



**22,000 SF  
UNIQUE MANUFACTURING  
OPPORTUNITY AVAILABLE**

**4600 WEDGEWOOD BLVD  
FREDERICK, MD**

**FREDERICK  
MANUFACTURING  
FACILITY**

**CBRE**

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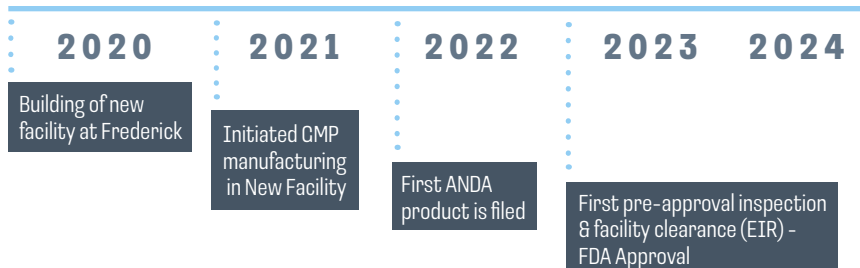
# EXECUTIVE SUMMARY

## State of the Art Equipped Pre-Clinical and Scale Up Commercial Manufacturing Facility Offering Speed to Market, and Mitigating Capital & Development Risk Capital

CBRE is pleased to offer this state-of-the-art manufacturing facility located in Frederick, MD. The 22,000 sq ft facility hosts two GMP manufacturing lines for solids, non-sterile liquids and semisolids, in addition to Formulation and Analytical Laboratories and a warehouse. In addition to standard manufacturing capabilities, the facility is designed to surpass the standards for manufacturing hormones and other potent drugs under containment suites. The facility is DEA licensed developed to handle controlled substances and products (Class II to Class V).

The current owner of the infrastructure can provide a turn-key contract development and manufacturing arrangement who can also welcome collaborations at all stages of the product lifecycle, from concept to commercial. The quality management systems have been evaluated by the FDA, are reliable, and sustainable. Our team members and leadership have the experience, technical knowledge to provide solutions and customer satisfaction.

## PLANT TIMELINE



## FACILITY HIGHLIGHTS



### Flooring

Clean Room anti-skid Epoxy floors



### Lighting

Environmentally sustainable LED light fixtures



### In-Line Monitoring System

- TOC and Conductivity of Purified water, USP
- Temperature, %RH, Pressure differentials of Manufacturing Rooms



### Emergency Power Generation System

Support critical utilities, Lab equipment, and Electronic systems



## KEY EQUIPMENT SNAPSHOT

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High Shear Granulator

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Mechanical sifters

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Extruder and Spheronizer

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Tablet coating machine with interchangeable pans

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Liquid manufacturing vessels

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Isolator ( Glove box )

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Ointment tube filling machine

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Liquid, Gel, piston filling machine

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Tablet counting and filling machine

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Complete equipment list is available upon request.



## TECHNOLOGY OVERVIEW

### Potent Drug Manufacturing

- Dedicated single-pass air handling systems
- Cown-in/ Cown-out Rooms for every manufacturing area
- Separate Entry / Exit Rooms for Men and Material

### Controlled Substance (C II – C IV) handling (DEA Approved)

- Vault & Cage
- Building Security controls: Electronic Card access; Burglar Alarm and security camera system

### Solid Oral Dosage Forms

- Wet Granulation
- Extrusion / Spheronization
- Mega Beads technology
- Drug layering and film Coating

### Semisolid Topical Dosage Forms

- Gel Formulations
- Ointment Formulations
- Creams, Suspensions and Emulsions

## QUALITY OPERATIONS

- Facility is FDA inspected in Feb 2023 and cleared with Establishment Inspection Report
- SOPs & Work Instructions are in place for meeting FDA/EMA/OSHA/DEA/Federal and state regulatory requirements
- Monitor Quality metrics on a daily/weekly basis to ensure all activities are completed on time. Conduct training to New Hires and refresher course on current Good Manufacturing Practices (cGMPs) and Data Integrity (DI) aspects along with Good documentation practices (GDPs).
- QA is the custodian of all master and executed documents required to facilitate Regulatory and customer audits. Perform internal audits periodically to ensure compliance on-site at all times and have audit readiness
- Strong leadership team with 30+ years of proven expertise in innovative and novel formulations

