# BioMaP-Consortium Industry Day

## Tuesday, October 29-30, 2024

## Member Introduction and Reverse Networking Presentations

# Member Introductions

Slides presented for Member Introductions are introducing companies who are new to the BioMaP-Consortium.

# CELLTHEON CORPORATION

- **Company Overview**
  - **Mission:** Provide the highest performing and most cost-effective technologies for Biotherapeutics development and commercial manufacturing
  - **Size & Nature of Business:** Provider of Protein Expression Biotherapeutics Technologies and CRO Services to Pharma & CDMOs. R&D focused company building high-value technologies. TAM: > $5B+
  - **Technologies:**
    - **ALTHEA™/AI** Drug Developability & Humanization
    - **SUPERCELLS™**/Next Gen CHO-K1 host cell line
    - **OmniCHO™**/Multigram per liter transient transfection kit
    - **GOLDILOCKS™**/ hyperactive transposase
    - **pGL™/** vector libraries
    - **PIXIE™**/rapid enzymatic plasmid mfg platform
    - **PEGASUS™**/liposomal non-viral gene delivery
  - **Services:** Drug developability services, early and tox-studies bioproductions, cell line development, upstream & downstream process development, analytical services, gene sequencing and synthesis
  - **Areas of Expertise:** Drug Developability, Cell Line Development, Bioproduction, Process Development, Protein Engineering, Molecular Biology, Analytics, Assay Development, Nonviral gene therapy

- **Company Interests**
  - **Continuing Technology Development**
    - Next generations of protein expression technologies
    - Expand Reagent product lines
    - Gene Therapy technologies
  - **Commercial**
    - Expand Reagent Product and kit sales
    - Expansion of PIXIE™ production and related services
    - Provide HTP services for Gene Sequencing & Synthesis
    - Outlicensing Platform technologies to large Pharmas and CDMOs
    - Partnering with CDMOs to provide GMP services
    - Continue to provided Services to the Pharma industry
    - Participate in biotechnology programs of national security and commercial interests

- **Company Points of Contact:** (Divya Goel/VP Business Development, divya@celltheon.com)

VULCAN BIOWORKS

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# Optimizing Design of Single-Use Technology

## The Vulcan Forge™
- 3D Neutral Design Tool
- Rapid Prototyping
- Reduction in engineering time
- Rapid RFP response

## Single Use Genome Project™
- Enterprise design library management
- Functional evaluation and comparison of designs
- Inherent drive toward standards and SKU reduction

## Contract Development
- Developing fit-for-purpose solutions
- Unique Single-Use Components
- Solving unmet needs

**Trayce Slumsky | Co-Founder**
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**VULCANBIOWORKS.COM**

GET STARTED DESIGNING

# Sunflower Therapeutics

Sunflower is a pioneering biotech delivering next-generation biomanufacturing solutions to global innovators servicing a >$500B market for protein products, including medicines, vaccines and food.

## Company Overview

| | |
|---|---|
| **Mission** | Democratization of protein-based therapeutics and other bioinspired products through accessible biomanufacturing |
| **Traction** | Profitable since operationalization in 2019;<br>Major programs completed for US DoD and BMGF;<br>Commercial launch of first product ongoing (Daisy Petal™) |
| **Operations** | 22 Employees (>80% scientists and engineers)<br>~9,500 sq ft R&D/engineering labs in Medford, MA |
| **Capabilities** | Bioprocessing equipment development from design to commercialization; agile, user-friendly perfusion bioreactor systems for protein product development; microbial strain development, end-to-end process development |
| **Areas of Expertise** | Continuous biomanufacturing, automation and software development, strain engineering, bioprocess intensification |
| **Key Contact** | Kerry R. Love, PhD; CEO/President; kerry@sunflowertx.com<br>+1.781.539.8100 |

## Company Interests

### Related Technology Development

- Single-use assemblies for end-to-end production of drug substance
- Tech transfer package development for protein biologics including subunit vaccine components
- Workforce training modules for continuous biomanufacturing

### Future Growth Areas

- Additional software and AI tools for equipment and process control and machine learning (ML) tools
- New bioprocessing modules including CHO-ready perfusion bioreactors with built in cell retention devices

### Co-Development Opportunities

- Feasibility of biologics production using microbial perfusion fermentation and small-footprint continuous approaches
- Manufacturing scale-up de-risking

### Partnering Opportunities and Capabilities We Seek

- Cleanroom assembly for single use parts
- Prototyping capabilities for fluidic devices
- Machine learning expertise
- Next-generation in-line process monitoring tools

# KOMO BIOSCIENCES

**KOMO is a next-generation precision genome engineering technology company commercializing a pipeline of high efficiency integrase enzymes with applications in multiple multibillion dollar industries including cell and gene therapy, biologics, agriculture and synthetic biology.** KOMO's mission is to revolutionize the future of genome engineering by developing technologies that enable precise, efficient, safe and scalable genetic modifications to address urgent unmet needs and solve complex global challenges.

**KOMO's non-viral, non-nuclease genome engineering technology has demonstrated large gene insertion into a pre-defined, high-expressing region in the human genome at up to 80% integration efficiency per chromosome in up to 96% of cells with unprecedented high efficiencies.** The technology does not induce unprotected double strand DNA breaks thereby potentially addressing limitations of current genome engineering methods (CRISPR and its derivatives) with respect to off target editing, low efficiency, and inability to insert large fragments of DNA.

**KOMO addresses four critical pain points: the need for site-specific, highly efficient, and safe genome insertion, urgency for accelerated manufacturing timelines, the need for non-viral delivery of cell and gene therapies, and the need for high integration efficiency for application in ex-vivo cell therapy.** Additionally, KOMO's technology enables rapid design-test cycles, antibiotic-free systems, and is capable of large, sophisticated molecular constructs to enable complex engineering. Our platform's scalability and predictability, coupled with ongoing advancements, position KOMO as a leader in genome engineering.

