Part of the Microbiome Movement Series

June 19-22, 2018 | Boston, MA
www.microbiome-summit.com

MICROBIOME DRUG DEVELOPMENT

Pioneering the Microbiome into Simply Effective Medicines

World Class Researchers Including:

Cathryn Nagler
President and Co-Founder
ClostraBio

Christophe Bonny
Chief Scientific Officer
Enterome Bioscience

Mark Smith
CEO
Finch Group Therapeutics

Anuk Das
Head, Scientific Innovation
Janssen Human Microbiome Institute

Jean Luc-Treillou
CEO
LNC Therapeutics

Trevor Lawley
Chief Scientific Officer
Microbiotica

Ken Blount
Chief Scientific Officer
Rebiotix

Daniel Couto
CTO
Vedanta Biosciences

Jessica Schneider
Associate Scientific Director
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WELCOME TO THE MICROBIOME MOVEMENT

As the knowledge of the microbiome continues to deepen, fundamental understanding of mechanism of action and demonstrating causality continue to improve. As such, The Microbiome Movement has become more committed than ever to work alongside innovative researchers and industry leaders to build events that focus on applied science and translate cutting edge microbiome R&D into safe, effective and commercially successful products across a number of industry-specific verticals.

Positioned at the heart of pharmaceutical, agricultural, nutritional and animal health R&D, The Microbiome Movement continues to help accelerate the discovery, development and delivery of breakthrough solutions to global challenges to benefit human health. For each specific industry where the microbiome will have a real impact, we're building an exclusive community for you to maximize the opportunity.

Alexander Puttick
Program Director
The Microbiome Movement

Mo Langhi
Commercial Director
The Microbiome Movement

2018/2019 Event Series

MICROBIOME ANIMAL HEALTH
May 2018: St. Louis, MO

MICROBIOME DRUG DEVELOPMENT
June 2018: Boston, MA

MICROBIOME SKIN HEALTH & DERMATOLOGY
September 2018: San Diego, CA

MICROBIOME HUMAN NUTRITION
November 2018: Boston, MA

MICROBIOME GUT-BRAIN AXIS
November 2018: Boston, MA

MICROBIOME DRUG DEVELOPMENT *Europe*
January 2019: Paris, FR

MICROBIOME AgBioTech
February 2019: Raleigh, NC

MICROBIOME MOVEMENT
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MICROBIOME DRUG DEVELOPMENT

Pioneer the Complex Human Microbiome into Simply Effective Medicines

The Microbiome Drug Development Summit continues to be the industry leading forum that focuses exclusively on the development and commercialization of microbiome-based therapeutics; with case-studies from target discovery all the way through to clinical trial development, manufacturing and beyond.

As microbiome-based therapeutics come in many forms, drug developers battle with critical challenges in product development such as pre-clinical evaluation, clinical trial design, CMC considerations and regulatory uncertainty. With that in mind, the **3rd Annual Microbiome Drug Development Summit** will once again unite KOL's, senior drug developers, microbiome-technology experts and breakthrough researchers to translate the human microbiome into simply effective medicines.

Six Reasons To Join Us

One entire focus day dedicated to '**Microbiome and Immuno-Oncology**' that aims to offer the latest discoveries in the human microbiome which could be harnessed to improve and enhance the efficacy and response rates of promising immuno-oncology drug candidates.

Two dedicated conference tracks on the main agenda that will explore drug development-focused case studies in two key areas:

- '**Discovery, Preclinical Development & Translational Research**' of next generation microbiome-based therapeutics across modalities most widely used within industry (bugs as drug, small molecules/bioactives, subtractive therapies).
- '**Clinical Development, Manufacturing & Commercialization**' of late stage microbiome candidates and how to accelerate them into the market and to patients in need.

Three interactive pre-conference workshops which will deep-dive into the hottest emerging tools and therapeutic areas which can be addressed by modulating the microbiome.

Four interactive panel discussions throughout the main conference covering the most pressing challenges in microbiome development including pre-clinical translation, clinical development, CMC and regulation.

Five emerging and pioneering biotech's showcased throughout the program, launched from some of the most cutting-edge academic research.

Six plus hours of allocated networking time scheduled throughout the main conference alone!

