilization | Terminal sterilization in BetaStar autoclave for early phase clinical supply. Validated and mapped autoclave ready for use. ISO 5 Environment. |
| Lyophilization | FTS Lyophilizer for preclinical and early phase clinical supplies. Additional R&D lyophilizer for cycle development. |
| Depyrogenation | Despatch depyrogenation oven. |

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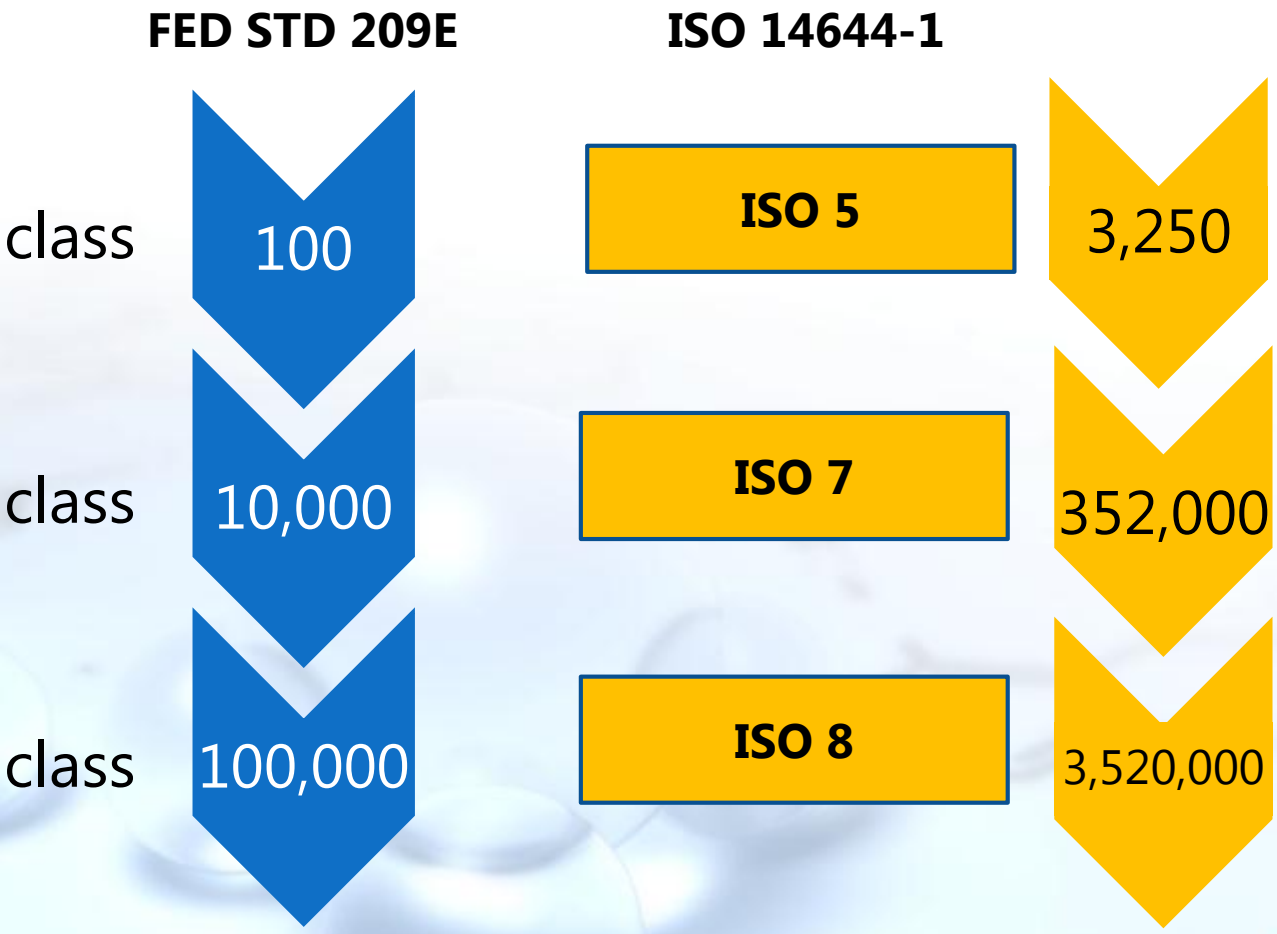
# Cleanroom Controlled Environment Classifications