**KOMO's site-specific, integrase-mediated cell line development platform offers a rapid, flexible solution for biologics development and manufacturing by significantly reducing cell line development timelines from several months to mere weeks. This acceleration is crucial for therapeutic developers and the U.S. Government, particularly in pandemic preparedness, where speed and precision can save lives.** By enhancing cell health and expression stability, KOMO's highly efficient integrase technology can deliver large, complex DNA cargo, ensuring high titers and consistent performance, making it a valuable tool in the development of biologics, cell and gene therapy, veterinary medicine, AgBio, and SynBio.


www.komobiosciences.com
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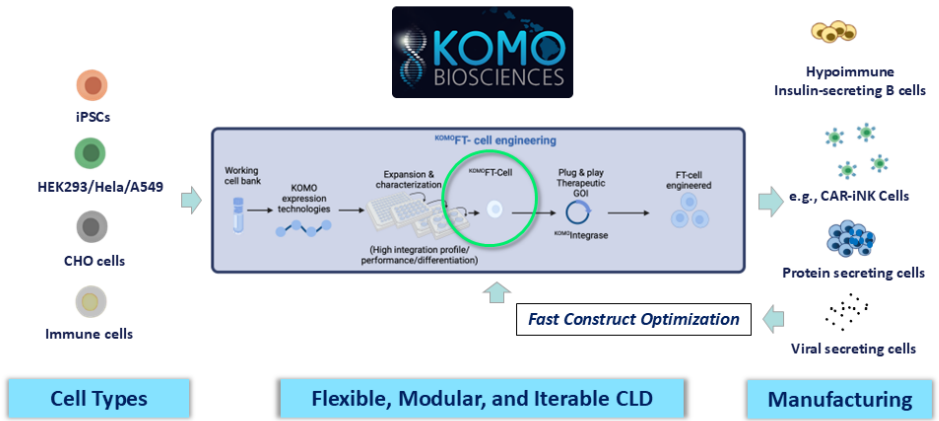
Significant gaps and issues persist in centralized, large-scale, on demand manufacture and deployment of medical counter measures (MCM) required to prepare for and address public health threats. **These issues include inefficient genome engineering, lengthy cell line development (CLD) timelines, supply chain disruptions, diverse drug product types, storage and transportation complexities, limited flexibility in shifting production targets, and resource constraints in manufacturing environments.**

**KOMO's proposed approach addresses these vulnerabilities by tech stacking our highly efficient, next generation, precision genome engineering, with AthemBio's column-less chromatography, and other enabling technologies. Together, the technologies support rapid cell line development and decentralized on-demand manufacturing (ODM) by way of a portable, self-contained module.** Our strategic approach is to tech stack disruptive, next generation technologies, and eliminate every non-essential unit operation with novel control strategies driven by detailed risk assessment.

**The core technology elements include highly evolved, site-specific integrases which enable the development of rapid, stable cell lines delivered as high-density clonal research cell banks in less than 27 days, coupled to advanced single-step purification optimized for each class of vaccines.** This approach of combining rapid CLD to column-less chromatography significantly accelerates development and manufacturing timelines and reduces the overall footprint required. The approach can be further compressed to allow efficient, modular, safe, and scalable production of proteins and vector-based products.




## KOMO Advantages

- **Clonal KOMOFT cell lines:** Optimized, highly efficient DNA integration and differentiation, stable, scalable, and predictable, high gene expression.
- **Control of gene expression through programmed insertion:** Simplicity of engineering with significantly faster cell generation timelines compared to conventional methods.
- **Demonstration of efficacy, durability, and persistence:** Goal is, *in vivo*, ability to regulate expression using molecular switch technology.

# U.S. Pharmacopeia (USP)

www.usp.org

## Company Overview

- Founded in 1820, USP is an independent, scientific nonprofit focused on building trust in the supply of safe, quality medicines through rigorous science, technical capabilities and public safety standards setting.
- We provide the Federal Government with solutions that advance supply chain resiliency, advanced manufacturing processes, innovative quality testing/process control strategies, and improve health equity and patient safety.
- Capabilities and areas of expertise include:
  - Advanced manufacturing technologies (AMT)
  - Biologics and emerging modalities
  - Data analytics and digital solutions
  - Supply chain resiliency
  - Process control strategies for new manufacturing platforms
  - Methods for impurity profiling and novel excipients

## Company Points of Contact


- Betsy Baer – Senior Director, Federal Business Development
  Betsy.Baer@usp.org; (703) 407-7402
- Morgan Jacobs – Federal Practice Engagement Manager
  Morgan.Jacobs@usp.org; (954) 649-7297


## Company Interests

- Opportunities to partner:
  - Standards, solutions, quality processes for AMT (small molecules, biologics, platforms); Quality systems
  - Standardized methods for emerging modalities
    - mRNA, mAbs, oligos, vaccines and therapeutics
    - Multi-Attribute Method and comparability studies
  - Supply chain analytics and insights including USP Medicine Supply Map (pharmaceutical supply chain analytics tool) and upstream mapping of APIs and KSMs.
- Current and past US government work:
  - USP has completed a project to map essential medicine APIs and their KSMs to assess vulnerabilities, with suggested alternative pathways.
  - Working with Phlow Corp., our AMT lab supports BARDA and JPEO-CBRND with analytical methods development and testing services to produce selected APIs using continuous manufacturing.
  - USP has provided government agencies with USP Medicine Supply Map data to assess pharmaceutical supply chain risks and assist with mitigation strategies.

innerspace
THE SIMULATOR COMPANY

# Innerspace

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- Company Overview
  - Based In Innsbruck Austria (US HQ in Charlotte NC)
  - Use Modern Technology To Improve The Pharmaceutical Industry
  - Virtual Reality Training For Aseptic Processing Behaviors
  - AI Driven Risk Profiling, Process Mapping, Knowledge Management
  - Workforce Development

- Company Interests
  - Training
  - Pharmaceutical Automation
  - Validation Services
  - Augmented Reality


- Chuck Gagnon – US Director Of Sales – Chuck.Gagnon@innerspace.eu – 224 258 5776


# MustardSeed

## MustardSeed Overview

- Mission: Scientific advancement through effective project management
- Size: 15 staff, remotely distributed throughout the US
- Certifications & Expertise: SBA Certified Small Business, PMP, CAPM, MBA, PMI-ACP, PSM, Lean Six Sigma Black Belt, U.S. Security Top Secret Clearance
- Capabilities: Product & Drug Development, Client Delivery, Diagnostic Test Kits, Clinical Trials, Medical Device, Supply Chain & Logistics, Cost and Resource Management & Reporting
- Recent projects:
  - **Phase 1 Clinical Trial.** MustardSeed led project management for a client working on an ongoing gene therapy clinical trial, including implementation of a comprehensive dashboard to capture and organize clinical trial patient scheduling.
  - **Project Management Office (PMO).** MustardSeed provides PMOaaS to a leading biotech company. We work with product managers, scientists, and engineers to speed up their NPI progress, along with delivering on fee-for-service client facing projects.
  - **Business Process Improvement.** MustardSeed led project management activities for high-visibility pharmaceutical development process, including process development, supply chain integration, and equipment qualification.
  - **Technology Transfer.** Managed transfer of production from APAC to the US for reliable at-home COVID tests.