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MEET THE EXPERTS

David Donabedian
CEO
Axial Biotherapeutics

Ravi Starzl
CEO
BioIx

Jeffrey Heiser
Director Microbiology
Boston Analytical

Adrien Nivoliez
CEO
Biose Industrie

Adham Aljahami
Co-founder, CEO
Blue Turtle Bio Technologies, Inc

Ben Bradley
Technology Innovation Lead
CHAIN Biotechnology Ltd

Ian Parsons
Director Analytical Laboratories
Charles River Laboratories

Hajo Schiewe
Senior Sales Specialist Discovery Services
Charles River Laboratories

Stanley Hazen
Head of Preventative Cardiology & Rehabilitation
Cleveland Clinic

Manoj Dadlani
CEO
CosmosID

Dan Knights
CEO
CoreBiome

Cathryn Nagler
President & Co-Founder
ClostraBio

Bjorn Nielsen
Chief Scientific Officer
Clinical-Microbiomics

Julia Cope
Director Scientific Operations
Diversigen

Lisa Gamswell
Microbiome Project Manager
DNA Genotek

Xavier Duportet
CEO
Eligo Biosciences

Christophe Bonny
Chief Scientific Officer
Enterome Bioscience

Rodolphe Clerval
Chief Business Officer
Enterome Bioscience

Paul Carlson
Principal Investigator
FDA

Mark Smith
CEO
Finch Group Therapeutics

Kirk Taylor
Chief Medical Officer
Finch Group Therapeutics

Bharat Dixit
VP Bioprocess Development & Manufacturing
Finch Group Therapeutics

Phil Strandwitz
Co-Founder & CEO
Holobiome, Inc

Anuk Das
Head, Scientific Innovation
Janssen Human Microbiome Institute

Jean Luc-Treillou
CEO
LNC Therapeutics

Les Tillack
Managing Director
Luina Bio

Michael Romanos
CEO
Microbiotica

MEET THE EXPERTS

Trevor Lawley
Chief Scientific Officer
Microbiotica

Henry Haiser
Investigator III
Novartis Institutes for BioMedical Research (NIBR)

Els van Hoffen
Project Manager Health
NIZO

Magali Cordaillat-Simmons
Scientific & Regulatory Affairs Director
PRI

Massimo Mazorati
Director, Business Development
ProDigest

Dean Scholl
VP, Research
Pylum Biosciences

Eva Berkes
Chief Scientific Officer
Quorum Innovations

Mike Frodsham
Pharmaceutical Development Manager
Quay Pharma

Ken Blount
Chief Scientific Officer
Rebiotix

Edward Burd
Head of Regulatory Affairs
Rebiotix

Christopher Belnap
CEO
Resilient Biotics

David Cook
EVP & Chief Scientific Officer
Seres Therapeutics

Ward Peterson
CEO
Symberix

Isil Tuzun Weber
Process Engineer
SynCo Bio Partners

Caroline Kurtz
Head of Translational Sciences & Product Development
Synlogic Therapeutics

Dick Schwartz
SVP Process Development & Manufacturing
Synlogic Therapeutics

Christian Furlan Freguia
Director of Research
Synthetic Biologics

Jessica Schneider
Associate Scientific Director
Takeda

Daniel Couto
CTO
Vedanta Biosciences

Bruce Roberts
Chief Scientific Officer
Vedanta Biosciences

David Beno
Chief Scientific Officer
Xeno Biosciences

> Great speakers, great topics, and good engagement. I found it one of the best meetings on the microbiome that I've been to in a few years.
>
> **Evolve Biosystems Previous Speaker & Attendee, Microbiome Human Nutrition Summit 2017**

CONFERENCE DAY ONE
THURSDAY, 21 JUNE

8.20 Chairperson Opening Remarks

Optimizing Drug Target Validation & Candidate Selection- Crosstalk between the Microbiome & the Host

Introduction and Purpose:
It's clear that research in the human microbiome has already redefined our understanding of human health and disease. Using sophisticated science, the microbiome can provide alternative approaches to known targets, as well as elucidate new targets. The purpose of this theme will be to demonstrate novel research that substantiates the link between microbial diversity/function with gastrointestinal, metabolic, neurological and cancer diseases.