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# Sterile Filling

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# Terminal Sterilization/Depyrogenation

# Lyophilization/Terminal Sterilization


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# Small Molecule Services and Capabilities

| | |
|---|---|
| Drug Discovery | Discovery candidates based on therapeutic areas, analogs, library synthesis, reference standards. |
| Process R&D/Scale-up | Develop efficient scalable processes<br>Chemical reactors from 1L up to 30L |
| NCE, API and chemical intermediate Manufacturing | API and intermediates manufacturing suite with Buchiglas 60L reactors, filter dryer in an explosion proof environment. |

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# Process R&D

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# Chemical Synthesis

## Buchiglas Reactor (s) 60 L (XP Environment)

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# Rotary Evaporator

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# High Containment and Filter Dryer Systems

**XP Environment**

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# Analytical and Formulation Development

| | |
|---|---|
| Discovery and cGMP Analytical Support | Axcellerate offers complete Analytical Support for release, in-process testing of cGMP clinical material and support for PR&D and custom synthesis divisions. |
| Methods Development | Development of analytical methods for drug substance and drug product. Analytical Methods qualification and validation. |
| Formulation Development | Optimization of dosage form delivery. Liposomal formulation, PEGylation, Microspehere encapsulation |

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# Analytical Laboratories

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# Management Team

**Ashwin A. Mehta - Director**

An accomplished professional. A seasoned business executive with a world view of business.

A bold, dynamic, creative, visionary, with real entrepreneurial spirit, driven by the need to make a big impact, founder and leader of a multi-facilities, specialty company, with a Global Footprint.

Big picture, long-term forward thinker with deep scientific and business insight. Able to think way outside the box, adept in leading, inspiring, coaching, developing others to challenge current thinking and change the status quo with big questions, bold entrepreneurial ideas and solutions.

Specialist in acquisitions of valued assets and companies, following the M&A route to acquire businesses, facilities and assets.

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# Management Team

**Dilip Mehta- COO**

As a co-founder of Axcellerate, Dilip has led many of the firm's projects, which have shaped the direction and quality of the work at Axcellerate.

Dilip has over 25 years of process engineering experience serving the Nano-Technology, Biopharmaceutical, Pharmaceutical, Chemical, Specialty Chemical and Polymer industries.

His experience encompasses all phases of project execution and is rightly so COO of Axcellerate.

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# Management Team

## George Diamantidis- Vice President

## Head of Regulatory Affairs & Quality Management

George brings more than 25 years of diversified

pharmaceutical and biotechnology experience to his position. As the VP and head of Regulatory Affairs, George plays a multi-specialty role in the RA, Advisory team building, working with R&D teams and taking care of the technical packages from CMO clients. George is a core member of the inner team running the business and acts as the Regulatory and technical adviser to the CEO.

George is leading, providing strategic regulatory guidance and delivering the global regulatory strategy for facilities development, registration, building and maintaining a credible relationship with regulatory authorities with effective written and verbal communication, and ensuring functional units comply with regulatory requirements and good regulatory practices.

George earned his BS from Temple University, M.Sc. in Pharmacology from LIU College of Pharmacy, M.Sc. – PhD in Medicinal Chemistry from Seton Hall University, and Executive MBA from Fairleigh Dickinson University.

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# Management Team

## Joseph Lobman- Director, Quality Assurance

Joe brings over 30 years of diversified pharmaceutical and biotechnology experience to his position. As the Director of Quality Assurance, Joe is responsible for ensuring compliance with FDA (and other) regulations for Validation, Operations, Quality Control, Product Release, Document Control, Auditing and general cGMP.

Prior to joining Axcellerate Pharma; Joe has worked in a number of management roles at Bristol-Myers Squibb, Immunomedics, and Enzon Pharmaceuticals.

Joe received Bachelor of Science degrees from Trenton State College; MBA from Fairleigh Dickinson University; and MS from Rutgers University.

# Contact

## Corporate Headquarters

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