- Steve Curry | CEO | Steve@mustardseedpmo.com
- Cameron Robinson | Business Dev | Cameron.Robinson@mustardseedpmo.com


- Project & Program Management
  - Project Management Office (PMO)
  - PM Staff Augmentation
  - Integrated Master Planning & Scheduling
  - Project Management Consulting
- Partnering Opportunities of interest
  - Bidding on projects
  - Subcontractor to your prime award

DoD SKILLBRIDGE

MILITARY SPOUSE EMPLOYMENT PARTNERSHIP
DEPARTMENT OF DEFENSE

COMMITTED TO HIRING MILITARY SPOUSES

# CONTINUUS Pharmaceuticals

CONTINUUS™ pharmaceuticals

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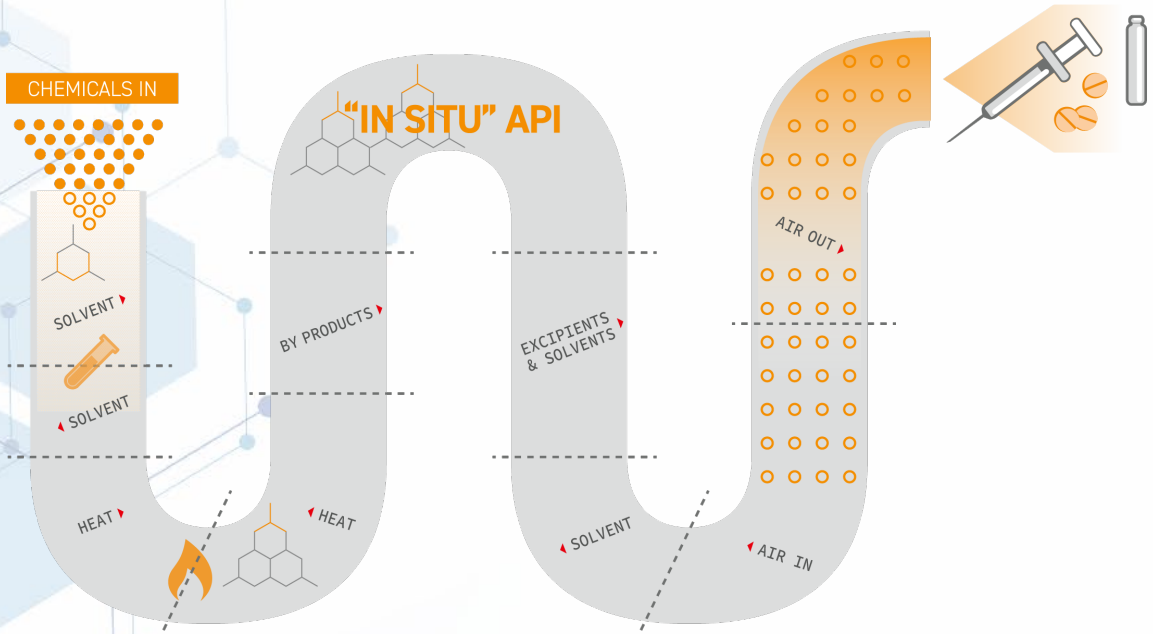


## On-Demand Manufacturing of Pharmaceuticals

- Continuous Flow
- End-to-End Integration
- Systems Approach
- Integrated Control Strategy


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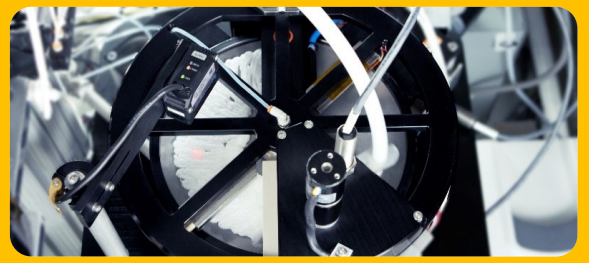
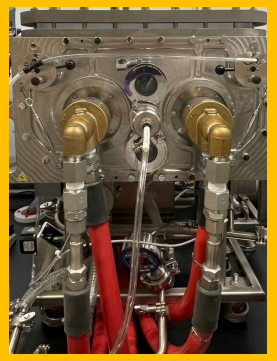
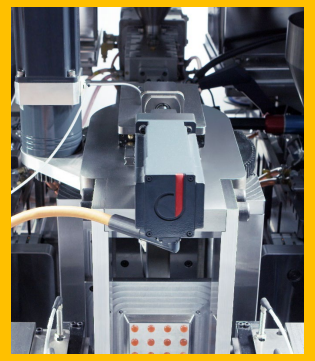
## Targeted Solutions







## End-to-end Solutions

## Throughout the supply chain, ICM adds significant value


Development


Manufacturing

Sales/Distribution


Patient Care

Women Owned Small Business

# QooLAbs

Innovating Qool Antibodies

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**Advancing research, diagnostics, and therapeutic drug development through innovative antibody products**

## About Us

- Global leader of innovative rabbit monoclonal antibody discovery
- 17 NIH funded SBIR phase I/II grants/contracts
- QMAb™ antibody platform: Quick Monoclonal Antibodies from Blood
- Recombinant antibody production from cell line development to Ab purification
- CHO cell antibody production: ~12g/L

ViVASOR charles river Catalent BIOLOGICS

## Company Interests and Future Growth

- AI driven antibody design
- Cell line development and optimization
- Therapeutics for infectious disease
- POC diagnostics

## Partnering Opportunities of Interest:

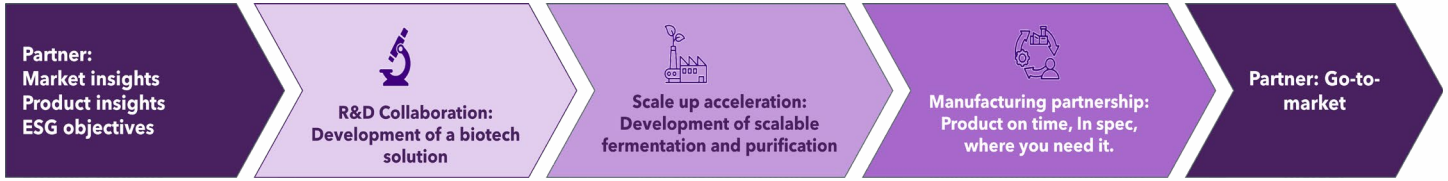
- Preclinical and clinical development
- Technology licensing and co-development