David Cook
EVP and Chief Scientific Officer
Seres Therapeutics

8.30 Inflammatory Bowel Disease & Immuno-Oncology: the Prospects for Clinical Immune Modulation by Microbiome Drugs

Julia Cope
Director Scientific Operations
Diversigen

9.00 Microbiome Tools & Trends for the Pharmaceutical Industry
- Delivering actionable results through ideal study design in microbiome projects
- Industry standards on quality are nascent and expanding
- Analyzing the microbiome across disease states

Cathryn Nagler
President and Co-Founder
ClostraBio

9.30 The Gut Microbiome, Immunity and Allergic Disease

Henrik Bjorn Nielsen
Chief Scientific Officer
Clinical-Microbiomics

10.00 What Microbiome Systems Biology Can Tell About Mechanism
- Studies have shown associations between host disorders and microbiome compositions without indicating underlying mechanisms
- Demonstrating how integrative systems biology and ultra-high resolution microbiomics can provide important clues to identify key mechanistic links
- Outlining how advances in integrative systems biology can indicate function to previously uncharacterized proteins

10.30 Speed Networking
This session is the ideal opportunity to get face-to-face time with many of the brightest minds working with microbiome-based therapeutics. Benchmark against the industry leaders and establish meaningful business relationships to pursue for the rest of the conference and beyond.

11.00 Morning Refreshments

Track A: Discovery & Pre-Clinical Development

Bugs as Drugs Discovery & Identification

Introduction and Purpose:
New research in NGS and multi-omic technologies is expected to greatly assist with the accurate mining of the animal microbiome to help identify new industrial applications within nutrition, in-feed additives and pharmaceuticals. The purpose of this theme will be to review how researchers are applying new technologies to accelerate discovery and development.

11.30 Leveraging Reverse Translation to Develop Microbial Therapies
- How broad spectrum-microbial interventions such as FMT show proven safety profiles across a range of therapeutic areas
- Outlining how Finch Group use machine learning to mine high-throughput molecular data generated from FMT trials to identify bacteria associated with positive clinical outcomes
- Translating these targets to create rationally selected bacterial cocktails, such as FIN-524 for the treatment of IBD

Mark Smith, CEO, **Finch Group Therapeutics**

11.50 Novel Therapeutic Approaches Targeting the Microbiome in Metabolic Diseases
- Understanding the role of the gut microbiome in metabolic diseases
- From clinic and medical food to microbiome-targeted drugs
- Discussing the challenges of strain identification and culture of LBPs

Jean Luc- Treillou, CEO, **LNC Therapeutics**

12.10 Delivery, Survival, Engraftment & Activity of LBPs in the Gastrointestinal Tract
- Validated *in-vitro* technology platforms are a key tool for the pre-clinical work in LBPs development
- The SHIME® is an enabling technology which allows an integrated simulation of the full GI tract, including lumen, mucosa and host
- The SHIME® allows you to investigate the mechanism of action of LBPs in areas of the gut, which are not easily accessible, generating data complementary to *in vivo* studies

Massimo Mazorati, Director Business Development, **ProDigest**

Track B: Clinical Development & Commercialization

CMC/Manufacturing & Scale-Up

Introduction and Purpose:
As companies prepare to scale from early phase product development to commercial scale microbiome therapeutics, challenges around guidelines and best practice relating to CMC/Manufacturing that ensure microbiome-based products are produced to GMP-compliant standards. The purpose of this theme will be to review the current industry thinking on manufacturing.

11.30 Quality & GMP Aspects of Manufacturing Live Biotherapeutic Products – a CMO Quality Perspective
- Defining the product (cell bank characteristics, recombinant or not, API or Finished Product, Dosage Form)
- Food or drug?
- Addressing GMP manufacturing challenges (early clinical trial material)

Tina Christensen Ram, Head of Quality, **Luina Bio**

11.40 Panel Presentation: Manufacturing & Scaling Microbiome-Based Therapeutics
- What are the common challenges with manufacturing LBPS? How are organizations modulating capabilities to accommodate for that?
- How to successfully interact with global regulatory agencies to meet guidelines and optimize production
- Are new standards required to ensure GMP and safety of samples?
- How are organizations thinking about scaling manufacturing as they progress through clinical development? What are the greatest hurdles associated with this?
- What are the most successful case-studies that organizations can learn from?

