

BioMaP-Consortium Industry Day

Tuesday, October 29, 2024

Scan the QR code
below for a digital
copy of the
agenda:



Wi-Fi Info:

- Network Name: Biomap Consortium
- Passcode: IndustryDay2024

Administrative Information

In-Person Attendees

- **Security:** Please keep badge visible throughout the event
- **Please silence electronic devices**
- **Posters displayed in the foyer for the duration of the event**
- **Questions?** Please see an ATI staff member at the registration desk.

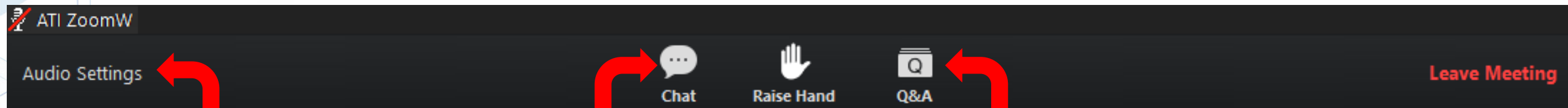
Wi-Fi Info:

- Network Name: Biomap Consortium
- Passcode: IndustryDay2024

Administrative Information

Virtual Attendees

- All participants are muted and will not be able to unmute themselves.
- Please use the “chat” function for technical difficulties only.
- Place all questions in the Q&A box.
- Please check your audio settings if you are having difficulties hearing us.



Check **Audio Settings** if
you can't hear us.

Click **Chat** to ask for
technical assistance.

Use **Q&A** for direct questions
on meeting content.

Agenda

08:00 AM - 09:15 AM	Registration and Networking Breakfast
09:15 AM - 09:25 AM	Opening Remarks
09:25 AM - 10:00 AM	Keynote
10:00 AM - 10:30 AM	Panel Discussion: “Onshoring Domestic Manufacturing Capability”
10:30 AM - 11:00 AM	Networking Break
11:00 AM - 12:00 PM	Panel Discussion: “Fireside Chat with BioMaP-Consortium 2024 Awardees”
12:00 PM - 01:00 PM	Working Lunch
12:30 PM - 01:00 PM	Reverse Networking
01:00 PM - 02:00 PM	Panel Discussion: “Overcoming Challenges in Supply Chain Manufacturing Scalability”
02:00 PM - 03:00 PM	BARDA Programs Discussion: “Lessons Learned from COVID Response”
03:00 PM - 03:30 PM	Networking Break
03:30 PM - 04:30 PM	BioMaP-C Executive Steering Committee
04:30 PM - 06:30 PM	Networking Reception

Keynote



Innovations in Biopharmaceutical Manufacturing: Scaling Up for Global Health

Chandresh Harjivan

Associate Director

Domestic Preparedness and Response to Pandemics and Biological Threats

Office of Pandemic Preparedness and Response Policy



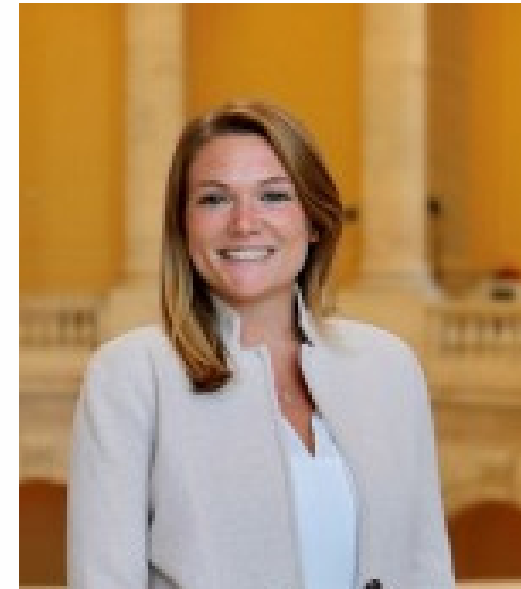
Panel Discussion: Onshoring Domestic Manufacturing Capability



Jill Hamaker
Partner, CGCN



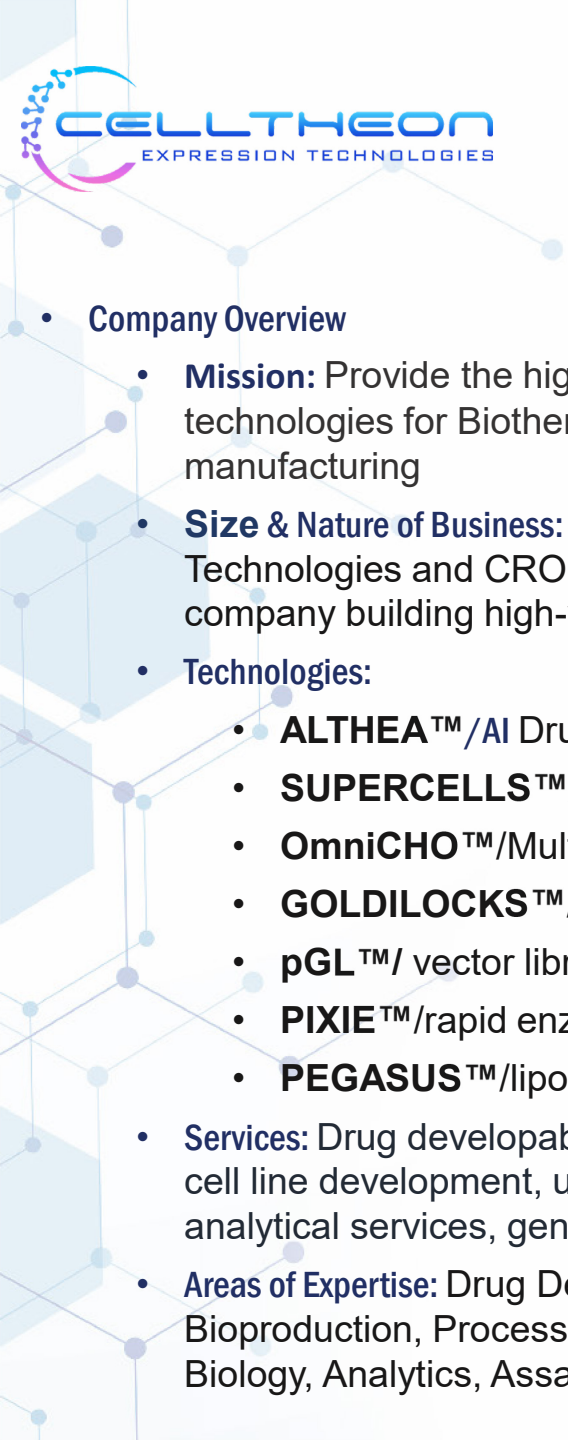
Melodie Ha
Sr Professional Staff Member
Minority, House Select Committee on
Strategic Competition between the
U.S. and the Chinese Communist Party



