



ACCELERATE

A Genericspecialties.com Company

PHARMA LLC

Corporate

- Established in 2013
- Acquired facilities of:
 - **Enzon Pharmaceuticals- NJ, USA- 2013**
 - **Pfizer- NY, USA- 2016**
- Competencies across the Generics & Biologics, value chain.



Contract Manufacturing

- **Fully scalable formulation facility of 2 million square feet.**
- **Approved by USFDA and EU**
- **Annual Capacity 150 million vial dosages and 150 million PFS's**
- **Formulation and Analytical R&D**
- **Conceptualization to Commercialization**
- **Clientel: Big Pharma, Generic majors, Orphan drug majors, 505(b)(2) majors & Biologics majors.**



Facilities

New York, USA (Ex Pfizer)



- **Commercial Manufacturing**

New Jersey, USA (Ex-Enzon)

**Developmental &
Scale up facility with
in-house Clean
Rooms for a
complete fill finish
operation, for:**

- **New Drugs**
- **Generics**
- **Biologics**



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.

Capabilities

• **Generics**

- ✓ Lyophilization
- ✓ Control Substances
- ✓ Hormones & Steroids
- ✓ Cytotoxic, Oncology
- ✓ Nanotechnology & Microsphere Development

• **Biologics**

- ✓ Mammalian Cell Culture
- ✓ Microbial Fermentation
- ✓ Oligonucleotides
- ✓ PEGylation

• **Sterile Injectable**

- ✓ Vials
- ✓ Syringes
- ✓ Cartridges

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.

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, Microsphere encapsulation

Why Axcellerate

- BA/BE Studies
- Clinical Trials
- R&D

**Contract
Research**

API

- US-FDA, EU
- API Proficiencies

AXCELLERATE
PHARMA LLC

**Contract
Manufacturing**

Formulations

- US-FDA, EU
- World scale capacity

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.

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 the COO of Axcellerate.

Dilip is responsible for the overall functioning of the manufacturing facilities that the company owns and its growth.

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.



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.

Picture Gallery



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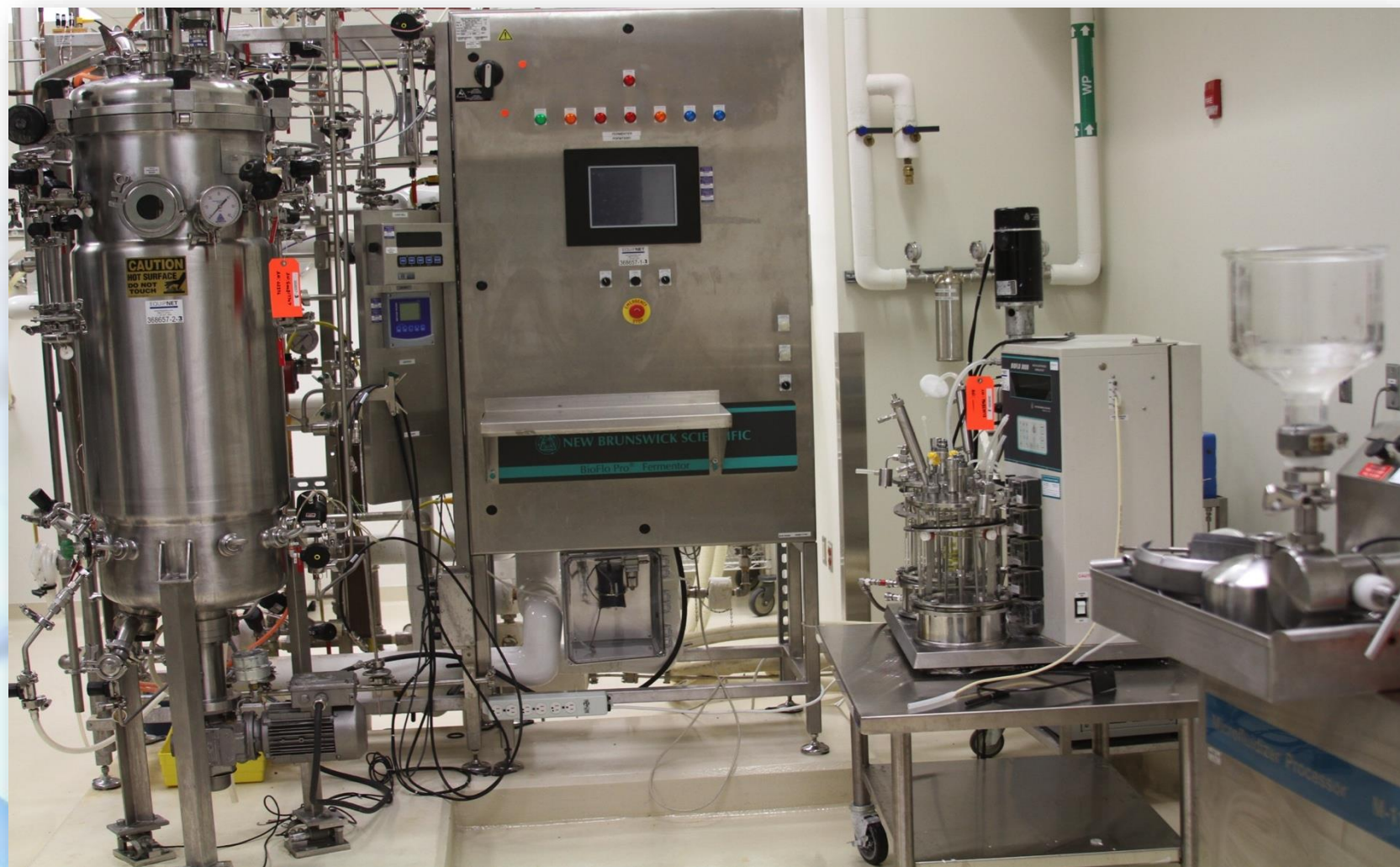
PHARMA LLC



Cell Culture



Microbial Fermentation



Analytical Laboratories



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