Bharat Dixit, VP Bioprocess Development & Manufacturing, **Finch Group Therapeutics**

Daniel Couto, CTO, **Vedanta Biosciences**

Dick Schwartz, SVP Process Development & Manufacturing, **Synlogic Therapeutics**

Adrien Nivoliez, CEO, **Biose Industrie**

12.10 Oral Delivery of Live Bio-Therapeutics: Drug Product Development for FIM Studies
- Key CMC considerations for the development of an LBT product
- Critical factors affecting timelines when outsourcing GMP manufacturing activities of LBT drug products
- Incorporating 'quality' (systems and regulations) into early phase dosage form design of LBT products

Mike Frodsham, Pharmaceutical Development Manager, **Quay Pharma**

12.40 Lunch & Networking

Small Molecule Discovery & Identification

Introduction and Purpose:

Often cited as "Drugs from Bugs", many researchers are either identifying and characterizing microbial by-products that modulate host function or introduce compounds that act on known pathways, known as "microbiome mimics" that can be applied as a viable therapeutic.
Due to the unknown regulatory and manufacturing requirements for cocktail-based therapeutics, many organizations are exploring these novel methodologies to modify microbiome composition and structure. The purpose of this theme will be to review how organizations are discovering and validating new therapeutics based on these techniques.

1.40 Drugs from Bugs – Using Metagenomic Dataset Delivers Druggable Targets

- Using the human microbiome as a source of bioactives and novel targets
- Outlining quantitative and functional metagenomics to identify novel therapeutics
- Gut-restricted therapeutics

Christoph Bonny, Chief Scientific Officer, **Enterome BioScience**

2.00 Microbial Metabolites That Modulate Host Functions

- Building a pre-clinical microbiome program to uncover small molecule mediators of disease relevant microbe/host interactions
- Identifying new pharmacological targets that assimilate microbiome-derived signals
- Opening a framework that embraces external collaborations with academic and clinical researchers

Henry Haiser, Investigator III, **Novartis Institutes for Biomedical Research**

2.20 Developing Clostridum-Based Microbial Therapeutics for the Treatment of Chronic Gut-Related Diseases

Ben Bradley, Technology Innovation Lead, **CHAIN Biotechnology Ltd**

Early Stage Clinical Trial Design & Development

Introduction and Purpose:

With a number of important therapeutics entering a clinical setting, there are still major questions surrounding best practice in designing, scaling and progressing through clinical trials. Without a doubt, successful in-human clinical efficacy data will help cement the success of microbiome-based therapeutics in the future. The purpose of this theme will be to outline industry developments when executing clinical trials for microbiome-based therapeutics whilst addressing the challenges that still remain in an emerging space.

1.40 Validation of the Intellicap® System as a Tool to Study Changes in the Small Intestinal Microbiota in a Dietary Intervention Study

- Learning how the Intellicap system can be used a minimally-invasive tool for sampling from the human small intestinal tract
- Outlining the methods and results for a randomized cross-over controlled dietary trial in 10 healthy males
- Data shows the Intellicap system can be used as an important tool in the discovery of biomarkers and clinical validation

Els van Hoffen, Project Manager Health, **NIZO**

2.10 Translational Development and Clinical Trial Design of a Synthetic Biotic for Rare Disease

Caroline Kurtz, Head of Translational Sciences & Product Development, **Synlogic Therapeutics**

2.30 You've Collected Your Microbiome Samples – Now What?

- Reducing the phenomena of "garbage in" = "garbage out"
- Key considerations in analyzing your microbiome data
- Driving actionable results and discoveries in a controlled and reproducible way

Manoj Dadlani, CEO, **CosmosID**

Telling the Perfect Pre-Clinical Story for Microbiome-Based Therapeutics

Introduction and Purpose:

Prior to entering clinical development, organizations aim to create viable pre-clinical packages that consist of valuable *in-vivo* and computational results that demonstrate efficacy and provide clues to potential modes of action. The purpose of this theme will be to review what pre-clinical development means in microbiome-based drug development and how research may redefine our definition of this concept.

2.40 The Supporting Role of the Pre-Clinical CRO when Conducting Microbiome Research

- What are the critical pre-clinical challenges that will hinder the power of the microbiome in drug development?
- When thinking about different modalities, how do organizations have to consider study design, dosing regimes, efficacy results?
- Does this industry need *in-vivo/in-vitro* models? Are there any "gold standard" models?
- How do researchers design optimal pre-clinical packages for different recipients (investors, regulators)? Are the hallmarks for success different?