Sarah Gilbert
Chief of Staff, Rep. Neal Dunn –
Energy and Commerce Committee

Networking Break





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)



Optimizing Design of Single-Use Technology

The Vulcan Forge™

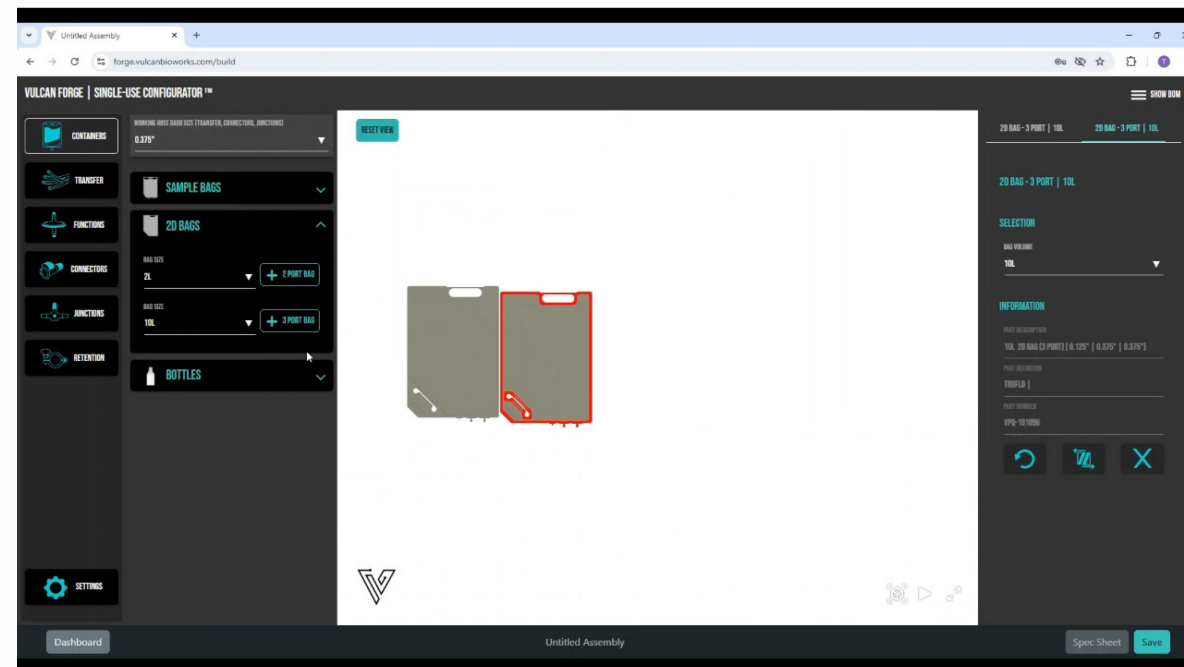
- 3D Neutral Design Tool
- Rapid Prototyping
- Reduction in engineering time
- Rapid RFP response

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

+1.215.987.7477 [mobile]

trayce.slumsky@vulcanbioworks.com

VULCANBIOWORKS.COM



GET STARTED DESIGNING

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;
Major programs completed for US DoD and BMGF;
Commercial launch of first product ongoing (Daisy Petal™)

Operations

22 Employees (>80% scientists and engineers)
~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
+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

Jennifer Manning, CEO, jennifer.manning@komobiosciences.com 301-605-5375

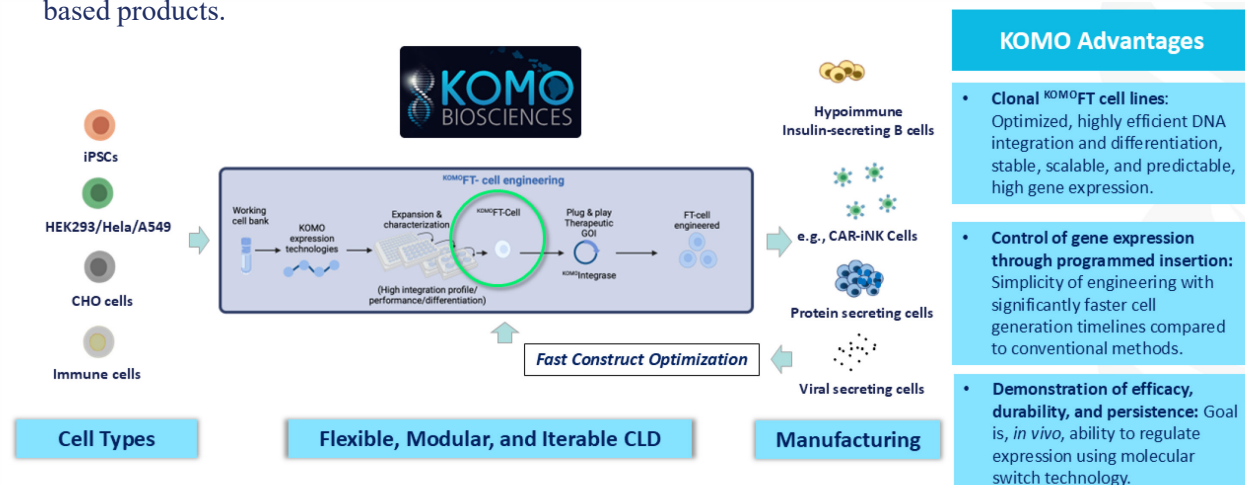
Thomas Page, CTO, thomas.page@komobiosciences.com 339-927-0678

Omid Harandi, CSO, omid.harandi@komobiosciences.com 814-933-9263

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.