**Hong Qi, President**
(858) 348-0988, hqi@qoolabs.com
www.qoolabs.com

# Amyris, Inc.

- **Company Overview**
  - Amyris innovates to deliver clean molecules to the world as a fully-integrated biotech company
  - Headquartered in Emeryville, CA (SF Bay Area) with manufacturing sites in US and Brazil
  - 550 employees
  - 15 commercialized ingredients
- **Company Points of Contact**
  - General Information: info@amyris.com
  - Partnership inquiries: inquiry@amyris.com

- **Company Interest -** Amyris is a strategic growth partner for companies seeking to transform their industries with advanced precision fermentation.




AI-powered strain development | Automation, Analytics, LIMs | Scaled-down infrastructure | State-of-the-art manufacturing

# BioFactura, Inc.

- **Company Overview**
  - BioFactura develops and manufactures high-value biologics using a range of mammalian expression systems (NS0, CHO, other) to accelerate critical products to market.
  - BioFactura is a Small Business with over 40 fulltime employees
  - BioFactura is a proven, non-virtual and fully-integrated biologics drug developer with capabilities including:
    - Cell Line Development
    - Process Development
    - Analytical Method Development
    - GMP Drug Substance Manufacturing for Phase 1 & 2 Clinical Trials
    - Full Quality Assurance Oversight with Independent QC Release and Stability
    - Clinical Trials Management/Oversight
    - Tech Transfer to Phase 3/Commercial-Scale CMO
  - Areas of Expertise—Development and Manufacturing of:
    - Monoclonal Antibodies Including Bi-/Multi-Specifics
    - Enzymes
    - Fusion Proteins
    - Vaccines
  - Successful Programs in:
    - Antiviral mAbs including mAb Cocktails (Smallpox/Mpox, Ebola, Marburg)
    - Biosimilars (ustekinumab, golimumab)
    - Novel Therapeutics (oncology, autoimmune disorders)
    - Vaccines (VEE/EEE)

- **Company Interests**
  - Related Technology Development:
    - High-Throughput Process Development (Micro-/Mini-Bioreactors [ambr])
    - Continuous Bioprocesses (Perfusion, Continuous Fed-Batch)
    - High-Resolution Product Characterization (LC-MS/MS, Octet/BLI)
  - Current/Future Growth Areas
    - Phase 1& 2 GMP Manufacturing
    - Bioprocess Characterization
    - Cell-Based Assays (BSL-2 Capable)
  - Partnering Opportunities of Interest
    - Early-Stage Product & Process Development
    - IND-Enabling Studies and Preparation
    - Phase 1/2 Clinical Trial Material Production
    - Analytical Method Development and Qualification
  - Technologies or Services Needed
    - Biologic Drug Discovery
    - Animal Models

## Company Points of Contact


Darryl Sampey, Ph.D., President and CEO
Phone: 240-620-3566
Email: dsampey@biofactura.com

Jeffrey Hausfeld, M.D., M.B.A., Chairman and CMO
Phone: 301-792-8601
Email: jhausfeld@biofactura.com

# Watson-Marlow Fluid Technology Solutions (WMFTS)

## Company Overview

- To sustain growth by improving customer's performance using our knowledge and expertise
- WMFTS has under 2,000 employees and is a £400 million business
- Expertise in fluid management and handling

## Innovation in full flow

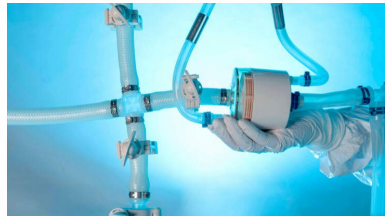
- In 1956, we have been making some of the most innovative fluid management solutions in the world. Thousands of companies employ our technologies to manage processes and manufacture products that touch the lives of people every day.
- We have helped thousands of process and maintenance engineers on every continent to solve their fluid management challenges. When you work with us, we supply more than our proven technologies. We partner with you and provide access to a global network of specialist industrial engineers.
- A global company with local focus

## Point of Contact

Sade Mokuolu, Ph.D. – Regional Business Development Manager, Life Sciences,

Email: Sade.Mokuolu@wmfts.com

## Our products

- Related technology areas: process analytics, flow dynamic measurements
- Research areas : Sustainable materials – biodegradable, predicative maintenance, digital applications
- Partners required with experience of CGT, digital applications, and bioreactor controllers
- Other areas of focus: use of digital to optimize supply chain, AI and smart bioprocessing equipment

# Reverse Networking

Slides presented for Reverse Networking are introducing companies who hosted 1-on-1 matchmaking sessions at the BioMaP-Consortium industry Day.

# Avid Bioservices, Inc.

**Avid Bioservices (NASDAQ: CDMO) is a dedicated contract development and manufacturing organization (CDMO) providing a comprehensive range of process development, CGMP clinical and commercial manufacturing services for the biotechnology, biopharmaceutical, and cell & gene therapy industries**

**30+ Years**

Over 30 years of experience manufacturing biopharmaceuticals

**500+ Batches**

Over 500 clinical and commercial batches produced

**220+ Commercial Batches**

Over 220 commercial batches produced for 5 commercial products

**90+ Countries**

Approved manufacturer for products marketed in over 90 countries

**Mission:** Improve patients' lives through the quality production of biologics

**Size & Nature of Business:** Midsize CDMO supporting the biotechnology, biopharmaceutical, and cell & gene therapy industries

**Services:** Mammalian protein and viral vector development and CGMP manufacturing of bulk drug substance

**Capabilities:** Full lifecycle – from early-stage development to commercial-scale production

**Areas of Expertise:** Our quality systems, global compliance, and track record of successful inspection history, combined with our collaborative, high-touch approach with SME's, ensure the success of your program