Panelists

Anuk Das, Head, Scientific Innovation, **Janssen Human Microbiome Institute**

Mike Romanos, CEO, **Microbiotica**

Ian Parsons, Director Analytical Laboratories, **Charles River Laboratories**

Mark Smith, CEO, **Finch Group Therapeutics**

Hajo Schiewe, Senior Sales Specialist Discovery Services, **Charles River Laboratories**

2.40 Clinical Considerations of Rationally Designed Live Bacterial Cocktails

Bruce Roberts, Chief Scientific Officer, **Vedanta Biosciences**

3.00 Panel Discussion – Clinical Development of Microbiome-based Therapeutics

- How do organizations have to think about clinical trial design when developing a microbiome-based therapeutic? (considering patient selection, primary/secondary endpoints and outcomes)
- What are the key learnings from clinical programs that have been conducted for microbiome-based therapeutics?
- In the microbiome, is clinical efficacy as valuable as MoA elucidation?

Panellists

Kirk Taylor, Chief Medical Officer, **Finch Group Therapeutics**

Caroline Kurtz, Head of Translational Sciences and Product Development, **Synlogic Therapeutics**

3.40 Afternoon Refreshments & Networking

Regulatory Challenges for Microbiome-Based Therapeutics

Introduction and Purpose:

As microbiome therapies constitute a novel paradigm in recent drug development, a clear regulatory framework that addresses key safety and biocontainment issues should be evaluated for successful implementation. Despite the rise in notoriety across the pharmaceutical industry, only a few regulatory agencies have provided clarity over the regulatory hurdles when developing a microbiome-based therapeutic. The purpose of this theme will be to outline how leading regulatory bodies in the US and EU currently review microbiome candidates across a number of modalities.

Paul Carlson
Principal Investigator
FDA

4.10 Regulatory Considerations for Live Biotherapeutic Products & Bacteriophage Therapy

- Overview of the IND process
- Discussing current FDA review of live biotherapeutic products and other microbiome based biologics
- Discussing current FDA review of bacteriophage therapy

Magali Cordaillat-Simmons Scientific and Regulatory Affairs Director **PRI**	4.30	**Regulatory Challenges for Registering Live Biotherapeutic Products in Europe** • Presenting the EU regulatory bodies in Europe in relation to the pharma industry • Discussing the regulatory status in which probiotics were commercialized within the EU and how the landscape is evolving • Sharing the pharmaceutical regulatory framework • Understanding the system and how to interact with authorities in order to clarify the regulatory framework
Paul Carlson Principal Investigator **FDA** **Magali Cordaillat-Simmons** Scientific and Regulatory Affairs Director **PRI** **Edward Burd** Head of Regulatory Affairs **Rebiotix**	4.50	**Panel Presentation – Building Clear Regulatory Guidelines for Microbiome-Based Therapeutics** • How can companies work with regulatory agencies to accelerate speed to market? • How do we overcome challenges in measuring purity, safety and product characterization when regulating microbiome-based therapeutics? • Food vs Pharma: What are the key considerations for making this determination as an organization in the microbiome? • How does drug modality impact regulatory guidelines? • What are the differences in strategy for US vs EU registration of microbiome-based therapeutics? • What are the critical considerations when working with regulators to understand key design elements for seamless product development?
	5.30	**Chairperson Closing Remarks**
	5.40	**End of Conference Day One**

CONFERENCE DAY TWO
FRIDAY, 22 JUNE

8.20 Chair's Opening Remarks

Biomarkers for Personalized Microbiome Diagnostics - Guiding Therapeutic Decisions

Introduction and Purpose:
As our knowledge of the microbiome's impact on health and disease continues to increase, one application area of the microbiome has remained fairly understudied: it's role as guidance for treatment monitoring and prediction of response of known therapeutics. In the near future, clinically relevant microbiome biomarkers could help with the diagnosis of disease, help predict the outcome of treatment options as well establish personalized therapeutics based on the microbiome. The purpose of this theme will be to review the research going into the development of microbiome diagnostics through growing clinical evidence for more sophisticated patient stratification.

Jessica Schneider
Associate Scientific Director
Takeda

8.30 Prioritizing Indications for Microbiome Therapeutics: Where do we go after C.difficile and UC?
- Identifying the next priority indications for microbiome therapeutics
- Understanding and expanding the causality toolkit for microbiome drug discovery
- Selecting patients: will companion diagnostics be the key?