## GROWTH OPPORTUNITIES

### CDMO

- Novel Drug delivery systems:
  - Mega bead technology platform- Specialty formulations
  - Nano-particle technology- For topicals and transdermal

### CMO / Clinical/Commercial Manufacturing

- High value/Low volume products such as Low dose, high potent drugs (OEB 3,4 & 5) in Liquid / Gel / Lotion / Ointment / Mega beads formulations

### Contract Testing

- IVPT/IVRT testing services

## FACILITY WORKFORCE OVERVIEW

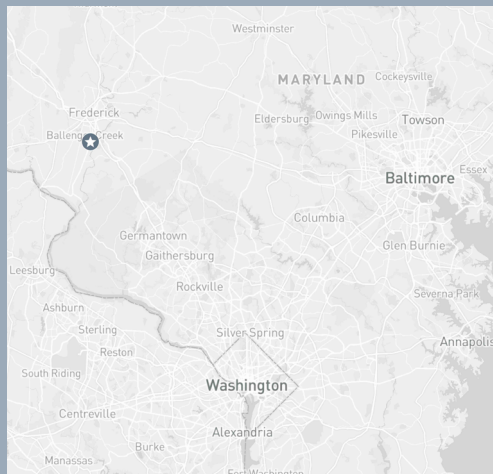
- Seasoned team of scientists
- 3 Quality Assurance
- 5 Quality Control
- 1 Facility Management
- 2 Manufacturing Support
- 1 Supply chain and sourcing
- 1 Chief Scientific Officer
- 2 Support Staff





# PROPERTY OVERVIEW

4600 Wedgewood Blvd, Frederick, MD 21703



**2 MILES**

TO I-270

**4 MILES**

TO I-70

**53 MILES**

TO BWI AIRPORT

**40 MILES**

TO IAD AIRPORT

**Zoning**

L-1

**Size**

22,000 SF

**Parking**

2/1,000

**Ceiling Height**

24'

**Power**

Back up Generator





## SITE INFRASTRUCTURE

Utility	Infrastructure Description
Power	Kohler Deisel standby by generator Model #50RE0ZK Date of Manufacturing: 9/14/2020 Start Date: 11/23/2020
Electrical	800 amps 3 ways / 480 3 phase
Water	Reverse Osmosis De-Ionized Water system with a 350-gallon storage tank able to generate 180 gallons per hour

## FACILITY INFRASTRUCTURE

### Purified Water System, USP

- Closed loop De-ionization and high-quality Purified water system
- Multiple user ports in the Manufacturing and Laboratory area
- 3.0 GPM Capacity

### Compressed Air System

- Two Air compressors ( Lead and Lag system )
- Meeting pharmaceutical gas quality standards

### HVAC Systems

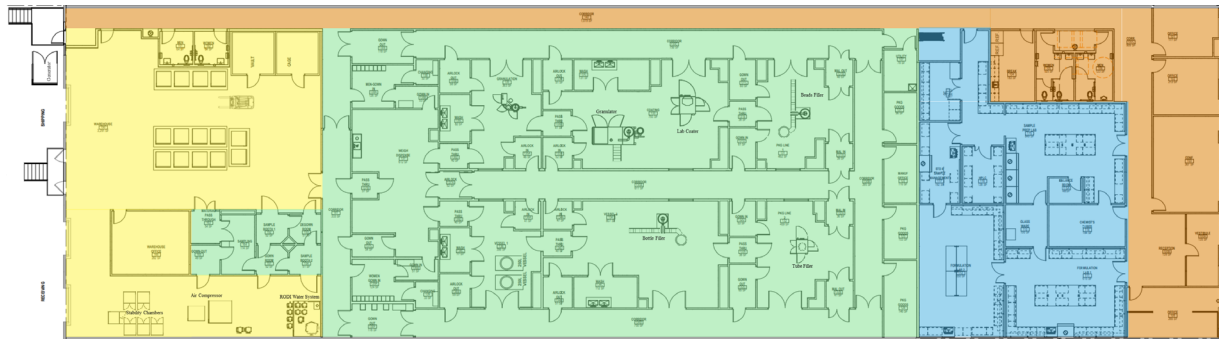
- Dedicated single pass HEPA filtered air handling systems
- Meeting ISO 8 standards for environmental quality
- Automated controls using Building Automation system