## Ready to discuss your next project? Connect with us.


**Greg Terry Sr. Director, BD – Key Accounts**
**gterry@avidbio.com | 816.536.5495**

**Phillip Hursey Sr. Director, BD**
**phursey@avidbio.com | 336.306.0558**

# Your trusted partner to support your journey from molecule to medicine

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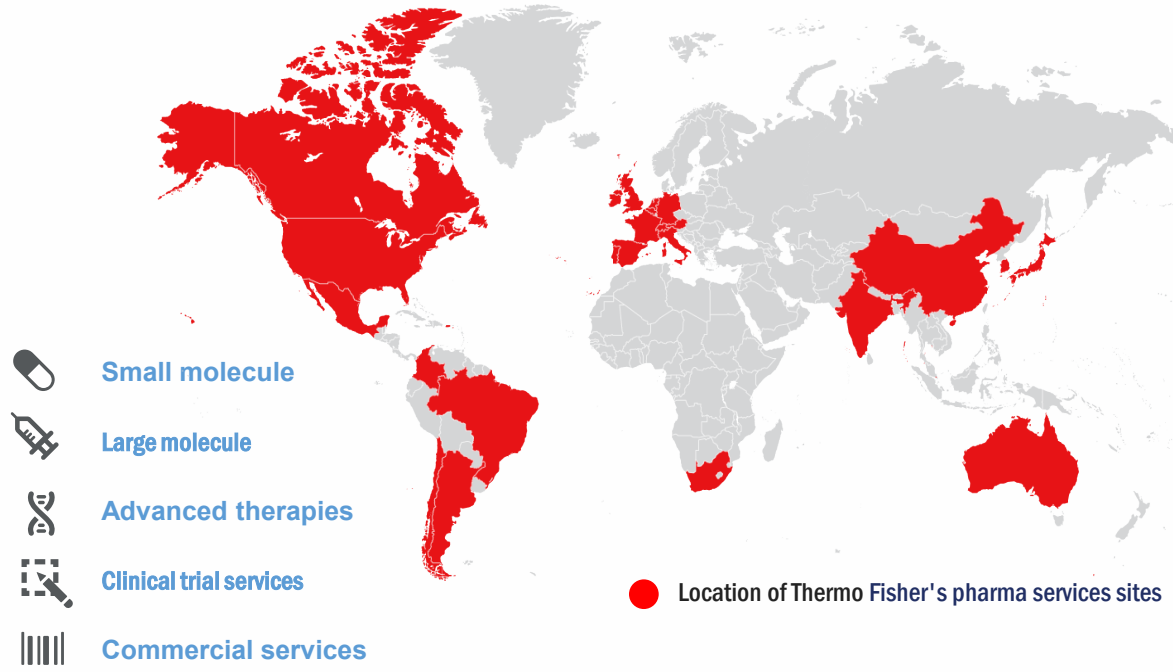
- Our mission is to enable our customers to make the world healthier, cleaner, and safer.
  - >$40B in revenue, with $1.3B invested in R&D yearly and >120,000 colleagues worldwide including 7,000+ R&D experts.
  - Flexible and innovative 360° CDMO and CRO solutions, supporting your aspiration to get treatments to patients faster
  - State-of-the-art facilities and equipment to expedite drug development without compromising quality or safety.
- Accelerator™ Drug Development
  - Speed: work with one partner to eliminate time gaps and regulatory challenges and proactively mitigate risk
  - Operational flexibility: innovative solutions across drug modalities – meet your unique requirements locally and globally
  - Collaborative partnership: providing you integrated expertise for all phases of your drug development




- 78% of customers in clinical phase are emerging biotech
- 30+ partnerships / sponsorships with Incubators
- 10,000+ clinical trials supported
- 1,000+ large & small molecules manufactured

Sarah Sink, Business Development Executive, Biologics
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Rebecca Harston, Executive Account Director of Business Development
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# RESILIENCE

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## BACKGROUND

- Subsidiary of National Resilience and approved prime systems contractor
- Manages the DOD Advanced Development and Manufacturing (ADM) facility in partnership with DOD JPEO

## CAPABILITIES

- Complies with FAR-based contract requirements
- Serves as prime systems contractor and supports commercial clients seeking government funding with reach to entire Resilience network
- Participates in multiple consortia, including MCDC, CWMD, MTEC, RRPV, BioMaP, and CxHub
- Provides regulatory strategy and clinical support services

| BIOLOGICS | VACCINES | NUCLEIC ACIDS | CELL THERAPY | GENE THERAPY |
|---|---|---|---|---|
| Recombinant protein and monoclonal antibodies (mAb) | Live viruses and bacteria, viral vectors, VLPs to BSL2+ | mRNA DS with complete analytical capabilities | Autologous and allogeneic platform technologies for blood and bone marrow-centered therapies | Viral vector production for AAV, lentiviral and next-gen testing methods |

DEVELOPMENT SERVICES | PLATFORM TECHNOLOGY | DRUG SUBSTANCE | DRUG PRODUCT

## GOVERNMENT CUSTOMERS

- Proven track record of delivery: 20+ active government contracts with $765M in current value

## WHERE TO FIND US


- Donald Ebersole, Business Head donald.ebersole@resilience.com
- Melissa Berquist, Technical Head melissa.berquist@resilience.com


- Website: https://resilience.com/
- LinkedIn: https://www.linkedin.com/company/weareresilience/

# Evonik Corporation

| Evonik Corporation | 4,500 headcount | >30 production sites | 8 R&D centers | 5 collaboration hubs |
|---|---|---|---|---|

**Nutrition & Care – the life sciences division of Evonik**

**Health Care**

## Pharmaceutical

### Parenteral drug delivery solutions

- High quality GMP lipids
- **PhytoChol**® plant-derived cholesterol
- **PhytoSquene**® plant-based squalene
- **Resomer**® & **Lactel**® PLA-PLG polymers
- CDMO: micro & nano particle products from feasibility to commercial (e.g. LNPs)
- **Lipex**® liposomal extruders
- Polymeric & lipid delivery technologies

### Drug substance

- CDMO for APIs and intermediates
- World's largest HPAPI capacity
- Portfolio of complex chemistries

### Cell culture applications

- **cQrex**® cell culture ingredients
- Oligopeptides, performance boosters
- Booster screening and development

### CDMO services for oral and parenteral dosage forms

| Formulation Development | → | cGMP Drug Manufacturing |
|---|---|---|
| Feasibility studies | | Clinical batches |
| Formulation optimization | | Scale-up and transfer |
| Formulation technologies | | Production support |
| Process development | | Commercial manufacturing* |
| Analytical method development | | Process equipment* |
| Regulatory support | | Aseptic vial filling* |