Dan Knights
CEO
CoreBiome

9.00 Powering Microbiome Discovery with Big Data
- Many microbiome studies are under-powered or low resolution. Actionable microbiome discovery requires careful study design, larger sample sizes, and high-resolution data
- With advances in informatics, shallow shotgun sequencing provides far higher resolution than 16S sequencing for the same cost
- For the first time, researchers can affordably profile species and functional variation in large, dense longitudinal studies

Ken Blount
Chief Scientific Officer
Rebiotix

9.30 Using the "Microbiome Health Index" to Identify Indicators for Microbiome Restoration

Michael Romanos
CEO
Microbiotica

10.00 Precision Discovery of Novel Biomarkers Based on Deep Microbiome Analysis

Jeffrey Heiser
Director Microbiology
Boston Analytical

10.30 Application of Multivalent Vaccine Manufacturing Testing Schemes in cGMP Characterization of Microbiome Defined Drug Products
- Navigation through the microbiome regulatory process can be based on testing schemes established in multivalent manufacturing programs
- Environmental Monitoring (EM) program design requires additional processes for microbiome product manufacturing
- Implementation of anaerobic best practices is critical in the accurate characterization of microbiome drug products

11.00 Morning Refreshments & Networking

Track A: Discovery & Pre-Clinical Development

Gut-Brain Axis to Develop Therapeutics

Introduction and Purpose:
Emerging data suggests that there is a link between changes in the gut microbiome and neurological disease and disorders. The purpose of this theme will be to outline recent scientific advances in unravelling the gut-brain connections and potential pathways to harness these findings for novel therapeutic approaches.

11.30 Targeting the Gut Microbiome to Treat Neurological Conditions: Elucidating a Causal Relationship Between the Gut & Disease

- Harnessing the link between the gut microbiome and CNS using a suite of in vitro and in vivo approaches to develop a new class of therapeutics in ASD and Parkinson's
- A discussion of AB-1224, a first-in class commensal bacteria-based intervention for the treatment ASD and a summary of promising preclinical data
- Reviewing the current hallmarks of success and looking to the future

David Donabedian, CEO, **Axial Biotherapeutics**

11.50 GABA Modulating Bacteria of the Human Gut Microbiota

- Identification of the first bacterium from the human microbiota completely dependent on GABA for growth
- Using this organism to identify and culture a panel of diverse GABA-producing bacteria
- GABA production and consumption capabilities are widespread throughout the microbiota, suggesting these organisms can modulate levels of this important neurotransmitter

Phil Strandwitz, Co-Founder & CEO, **Holobiome**

Track B: Clinical Development & Commercialization

Late Stage Clinical Development of Microbiome-Based Therapeutics

Introduction and Purpose:
As organizations scale into late-stage clinical development, it's important to consider the challenges that lie ahead. The purpose of this theme will be to review current progress at this stage and review solutions that will accelerate clinical development.

11.30 Curating Massive Amounts of Biological Material & Phenotypic Data for Efficient & Reproducible Microbiome Discovery

- Of the enormous pre-clinical and clinical developments in the microbiome, what proportion have generated real insight?
- How are leading investigators collecting biological samples in a standardized way to aggregate data, compare clinical trials and reproduce results?
- What solutions are currently available to conduct population scale research that lead to meaningful insights?

Lisa Gamwell, Microbiome Product Manager, **DNA Genotek**

11.40 Clinical Development of Ribaxamase, an Oral-Beta Lactamase Intended to Protect the Gut Microbiome and Prevent C.Difficile

- Learning how beta-lactam antibiotics excreted in bile can damage gut microbiome
- How ribaxamase (SYN-004) is designed to degrade residual antibiotics in the GI tract and protect the microbiome from antibiotic mediated side effects
- Successful Phase 1 and 2a studies showing safety/ efficacy and reducing risk of CDI by 71.4 %

Christian Furlan Freguia, Director of Research, **Synthetic Biologics**

12.00 Human Microbiota: Proof of Concept to Production

- General overview of live microbial production processes
- Step by step process description with emphasis on process development
- Considerations prior/ during tech transfer focusing on specific requirements for pharma (GMP) production

Isil Tuzun Weber, Process Engineer, **SynCo Bio Partners**

12.20 Lunch & Networking

Subtractive Microbiome Therapeutics Discovery & Identification

Introduction and Purpose:

Broad based subtractive approaches through the use of antibiotics can lead to unintended reduction of commensal bacteria, causing the patient to become vulnerable to chronic disease, including C.Difficile infection. Subtractive based therapies, including bacteriophages, focus on targeting highly specific strains of bacteria through the use of breakthrough technology. The purpose of this theme will be to review current practice in the discovery and pre-clinical development of subtractive therapeutic microbiome strategies that treat disease.