Member Success Story

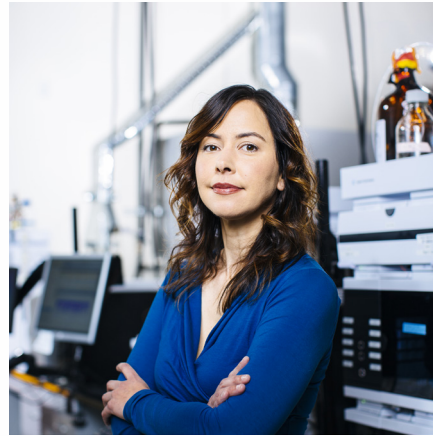
Victor Suarez, Blu Zone Bio



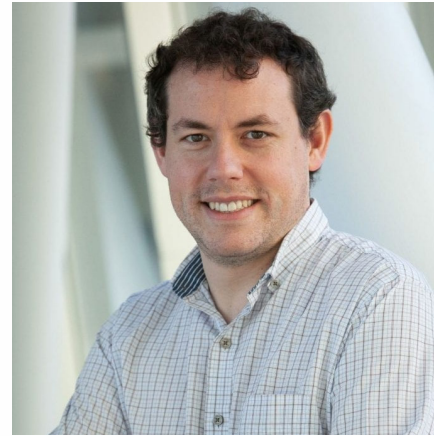
Panel Discussion: Fireside Chat with BioMaP-Consortium 2024 Awardees



Brooke Luck
BARDA Program Manager
BioMaP-Consortium



Christina Smolke
Co-Founder & CEO
Antheia Bio



Andrew Magyar
Co-Founder & CTO
Capra Biosciences



Kevin Webb
COO
API Innovation Center



Working Lunch

12:00 PM – 01:00 PM Working Lunch

12:30 PM – 01:00 PM Reverse Networking

01:00 PM – 02:00 PM Panel Discussion: “Overcoming Challenges in Supply Chain Manufacturing Scalability”

02:00 PM – 03:00 PM BARDA Programs Discussion: Lessons Learned from COVID Response

03:00 PM – 03:30 PM Networking Break

03:30 PM – 04:30 PM BioMaP-C Executive Steering Committee

04:30 PM – 06:30 PM Networking Reception

Reverse Networking





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

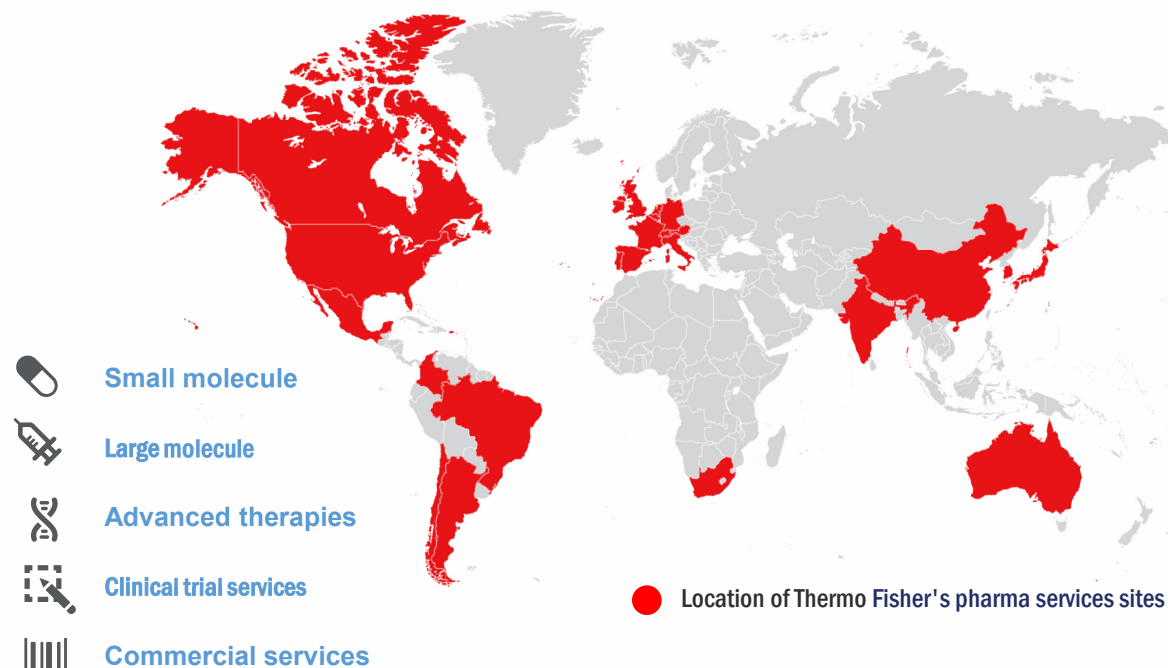
Ready to discuss your next project? Connect with us.