* Applicable to parenteral drug products

Contact: Yvonne Hurt, Head of Program Management Office, yvonne.hurt@evonik.com

CORNING

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# Corning Life Sciences helps you harness the power of cells by supporting Life Sciences and Pharmaceutical Technology workflows

Glass & Plastics consumables
Manufacturing
Surface treatments

- Corning Elplasia® technology
- Corning HYPERStack® vessels
- Corning Ascent® Fixed Bed Reactor
- Corning Velocity®, Viridian®, Valor® Vials


Partnering Opportunities:

- Harvesting
- Extracellular vesicles
- Faster Fill-and-Finish

Growth Areas:
Cell & Gene therapy
Vaccines
Drug storage & delivery
Media, Sera, High Quality Water

4,000 employees
Global Field Application Scientists

19 manufacturing sites
30,000 products

Erin Keaney, keaneyee@corning.com

VGXI, Inc
Palas Chanda, Operations Senior Manager, mRNA; pchanda@vgxii.com
Michael Stewart, COO; mstewart@vgxii.com

VGXI® Manufacturing Excellence for Next-generation Therapeutics

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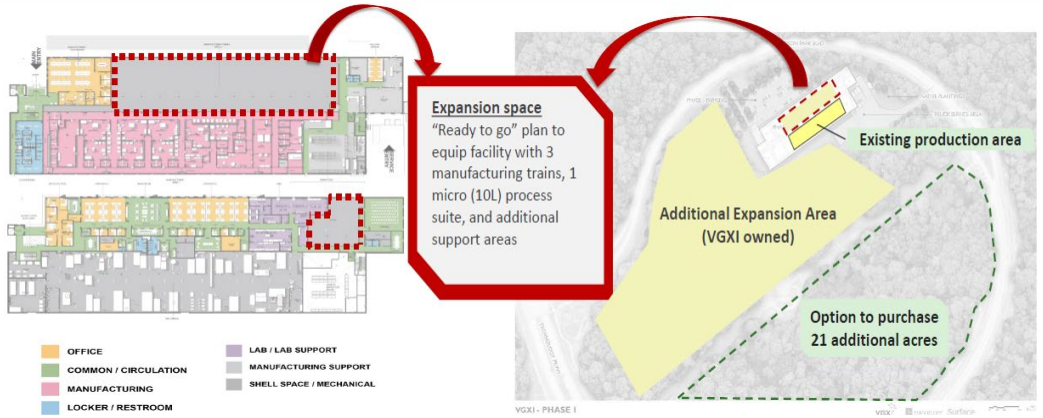
## Overview

- Leading CDMO specialized in manufacturing high-quality, pure nucleic acid biopharmaceuticals like plasmid DNA, linearized pDNA, and mRNA using proprietary platform technologies.
- Located in Houston-Conroe Metro area, adjacent to Texas Medical Center and Bush International Airport(IAH).
- More than 20 years of experience, manufactured over 325 batches of cGMP plasmid DNA(3130+ grams) for multiple modalities including infectious diseases.
- Two state-of-the-art facilities covering 160,000 sq. ft.
- World's largest manufacturing capacity (4000L including a 1500L fermenter).
- Established secure, stable, USA-based supply chain vendors.



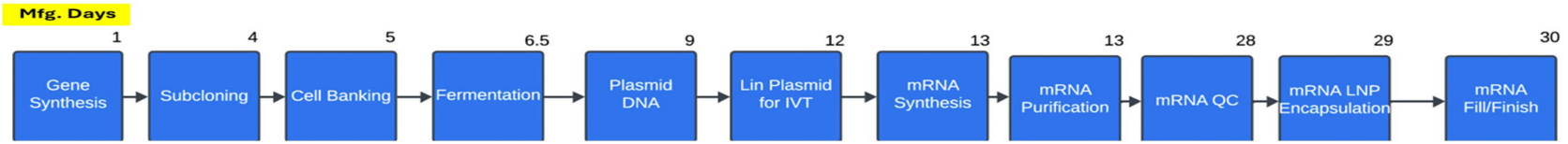

## Key Management

**Young K. Park**-President and CEO
**Michael Stewart**-Chief Operating Officer
**Jeff Whitmore**-Chief Commercial Officer
**Stephanie Burke**-Chief Accounting Officer

## VGXI's End-To-End mRNA Vaccine Manufacturing Solution in response to Public Health Emergency

***A) mRNA Vaccine Manufacturing using Synthetic DNA as Starting Material***


***B) mRNA Vaccine Manufacturing using plasmid DNA as Starting Material***




## Capabilities

**Current Manufacturing timeline**

- Plasmid DNA: 1 week; Linearized pDNA: 1.5 weeks; mRNA: 2 weeks

**What we are trying to achieve:**

- Vertical Integration of all technologies under one roof.
- Provide end-to-end, continuous mRNA vaccine manufacturing in a closed and automated system, from pathogen antigen sequence to mRNA in vial.
- Real time, in-line process controls, in portable space.
- Rapid scale, with reduced timeline and lowered cost.
- Decentralize vaccine administration to serve the entire U.S. population, including rural and underserved communities.

**Anticipated impacts/** help to BioMaP Consortium Members

- ✓ Remove domestic vaccine manufacturing capacity constraints.
- ✓ Address mRNA vaccine supply chain vulnerabilities.
- ✓ Accelerated product availability.
- ✓ Leverage rapid-response capacity as MCM to strengthen resiliency across medical industrial base.
- ✓ Reduced Cost.

**Potential Applications:**
Platform technology for any mRNA vaccine related to infectious diseases/any future biological threats/therapeutic applications.