Ward Peterson
CEO
Symberix

1.20 Symbiotic Drugs For Good Bugs Gone Bad

- Exploring how gut bacteria are involved in xenobiotic metabolism, sometimes causing severe GI toxicities
- Symberix has designed small molecule drugs (termed "Symbiotic Drugs") which selectively eliminate harmful bacterial activity without killing enteric bacteria
- Demonstrating that these Symbiotic Drugs improve the clinical efficacy and reduce toxicities of existing drugs

Ravi Starzl
CEO
Bioplx

1.40 A New Approach to Therapeutic Durability and Integration

- Reviewing the challenges of subtractive methods in microbiome therapies to achieve clinically relevant results
- Challenging the 'bottoms-up" approach of investigating these therapies to identify clinically observable and relevant biome-wide changes
- Exploring Bioplx's "top-down" approach by beginning with hypotheses driven by clinically observable phenomenon to pursue MoA elucidation and engineer the microbiome across a range of disease conditions including MRSA

Dean Scholl
VP, Research
Pylum Biosciences

2.00 Engineered Contractile Nanotubes for Precision, Targeted Microbiome Editing

- Introducing Avidocins, contractile, protein nanotubes that function as antimicrobial agents
- Developing a platform that precisely targets these bacterial targets to a species, or strain of choice
- Editing microbiome populations that remove problem bacteria without harming beneficial health-promoting flora

Xavier Duportet
CEO
Eligo Biosciences

2.20 Using Synthetic Biology for Targeted Antimicrobials & Microbiome Engineering

- How to design mechanisms that adapt to pathogen resistance
- Addressing the main challenges associated with treating microbiome imbalances with the limited tools the community has at their disposal
- Demonstrating the value of sequence-specific antimicrobials that can selectively eradicate harmful bacteria from the microbiome

2.40 Afternoon Refreshments & Networking

Innovation Power-Hour: Breakthrough Ideas in Microbiome Drug Development

Introduction and Purpose:

Emerging start-ups in the human microbiome are continuing to apply pioneering research and apply that information to create new therapeutics across a variety of complex disease states. The purpose of this theme will be to showcase novel methods to target the microbiome from the companies beginning their microbiome journey.

Eva Berkes
Chief Scientific Officer
Quorum Innovations

3.10 What is the Role of Biofilms in Human Microbiome Discovery?

- Outlining the underestimated clinical relevance in the disease treatment and microbiome drug discovery paradigms
- Why biofilms can be difficult to grow and do not fit within a developed diagnostic or regulatory rubric
- Discussing the relationship between biofilms, human disease and their applications to microbiome drug discovery

David Beno Chief Scientific Officer **Xeno Biosciences**	**3.30 Pharmacological Mimicry of the Gastric Bypass Microbiome to Treat Obesity** • Proposing the "air hypothesis" as a mechanism to explain the profound weight loss and associated microbiome shifts observed after gastric bypass surgery • Creating XEN-101, a first-in-class, oral anti-obesity medicine that demonstrates substantial weigh loss and corresponding shifts in the gut microbiome • Exploration of early preclinical and clinical pilot efficacy data
Adham Aljahami Co-founder, CEO **Blue Turtle Bio Technologies, Inc**	**3.50 Known Unknowns - An Outsiders Perspective On The Cost Of Being at The Forefront Of Biotech's New Chapter** • Sharing the impact of being an outsider and an amateur in the space and the cost plated on two young biotech founders • Exploring the costs of working in an industry filled with uncertainty • Pushing forward new forms of medicine that have been recently slowed by speculation and regulations
	4.10 Chairperson Closing Remarks
	4.20 Close of Summit

"A very productive conference allowing to get a true status of the industry from pharma, biotech and interfaces with academia."

Assaf Oron, CBO, BiomX

"A great mix of basic scientific research and product development from universities, multinationals and start-up companies. Congratulations."

BioConsortia

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Powering Microbiome Science with Big Data™

Expertise Partner

CoreBiome is a genomics platform company focused on accelerating discovery for customers in the pharmaceutical, agriculture, and research communities, to unleash the translational potential of the microbiome. The Company's proprietary BenchMark™, BoosterShot™, and Core Analysis™ platforms provide a rapid and high-resolution measurement and interpretation of microbial diversity. The recently launched BoostArray™platform provides an ideal method for the characterization of strain libraries. CoreBiome was founded in 2016 based on intellectual property originating from the University of Minnesota. The founding team has collective experience processing and analyzing hundreds of thousands of microbiome samples.