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

- 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**

RESILIENCE



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

GOVERNMENT CUSTOMERS

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



BIOLOGICS

Recombinant protein and monoclonal antibodies (mAb)



VACCINES

Live viruses and bacteria, viral vectors, VLPs to BSL2+



NUCLEIC ACIDS

mRNA DS with complete analytical capabilities



CELL THERAPY

Autologous and allogeneic platform technologies for blood and bone marrow-centered therapies



GENE THERAPY

Viral vector production for AAV, lentiviral and next-gen testing methods



DEVELOPMENT SERVICES



PLATFORM TECHNOLOGY



DRUG SUBSTANCE



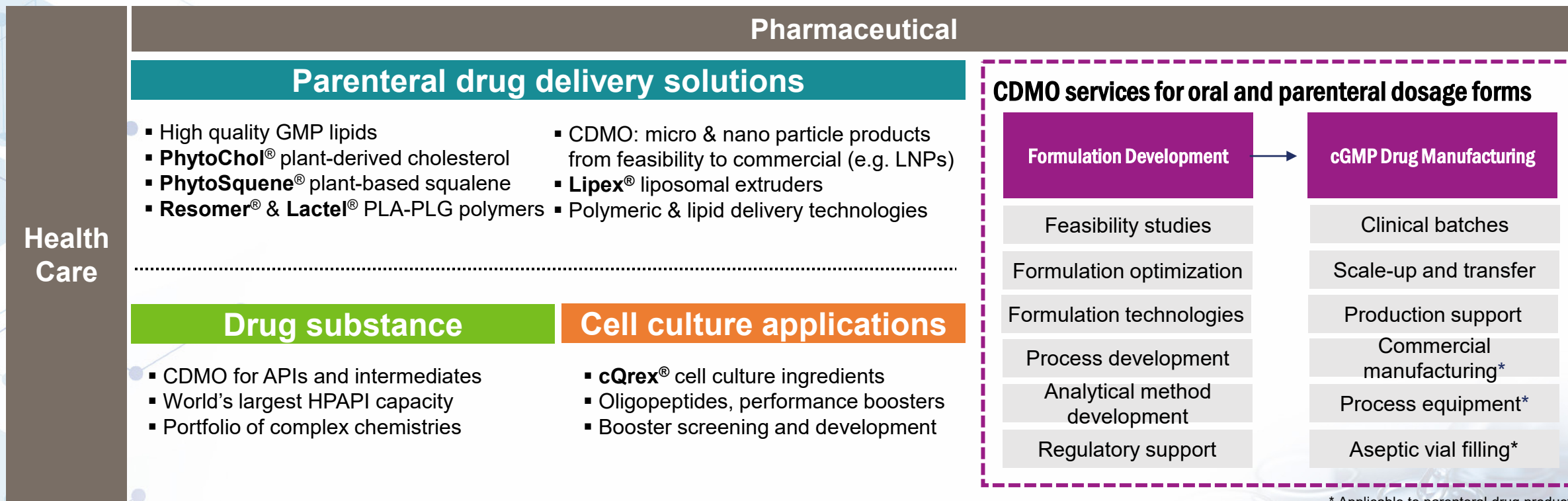
DRUG PRODUCT

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	4,500 headcount	>30 production sites	8 R&D centers	5 collaboration hubs
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Nutrition & Care – the life sciences division of Evonik



* Applicable to parenteral drug products

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

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

Glass & Plastics consumables
Manufacturing
Surface treatments

Partnering Opportunities:

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

4,000 employees
Global Field Application Scientists



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

Growth Areas:

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

19 manufacturing sites
30,000 products

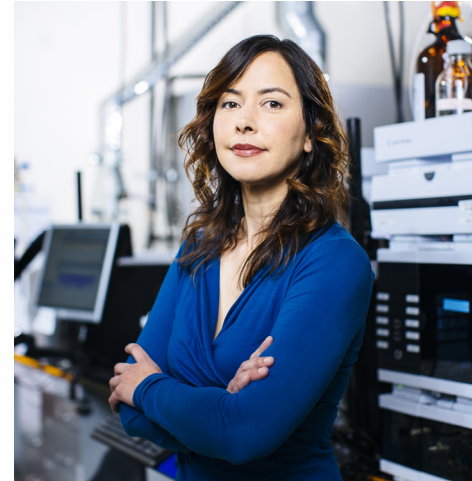
Panel Discussion: Overcoming Challenges in Supply Chain and Manufacturing Scalability



Sushma Savarala
Interdisciplinary Scientist,
IBMSC



Bob Huffman
Program Director,
Manufacturability &
Resilience, BARDA



Christina Smolke
CEO & Co-Founder,
Antheia Bio



Lisa Roessler
Chief Commercial Officer,
Amyris

BARDA Programs Discussion: Lessons Learned from COVID Response



Justin Yang
Executive Liaison,
BioMaP-Consortium



Mike Stebbins
Sr Vice President
Medical and Threat
Countermeasures Division,
Advanced Technology International



David Simon
Director,
Medical Countermeasures
Preparedness and Response,
BARDA



Tim Belski
Program Director,
Biopharmaceutical Manufacturing
Preparedness, BARDA



Networking Break





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



- **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

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

- **Company Interests**

- Training
- Pharmaceutical Automation
- Validation Services
- Augmented Reality



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

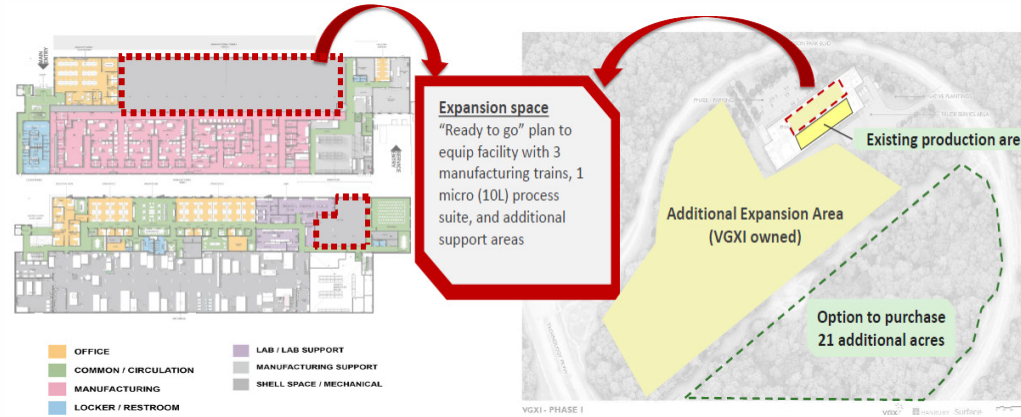
- Bidding on projects
- Subcontractor to your prime award