# Isolere Bio

A Donaldson Brand

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

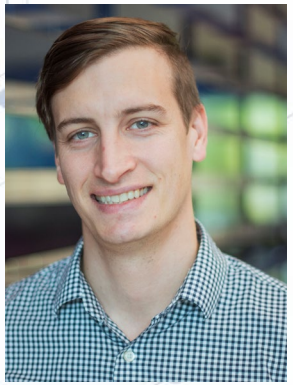
*Accelerate the development of therapeutics to improve human health and global accessibility*


## IsoTag™ AAV

Breakthrough yield and purity in under 4 hours with neutral pH for many AAV serotypes

## IsoTag™ LV

Concentrate and purify LV in a single unit operation with high functional recovery



Michael Dzuricky, Director of R&D (former CSO)

michael.dzuricky@donaldson.com, (814) 746 7711

## Seeking partnership to:

1) Support “off-label” use of AAV & LV purification products
2) Partner on early-stage development of ssRNA, mAb & AdV purification products
3) Partner on custom purification solutions for new & unique DSP challenges

# ApiJect Systems America, Inc.

## Company Overview

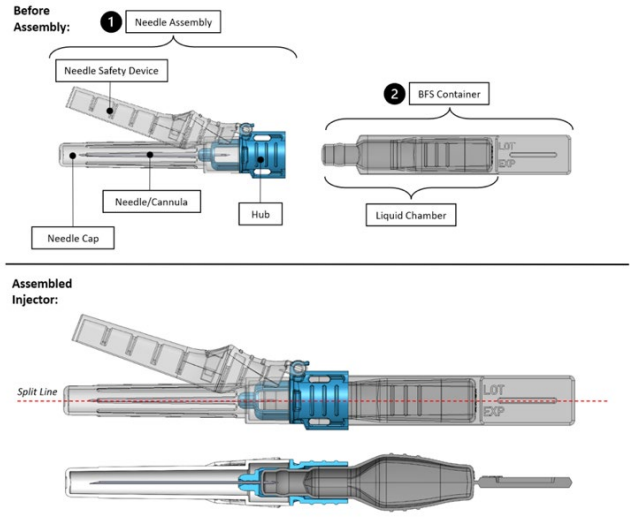
- Mission: To make injectable medicines and vaccines safe and accessible to everyone.
- Year Founded: 2019.
- Capabilities:
  - Developed first prefilled syringe product made with Blow-Fill-Seal (BFS) technology. FDA regulatory submission Q1-2025.
  - Established high-volume manufacturing capability for over 1 billion doses annually in U.S. and Europe, facilitated in part via role in Operation WARP Speed.
  - Research and development center in U.S. for product development and testing capabilities for BFS manufacturing.

## Company Point of Contact

Philip Tull VP, Government Projects and Contracts
ptull@apiject.com, (571) 235-7088

## Company Interests

- Additional drug-product partners interested in injectable drug shortage list.
- Expanded fill-finish capacity partnerships leveraging the ApiJect platform for wide-range of injectable drugs.
- Export opportunity for single-dose injectors focused on global health markets.
- Partners seeking to reduce dramatically costs and environmental footprint of fill-finish processes.




* Device has not been cleared by regulators.

# Amneal Pharmaceuticals

We make healthy possible.

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

## Company Overview

- Founded in 2002, in Paterson, NJ, by our Co-CEOs
- Largest U.S.-domiciled affordable medicines company, with ~2,500 U.S.-based employees, 810 scientists, manufacturing capacity of 10 billion doses, 365 FDA approved products to date, 10+ U.S. sites, and > $2B annual revenue
- Focus on complex generics with a growing portfolio of biosimilars, branded oncology and specialty products (movement disorder, neurology, oncology) and medical countermeasures
- Resilient internal supply chain with vertical integration and manufacturing redundancy -- 95% of products manufactured in-house

**INJECTABLES & STERILE**
Peptides
Microspheres
Liposomes
General and Oncology Injectables

**TRANSDERMALS**
Matrix
Hydrogel
Form Fill Seal
Hormonals

**ORAL SOLIDS, LIQUIDS & TOPICALS**
IR/ER tablets
Hard and Softgel Capsules
Oral liquids
Creams

**OPHTHALMICS & OTICS**
Solutions
Suspension
Emulsion

**INHALATION**
Metered Dose
Dry Powder
Nasal Spray Pumps
Blow Fill Seal
Inhalation

**DEVICES**
Rings
Autoinjectors

**DRUG DELIVERY TECHNOLOGY**
GRANDE: Advanced Gastric Retention System

## Company Points of Contact



J'Aime Conrod, VP, Government Business & Healthcare Policy
jaime.conrod@amneal.com ; 908.842.9690


Maryll Toufanian, SVP, Regulatory Strategy & Government Affairs
maryll.toufanian@amneal.com


Kapil Gupta, VP, Strategic Portfolio Management
kapilg@amneal.com ; 631.633.2444


## Company Interests

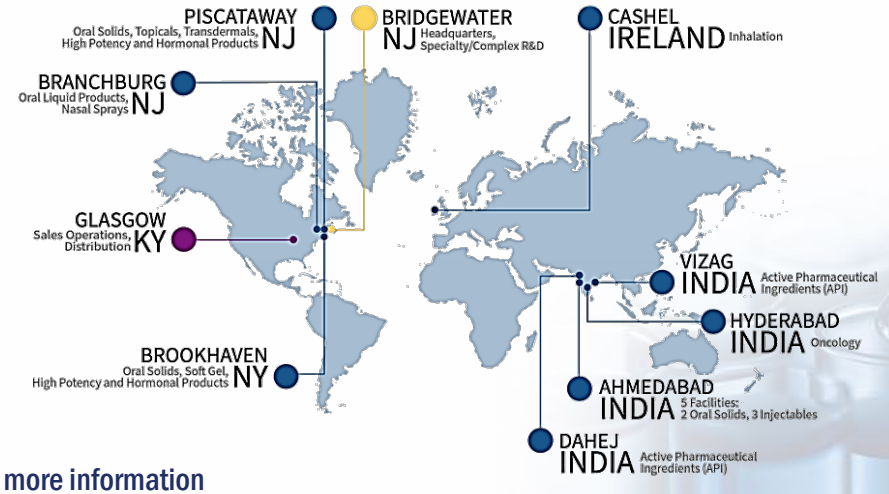
***GROWTH AREAS***

- **Injectables**: Vials, cartridges, infusion bags, prefilled syringes, autoinjectors, and multidose pens
- **Complex APIs**: Focus on high value, difficult APIs, such as peptides (GLP-1s, cyclic and poly peptides), iron complexes
- **Inhalation & Nasal Sprays**: MDIs, DPIs, and unit-dose nasal spray technologies

***PARTNERSHIP OPPORTUNITIES*** with innovative companies to accelerate biomanufacturing and customized solutions for the U.S. Government

- **Start-ups and Academia** with minimal experience in large scale manufacturing and government contracting
- **Companies** looking to divest , smaller IP-brands that aren't focused on Government space
- **Companies seeking installation and commissioning services** for sterile filling lines (Blow-fill seal, vials, prefilled syringes & infusion bags) at our U.S. manufacturing sites