## ANALYTICAL CAPABILITIES

High-Performance Liquid Chromatography (HPLC) • 8 HPLC systems (Empower software)	Differential Scanning Calorimeter
Gas Chromatography (GC) • 2 Gas Chromatography equipment	UV Spectrometer
Dissolution Apparatus • 4 Dissolution Apparatus USP I and II	Viscometer
Stability Chambers: • 2 CRT condition ( 25°C/60% RH ) • 2 Intermediate condition ( 30°C/65% RH ) • 2 Accelerated condition ( 40°C/70% RH )	TOC Analyzer
Photo Stability Chamber	Diffusion cells for IVPT/IVRT studies
FTIR	

# FLOOR PLAN

## Frederick Manufacturing Facility



### WAREHOUSE

Area

### MANUFACTURING

Area

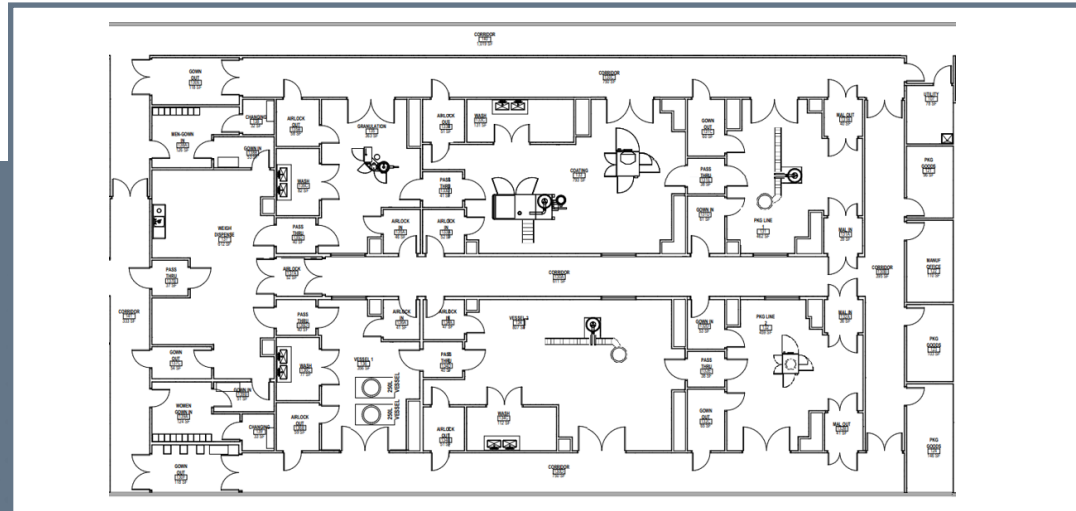
### LABORATORY

Area

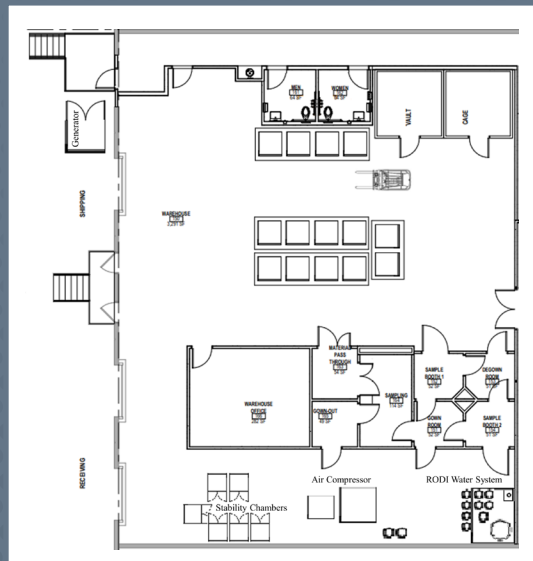
### OFFICE

Area

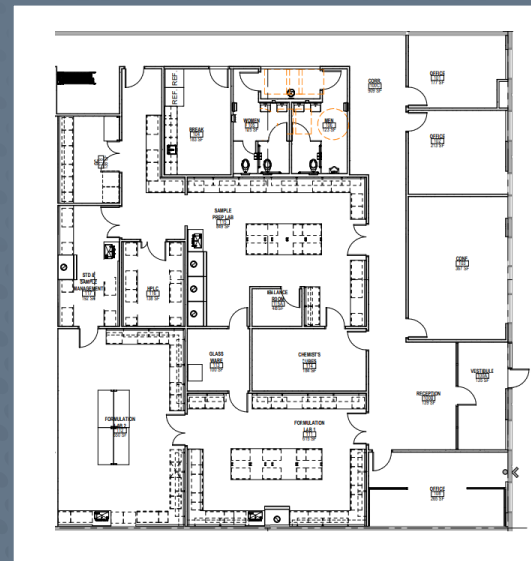
# FLOOR PLANS



Manufacturing Area



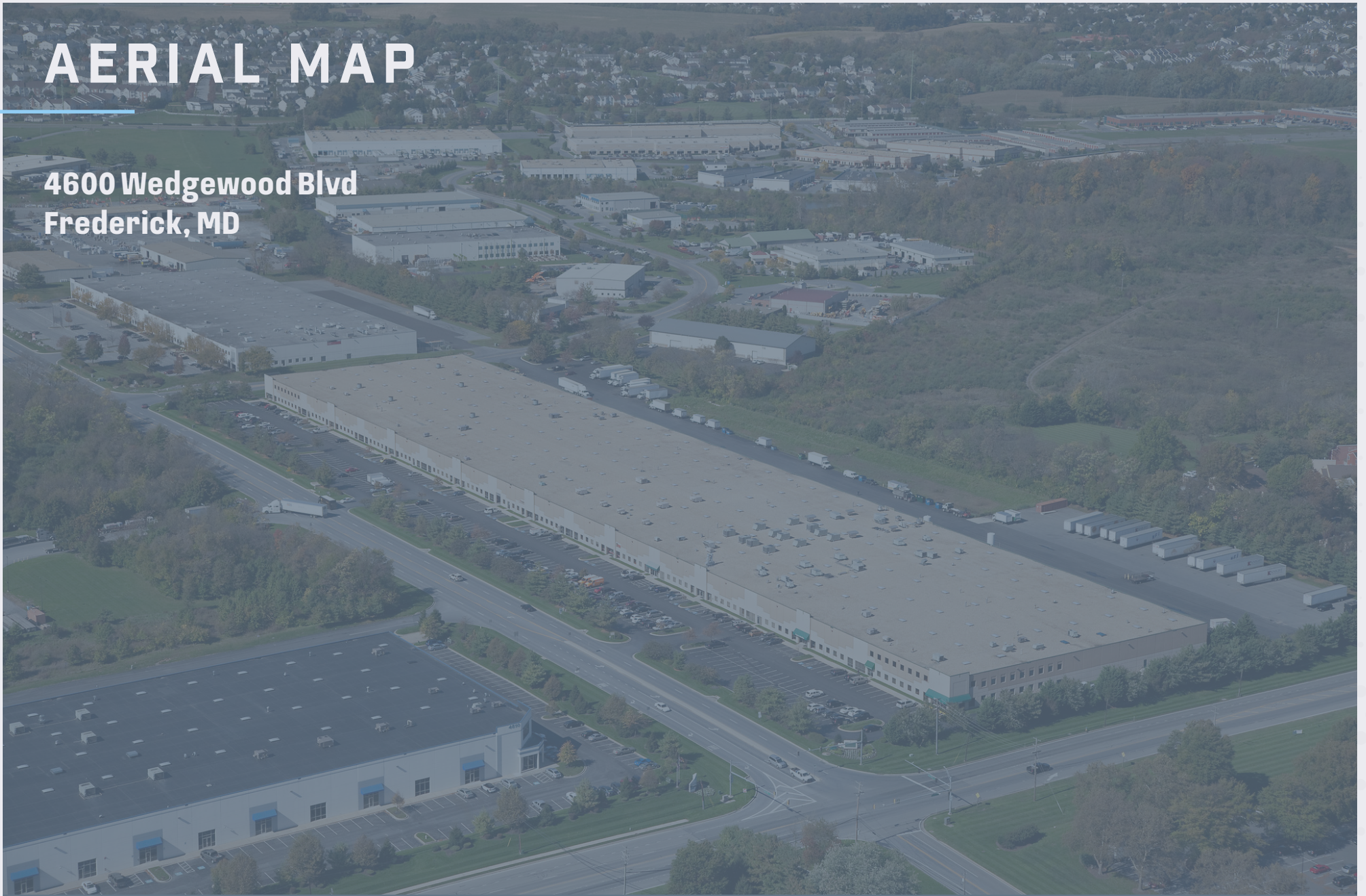
Warehouse Area



Laboratory & Offices Area

# AERIAL MAP

**4600 Wedgewood Blvd  
Frederick, MD**



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# FREDERICK BIOSCIENCE