COMMITTED TO
HIRING MILITARY
SPOUSES

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

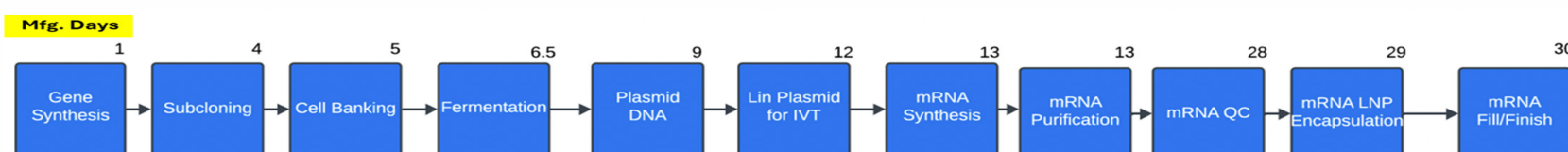
Young K. Park-President and CEO
Michael Stewart-Chief Operating Officer
Jeff Whitmore-Chief Commercial Officer
Stephanie Burke-Chief Accounting Officer

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.

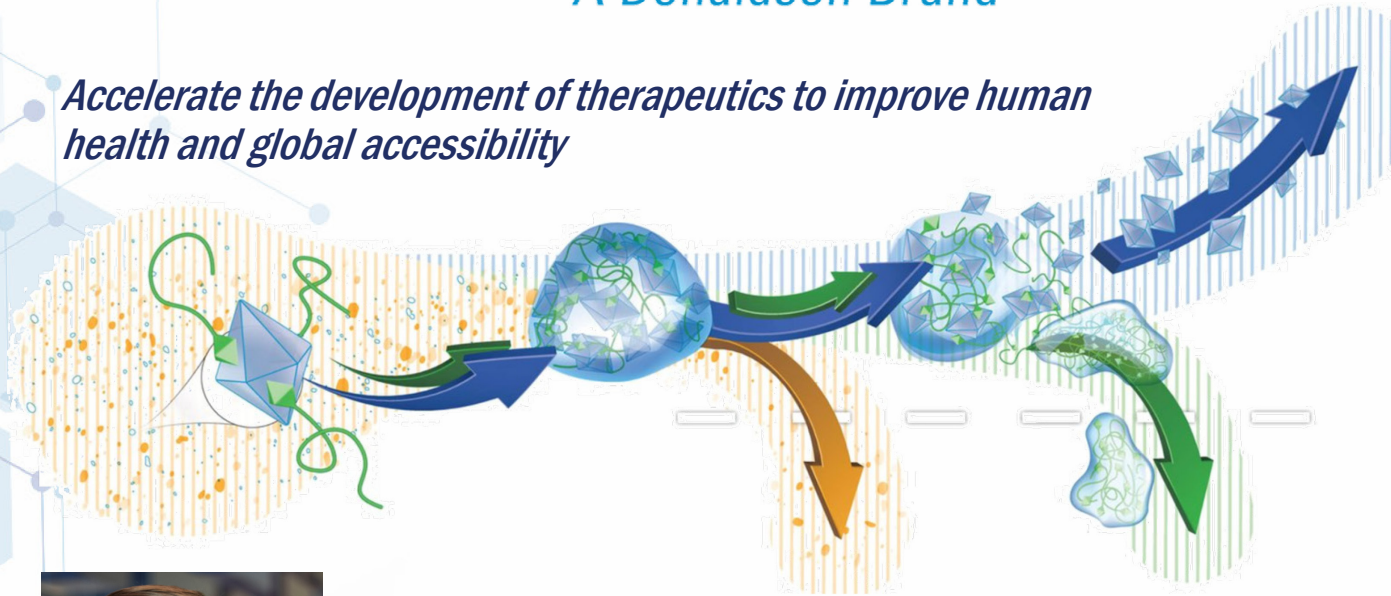
Anticipated impacts/ help to BioMaP Consortium Members

- ✓ 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.

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



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



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

Consortium Governance and Introduction to Leadership

Mike Stebbins

ATI Program Executive for the BioMaP-Consortium & Senior Vice President,
Medical and Threat Countermeasures Division, ATI



Articles of Collaboration

- Govern the rights and obligations of the Consortium Members as they relate to the Consortium and each other
 - Terms and Conditions
 - Definitions
 - Exit and Entry of Members
 - Intellectual Property
 - Data Rights
- Signed by Consortium Members and ATI (CMF)



Executive Steering Committee (ESC) Purpose



Assist BARDA, BioMaP, and ATI in their role overseeing the BioMaP-Consortium by:

- Reviewing consortium operations
- Examining and improving consortium best practices
- Adjudicating disagreements (member to member and member to Government)
- Addressing intra-consortium issues
- The ESC acts in an advisory role and thus has no expressed or implied power or authority

Executive Steering Committee (ESC) Key Roles



Promoting the key domain areas of:

- Industrial Base Expansion of Biomanufacturing Supply Chain
- Biomanufacturing Capacity Expansion and Reservation
- Advanced Biomanufacturing Technologies

The ESC will address the following:

- Status and expansion of MCM industrial base,
- Pre-positioning of contracts to expedite Public Health Emergency response,
- Understanding of capacity reservation and equipment warmbasing,
- Strengthening manufacturing capacity,
- Manufacturing and supply chain investments,
- Other topics as identified by BARDA, ESC members, ATI.

Executive Steering Committee (ESC) Key Roles



The ESC will seek alignment on how the BioMaP-Consortium meets:

- The National Biodefense Strategy,
- The American Pandemic Preparedness Plan,
- Executive Orders 13806, 14001 and 14017 as well as ASPR's and BARDA's Strategic Plans (2022-2026),
- The National Influenza Vaccine Modernization Strategy (2020-2030),
- The BioMaP mission.