### Global network of FDA-approved, cGMP manufacturing sites




Please visit www.Amneal.com for more information

# Jubilant HollisterStier CMO

## Company Overview

- Jubilant HollisterStier LLC, (JHS) is a leading integrated contract manufacturer of parenteral products and ophthalmics, located in Spokane, Washington, and Montreal, Canada.
- JHS supports manufacturing of multiple formats for sterile liquid/lyophilized vials, and sterile ophthalmic solutions and ointments and offers a full range of other support, from process qualification through commercial release with visual inspection, final packaging, serialization and analytical services.
- The JHS Spokane facilities are designed for multi-product operations; both commercial and clinical trial material of approved products in the US, EU, Australia, Canada, Japan, and numerous other countries. The facility includes four (4) GMP sterile parenteral manufacturing lines including a clinical trial material line.
- With 100 years of manufacturing excellence, JHS takes pride in a strong compliance history with multiple regulatory agencies including: FDA, Health Canada, EMA, MOH Russia, MOH Turkey, MFDS, PMDA, TGA, and ANVISA.
- JHS has a long history of supporting the US Department of Health and Human Services (HHS), Department of Defense biodefense and medical countermeasure programs as a Contract Manufacturing Organization (CMO), including products for the Strategic National Stockpile. We currently support production of vaccines for smallpox, anthrax, and influenza.
- With JHS' strong track record for delivering on-time, quality and budget, we look forward to supporting partnerships and collaborative opportunities within the mission of the USG, serving as a key supplier and one of the country's critical Public Health Emergency assets.

## Company Point of Contact:


Joseph Spampinato

Associate Director, Gov't Affairs and Strategic Initiatives

Joseph.Spampinato@jubl.com

M: 541-280-0203


## Company Interests

- JHS actively responds to all relevant USG solicitations and continues to foster partnerships with innovators, drug substance CMOs and others in the value chain
- JHS is a large scale Fill/Finish partner of choice with the USG and collaborator within BioMap
- JHS is known for its manufacturing excellence, flexibility and responsiveness to unique customer needs
- JHS has an extremely strong history of USG programs and USG relationships
- JHS is experienced in writing and submitting successful proposals for USG programs

| Line | Filling | Lyophilization | Capacity (vials/batch) | Est. Annual Capacity |
|---|---|---|---|---|
| Spokane Line 1 | TL filler in limited access barrier system | Two 240ft$^2$ IMA | Up to 350,000 | 42M |
| Spokane Line 2 | Bosch filler in limited access barrier system | Three 385ft$^2$ GEA | Up to 400,000 | 48M |
| Spokane Line 3 | Groninger filler in SKAN isolator | Two 325ft$^2$ IMA | Up to 460,000 | 55M |
| Spokane Line 4 | Groninger filler in SKAN isolator | Two 400ft$^2$ IMA | Up to 460,000 | 55M |
| Clinical Trial Manufacturing | IMA Life Sterifill 100 (MAC) | 30ft$^2$ IMA | Up to 10,000 | 1.2M |

| Post Fill Lines | Capabilities | Rate |
|---|---|---|
| Packaging Line 1 & 2 | Automated labeling, cartoning, serialization (manual available) | Up to 400 vials/minute |
| | Dabrico semi-automated, 4 per line | Up to 100 vials/minute per line |
| Inspection | Automated visual Inspection | Up to 600 vials/minute |

# Ocugen

| | Asset/Program | Indication | Current Status |
|---|---|---|---|
| **Vaccines** | **OCU500**<br>Inhaled mucosal vaccine | **COVID-19** | • License secured from Washington University<br>• Phase 1/2 pending FDA discussions<br>• Partnering with CanSino Bio – novel delivery device |
| **Gene therapies** | **OCU400 ****<br>AAV-hNR2E3 | **Gene mutation-associated retinal degeneration*** | • Completed Phase ½ study<br>• Encouraging safety and efficacy profile<br>• Phase 3 clinical trial on track |
| | | RHO Mutation (RP) | Phase 3 |
| | | Gene Agnostic (RP) | Phase 3 |
| | | CEP290 Mutation (LCA) | Phase 3 |
| | **OCU410**<br>AAV-hRORA | **Dry Age-Related Macular Degeneration (Dry AMD)*** | Phase 1/2 |
| | **OCU410ST**<br>AAV-hRORA | **Stargardt disease (orphan disease)** | Phase 1/2 |
| **Biologicals** | **OCU200**<br>Transferrin – Tumstatin | **Diabetic Macular Edema** | Phase 1/2 |
| **Cell therapies (Regenerative Medicine)** | **NeoCart®**<br>(Autologous chondrocyte-derived neocartilage) | **Treatment of Articular Cartilage Defects in the Knee** | • U.S. Regenerative Medicine Advanced Therapy (RMAT) designation<br>• Received concurrence from the FDA on the control (chondroplasty) to be used in the Phase 3 clinical trial<br>• Phase 3 clinical trial is planned to begin in 2024 |

***ORPHAN DRUG DESIGNATIONS in the U.S.; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of RP and LCA*

Speaker: Pushpendra Singh
Senior Director, Head of Product Development
Company: Ocugen Inc.
Website: https://ocugen.com/

# Walmart

- **Company Overview**
  - Walmart is a tech-powered, people-led omnichannel retailer dedicated to helping people save money and live better.
  - 10,500 stores and numerous eCommerce websites in 19 countries serve 255 million customers each week.
  - 2.1 million associates around the world; 1.6 million in the U.S.
  - Nearly 4,600 Walmart pharmacy locations nationwide, across 49 states, D.C., and Puerto Rico.
  - Walmart Healthcare Research Institute: Increasing access to health care research that may help lead to safer, higher quality, & more proactive health care, with a focus on underrepresented communities.


- Levi Simpson, Senior Director, Health & Wellness Sourcing Levi.Simpson@walmart.com
- Michael Edmonson, Director, Health & Wellness Strategic Sourcing Michael.Edmonson@walmart.com


- **Company Interests**
  - **Goal:** Build a resilient pharmaceutical supply chain that enables reliable access to affordable, high-quality pharmaceuticals.
  - Walmart has committed to spending $350 billion on products made, grown or assembled domestically, including pharmaceutical and medical supplies.
  - By sourcing products made, grown, or assembled in the U.S., Walmart seeks to promote supply chain surety and resilience and support creation of American jobs.
  - Walmart is investing in supply chain transformation to fulfill customer needs.
  - **Partnering opportunities of interest:** Companies or consortiums focused on delivering finished dose pharmaceuticals to the market.