The property is strategically located within the I-270 Technology Corridor in Frederick, 4600 Wedgewood represents a move-in-ready manufacturing facility offering strategic proximity to organizations such as Astra Zeneca, Fort Detrick, the National Cancer Institute as well as to 80+ bioscience companies.

**OVER 80** CUTTING EDGE BIOSCIENCE COMPANIES

**2<sup>ND</sup> LARGEST** CLUSTER OF BIOSCIENCE COMPANIES IN MARYLAND

**OVER 3K** BIOSCIENCE JOBS IN FREDERICK

**OVER \$1B** OF CAPITAL INVESTMENT IN THE PAST 36 MONTHS

## BIO COMPANIES IN FREDERICK

• AFAB Lab	• Express Genomics, Inc.	• MRI Global
• Akonni Biosystems, Inc.	• FiberCell Systems, Inc.	• National Cancer Institute
• Aliee Pathology	• Fisher BioServices	• Nexus Discovery Advisors
• AstraZeneca/MedImmune	• Frederick National Laboratory for Cancer Research	• Nanova
• BaneBio	• GM Biosciences	• Ology Bioservices
• BioAssay Works	• Harborgen Technology	• Phycin
• BioElectronics Corp	• HBVTech	• Poochon Scientific
• BioFactura	• HydroMax	• Precision Medicine
• Biological Mimetics, Inc.	• HypOxygen	• Prolias Technologies
• Biologics Resources	• Indivumed	• PSquare Scientific
• Bio-Molecular Technology, Inc.	• Imagilin Technology	• RoosterBio
• Bio-Stat Solutions, Inc.	• ImQuest Biosciences	• Royer Biomedical
• Bluepoint Bioscience	• Innovative Biotech USA	• RuRo