Executive Steering Committee (ESC) Key Roles



Assisting BARDA and ATI with an understanding of manufacturing capacity, and fill/finish capacity to effectively respond to a public health emergency (PHE).

Providing industry feedback on contractual considerations for developing the necessary agreement language to meet the required timelines for non-PHEs (60-days) and PHEs (5-days).

Assisting in defining and outlining a near-term, mid-term, and long-term strategy to ensure the capabilities within the BioMaP-Consortium can be activated at a moment's notice, to include an overarching PHE Response/Activation Plan.

ESC Members

- **Critical Infrastructure: Peter Stolba**
- **Sterilization: Whitney Tull**
- **Delivery Devices: David Powell**
- **DS Manufacturing: Melissa Berquist**
- **Enabling Platforms: Flavia D'Souza**
- **Logistics & Supply Chain: Helen Bush**
- **Commercial Scale Manufacturing: Sean Kirk**
- **Drug Product & Fill/Finish: John Clapham**



Executive Steering Committee



Peter Stolba

Vice President of Business Development,
Halozyme

Critical Infrastructure

Peter Stolba is the Vice President, Business Development at Halozyme, bringing extensive experience in business operations and development across the pharmaceutical industry. Before joining Halozyme, Peter was Vice President, Business Operations at TriLink Biotechnologies / Maravai LifeSciences, where he played a key role during a transformative growth phase that included advancing nucleic acid technologies and contributing to pandemic response efforts. Prior to that, he worked within the Clinical Strategy and Supply Management organization at Pfizer, and at Halo Pharmaceutical, where he led operations serving pharmaceutical companies ranging from large multinationals to emerging biotechs in API and drug product manufacturing. Peter holds a BA in Business and Supply Chain Management and an MBA from National University.

Executive Steering Committee



Whitney Tull

Vice President of Business Development
& Government Affairs, STERIS

Sterilization

Whitney Tull joined STERIS in April 2019 to lead Government Affairs for the Company. In this role, she coordinates external engagement with a broad set of stakeholders comprising of associations, government officials, policy makers, and Customers for STERIS. Additionally, Whitney serves on STERIS's Senior Management Team (SMT), comprised of key senior leaders within STERIS to support the daily operation of STERIS's business and provides shared services key to STERIS's success and global compliance. Prior to joining STERIS, she managed U.S. Government Affairs for 11 years at Zimmer Biomet, another medical technology company. Whitney has a proven record of developing strategic plans to address critical corporate challenges, focused on healthcare policy.



Executive Steering Committee



David Powell

Vice President of Business Development and
Government Affairs, Grand River Aseptic Manufacturing

Delivery Devices

Dave has worked in the pharmaceutical industry for over 30 years, mostly in various roles and companies in the CDMO industry. The majority of his experience is in the fill-and-finish segment of the industry, from early days as an engineer in operations to an executive role in a leading CDMO. He has been a member of the industry trade organization Pharma & Biopharma Outsourcing Association (PBOA) since its inception in 2014, and has gained considerable experience in the past four years working directly with BARDA leadership on the COVID-19 PHE response, the Mpxv PHE response, and the Industrial Base Expansion program. Being the lead Government Affairs contact for Grand River Aseptic Manufacturing during this time, he gained knowledge of the BARDA organization and Government contracting.

Executive Steering Committee



DS Manufacturing



Melissa Berquist

Technical Head and Director of Commercial Development,
Resilience



Executive Steering Committee



Enabling Platforms

Flavia D'Souza

Co-Founder & Head of Quality, Sentio BioSciences



Executive Steering Committee



Helen Bush

Director of Supply Chain, Evonik

Logistics & Supply Chain



Executive Steering Committee



Sean Kirk

Principal, Arena BioPharma Consulting

Commercial Scale Manufacturing



Executive Steering Committee



Drug Product & Fill/Finish

John Clapham

Chief Executive Officer, BioTechnique



Networking Reception



BioMaP-Consortium Industry Day

Wednesday, October 30, 2024



Today's Networking Breakfast Sponsored By:



The **API Innovation Center (APIIC)** is a 501(c)(3) nonprofit public benefit organization headquartered in St. Louis, Missouri, dedicated to driving health security and economic growth for the nation and its citizens through U.S.-based production of critical medicines. Through investments in and collaboration across the pharmaceutical supply chain, APIIC coordinates with its established partner network to advance novel technology, optimize existing facilities, manufacture critical ingredients, and reshore the production of vulnerable medications to the U.S. In September, the Biden-Harris Administration, through the Administration for Strategic Preparedness and Response (ASPR), awarded APIIC with approximately \$14 million in funding under the Defense Production Act Title III to bolster U.S. pharmaceutical manufacturing. Learn more at apicenter.org.

Agenda



08:00 AM – 09:00 AM	Networking Breakfast sponsored by API Innovation Center
09:00 AM – 09:30 AM	Keynote Address
09:30 AM – 10:00 AM	Reverse Networking
10:00 AM – 10:10 AM	Transition to First ESC Breakout Session
10:10 AM – 10:55 AM	Executive Steering Committee Breakout Session #1
10:55 AM – 11:00 AM	Transition to Second ESC Breakout Session
11:00 AM – 11:45 AM	Executive Steering Committee Breakout Session #2
11:45 AM – 11:55 AM	Reconvene in Main Ballroom
11:55 AM – 12:15 PM	BARDA Contracting and Working with the Government
12:15 PM – 01:15 PM	Lunch
01:15 PM – 01:45 PM	Member Introductions
01:45 PM – 02:45 PM	Panel Discussion: "Regulatory Innovation"
02:45 PM – 02:50 PM	Closing Remarks and Farewell
02:50 PM – 03:00 PM	Transition & Setup for Matchmaking
03:00 PM – 04:45 PM	Networking and Matchmaking Session

Scan the QR code
below for a digital
copy of the
agenda:



Keynote



Ashish Jha

Dean, School of Public Health
Brown University

Global Health Security: The Role of Biopharma in Future Pandemics



Company Overview

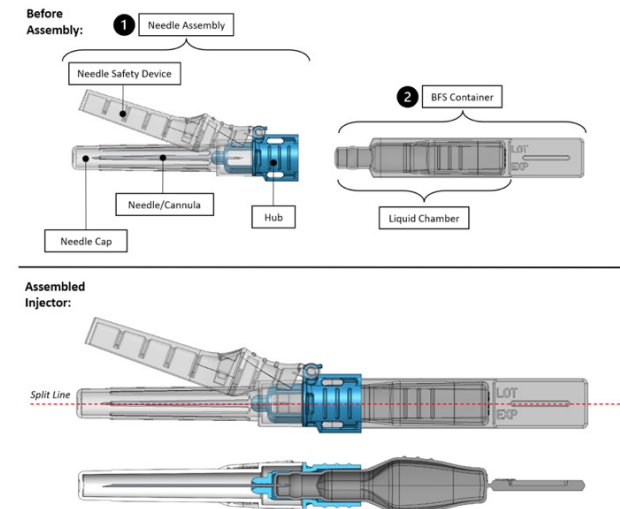
- Mission: To make injectable medicines and vaccines safe and accessible to everyone.
- Year Founded: 2019.
- Capabilities:
 - Developed first prefilled syringe product made with Blow-Fill-Seal (BFS) technology. FDA regulatory submission Q1-2025.
 - Established high-volume manufacturing capability for 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.



We make healthy possible.

Amneal Pharmaceuticals



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
kapiilg@amneal.com ; 631.633.2444

Company Interests

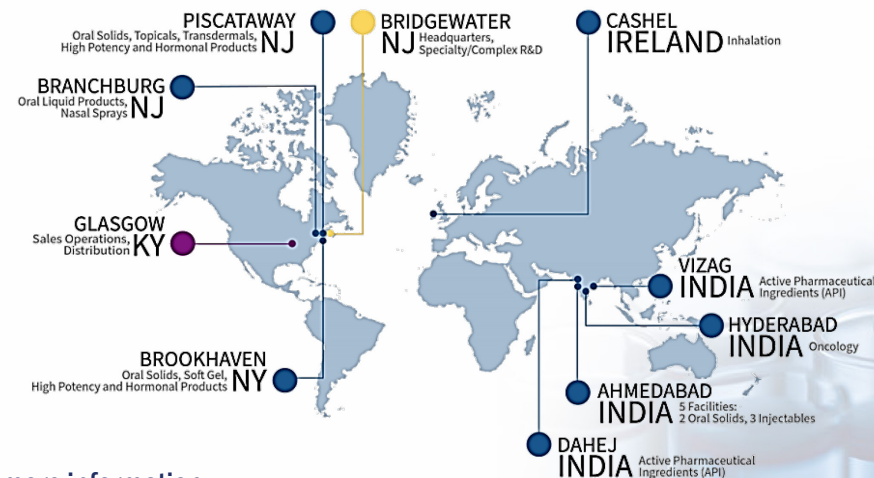
GROWTH AREAS

- **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 Inhaled mucosal vaccine	COVID-19	<ul style="list-style-type: none"> • License secured from Washington University • Phase 1/2 pending FDA discussions • Partnering with CanSino Bio – novel delivery device
Gene therapies	OCU400 ** AAV-hNR2E3	Gene mutation-associated retinal degeneration*	<ul style="list-style-type: none"> • Completed Phase ½ study • Encouraging safety and efficacy profile • Phase 3 clinical trial on track
		RHO Mutation (RP)	Phase 3
		Gene Agnostic (RP)	Phase 3
		CEP290 Mutation (LCA)	Phase 3
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)*	Phase 1/2
	OCU410ST AAV-hRORA	Stargardt disease (orphan disease)	Phase 1/2
Biologicals	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	Phase 1/2
Cell therapies (Regenerative Medicine)	NeoCart® (Autologous chondrocyte-derived neocartilage)	Treatment of Articular Cartilage Defects in the Knee	<ul style="list-style-type: none"> • U.S. Regenerative Medicine Advanced Therapy (RMAT) designation • Received concurrence from the FDA on the control (chondroplasty) to be used in the Phase 3 clinical trial • 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.

Executive Steering Committee Breakout #1



Take the elevator to MR floor

Critical Infrastructure with Justin Yang ** on behalf of Peter Stolba*
Patuxent/Embassy

Sterilization with Whitney Tull
Severn/Potomac

Delivery Devices with Jay Vasudevan **on behalf of David Powell*
Diplomat/Ambassador

Drug Substance Manufacturing with Melissa Berquist
Ballroom



Executive Steering Committee Breakout #2



Take the elevator to MR floor

Enabling Platforms with Flavia D'Souza
Diplomat/Ambassador

Logistics & Supply Chain with Helen Bush
Patuxent/Embassy

Commercial Scale Manufacturing with Sean Kirk
Severn/Potomac

Drug Products & Fill/Finish with John Clapham
Ballroom





Rebecca Harmon

Director of Contracts,
Advanced Technology International

BARDA Contracting and Working with the Government

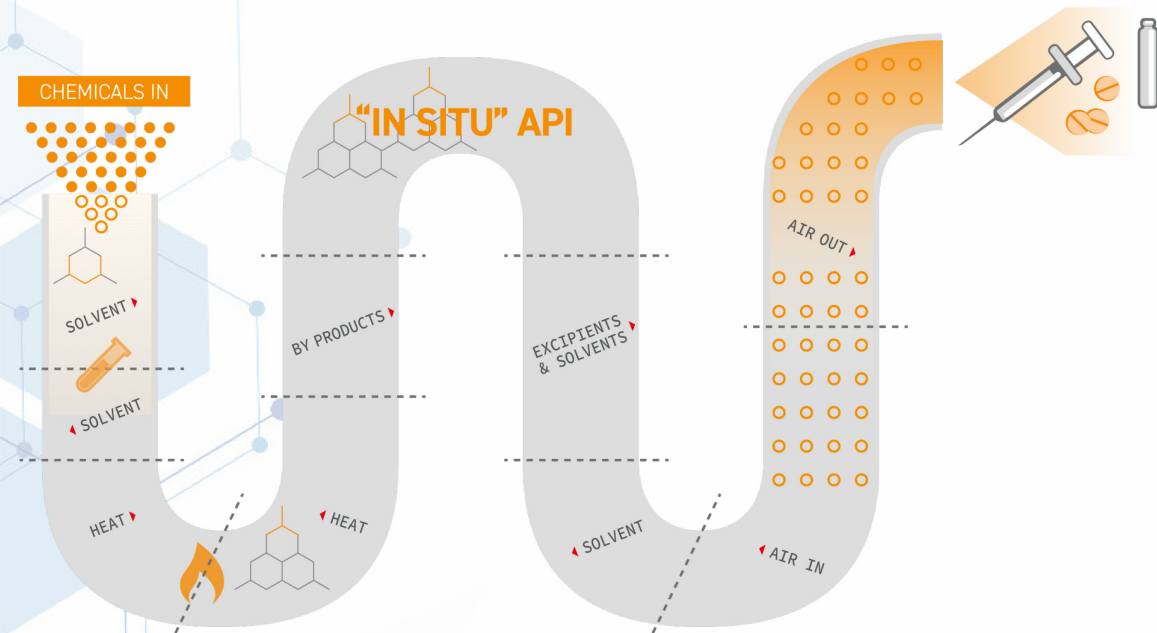


Lunch & Upcoming Agenda

12:15 PM – 01:15 PM	Lunch
01:15 PM – 01:45 PM	Networking Break
01:45 PM – 02:45 PM	Panel Discussion: Regulatory Innovation
02:45 PM – 02:50 PM	Closing Remarks and Farewell
02:50 PM – 03:00 PM	Transition & Setup for Matchmaking
03:00 PM – 04:45 PM	Networking and Matchmaking Session

Networking Break



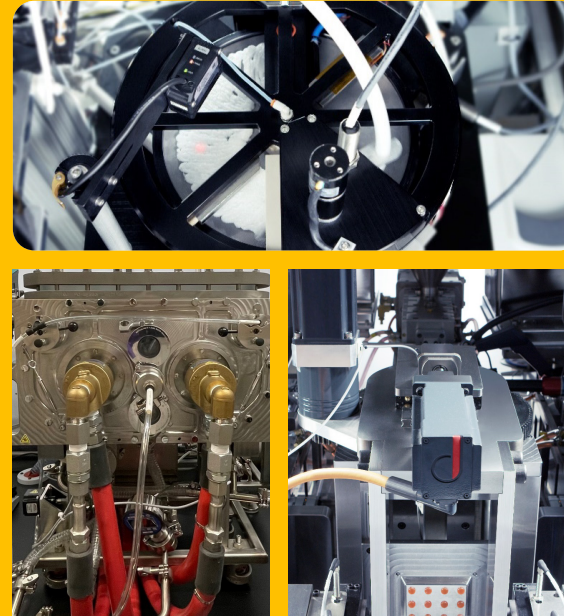


On-Demand Manufacturing of Pharmaceuticals

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

Contact/POC: Bayan Takizawa, Chief Business Officer
btakizawa@continuuspharma.com
 (781) 281-0099
<https://www.continuuspharma.com>

Targeted Solutions



End-to-end Solutions



Throughout the supply chain, ICM adds significant value



Development



Manufacturing



Sales/Distribution



Patient Care

Women
Owned
Small
Business



Innovating Qool Antibodies



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



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.



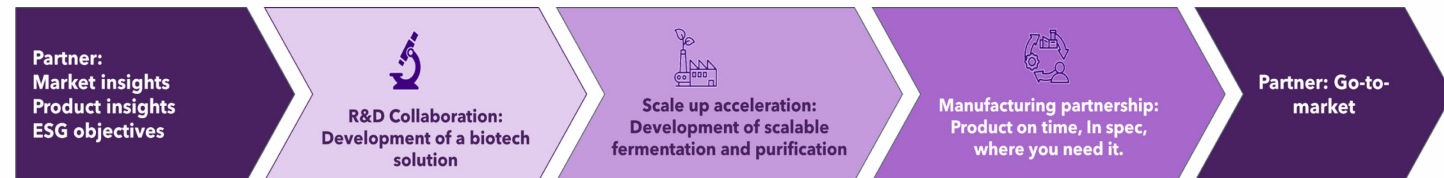
- **Company Overview**

- 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 (NSO, 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, predictive 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

Panel Discussion: Regulatory Pathways and Public-Private Partnerships in Health Emergencies



Kerrie DeMarco
Strategic Analysis Inc.



Jeremiah Kelly
Venable



Enlli Lewis
1 Day Sooner

FY25 Sneak Preview

- **Collaboration**
 - Virtual series (101's, AI/Legal, ESC working groups, member spotlights, etc.)
- **Events**
 - Oct Industry Day
 - Spring 2025 GMM/Industry Event
- **Trade Shows**
 - Jan 8-11, 2025: JP Morgan Health Week, San Francisco, CA
 - April 1-3, 2025: Interphex, New York, NY
 - April 21-24, 2025: World Vaccine Congress, Washington, DC
 - June 16-19, 2025: BIO 2025, Boston, MA
 - September 2025: BioProcess International, Boston, MA



Matchmaking

Table 1 – Walmart

Table 2 – Thermo Fisher

Table 3 – Resilience

Table 4 – Evonik

Table 5 – Corning

Table 6 – Avid Bioservices Inc

Table 7 – ApiJect

Table 8 – VGXI, Inc

Table 9 – Ocugen Inc

Table 10 – Donaldson Inc

Table 11 – Amneal Pharmaceuticals of New York, LLC

Table 12 – Jubilant HollisterStier