• BridgePath Scientific	• Inspirion Biosciences	• Qiagen
• Genomics Solutions	• Integrated Pharma Services	• Southern Research Institute
• Charles River	• Intracel Resources	• SriSai BioPharmaceutical Solutions
• Columbia Biosciences	• Jecho Laboratories	• Steven Lane Consulting
• CRSA	• KamTek	• Syngene
• Denova Biotechnology	• Kemp Bio	• Texcell
• DRMC	• Kite Pharma (Gilead Sciences)	• Theradaptive
• EduQuest	• Leidos Biomedical Research	• Thermo Fisher Scientific
• Electron Microscopy Bioservices	• Lifeline Cell Technology	• TOMI Environmental Solutions
• Eminent Services Corporation	• Lonza Bioscience	• Tox Path Specialists
• Emmes Corporation	• Meridian BioGroup	• U.S. Pharmacopeia
• Empirstat	• Medigen, Inc.	• Valogic
• Envigo	• Mesa Science Associates	• Veralox Therapeutics
• Express Biotech International	• Microbiology International	• XGene Diagnostics



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## VENDORS

Vendor	Name
Architect	Ewing Cole (Formerly Caudreau, Inc.)
Structural	Skarda & Associates
MEP	Jennerik Engineering Inc.
Contractor	Morgan Keller
Validation	Valogic

## CONTACT

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