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BClinical-Microbiomics is a client-centric contract research organization specialized in extracting key biological insights from microbiome metagenomics and big data integration, including metabolomics, transcriptomics and clinical data.

Through development of tailor-made bioinformatics tools, Clinical-Microbiomics assists partners across pharmaceutical, food, nutritional and agricultural industries to answer specific biomedical questions and increase the success rate of their drug discovery and development projects. Our team of molecular biologists and bioinformatics scientists put you at the forefront of microbiome science.

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Expertise Partner

Boston Analytical, the Life Sciences Division of Alpha Analytical, is a cGMP compliant, FDA/DEA registered, ISO/IEC-17025:2005 certified analytical laboratory located in Salem, NH. We can provide all of the identity, purity and potency analyses necessary to characterize your microbiome product. Boston Analytical has a proven track record with sponsors on a variety of Microbiome programs including both Spore Fraction and Defined Drug Product manufacturing processes. We employ Labware Inc's™ LIMS & ELN software with on-line data access for your convenience.

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Expertise Partner

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NIZO is world leading in contract research for better food and health. We believe food and health are becoming increasingly connected. That's why we are convinced that working closely with our customers, leading food and health companies, is the only road to success. For pharma companies we perform discovery and development programmes related to gut health, oral health and skin health with a specific focus on microbiome modulation.

www.nizo.com

QuayPharma

Program Partner

Quay Pharma is experienced in formulation development and is one of very few companies licensed to provide clinical manufacturing materials containing live bacterial strains being targeted for delivery to, and in, the digestive, urogenital, otorhinologic and pulmonary tracts. Understanding the client dosing requirements for the live biotherapeutic, Quay can prepare a formulation development strategy to bring your live bacterial strain rapidly and effectively to First in Man studies aiming to provide a formulation with the best chance of clinical

www.quaypharma.com

charles river

Program Partner

For more than 70 years, Charles River has seen technologies advance and new diseases emerge. By carefully cultivating our portfolio, our growth has become a continuous strategic effort in anticipating tomorrow's drug development needs. As a result, our microbiome services have continued to grow to meet demand. Clients can purchase germ-free mice, submit samples for health surveillance, or outsource their microbiome studies to us.

www.criver.com

Innovation Partner

LuinaBio is Australia's most experienced biopharmaceutical CDMO's with 20 years' experience in our field. More specifically Luina carries out microbial aerobic and anaerobic fermentation, yeast fermentation, cell banking, vaccine production, process development, analytical services, stability studies, storage and distribution of investigative material for clinical studies.

www.luinabio.com.au

Innovation Partner

CosmosID®, based in Rockville, Maryland, is a genomics big data company focused on rapid identification of microorganisms for pharmaceutical R&D, molecular diagnostics, public health, food safety, agriculture, and environmental applications. The CosmosID platform uses proprietary sequence analysis algorithms to accurately profile all microorganisms in a metagenomic sample employing next-generation DNA sequencing.

www.cosmosid.com

Innovation Partner

Biose Industrie is a Contract Development and Manufacturing Organization (CDMO), specialised in Live Biotherapeutic Products. Founded in 1951 by pharmacists and microbiologists, Biose Industrie has been manufacturing drug substance and drug products based on microorganisms for 60 years. Company, with 10 000m² of GMP facilty, offers product development at laboratory and pilot scale specialised in microbiology for aerobie and anaerobie strains and is Drug GMP certified for the manufacturing of API, clinical batches and commercial products.

www.biose.com/en/cdmo

Innovation Partner

ProDigest is a product leader in the development of unique laboratory models of the human and animal gastrointestinal tract (SHIME®). These models allow to obtain unique insight in gut processes associated to the intestinal fate of actives and to study the complete gut microbiome under controlled conditions. ProDigest is globally active as a service provider for food and pharmaceutical companies and installs its technology in selected R&D facilities around the world. Furthermore, ProDigest has set up a number of product development projects in relation to the gut microbiota management and novel biotherapeutics

www.prodigest.eu

Innovation Partner

SynCo Bio Partners B.V. is a world leading GMP contract manufacturer focused to support its customers with clinical and commercial supply with microbial drug substance manufacturing; live microbial biotherapeutics, vaccines, proteins and polysaccharides as well as aseptic fill and lyophilization of a wide variety of biologics. SynCo has more experience than any other CMO to support a live microbial project. Our commitment to quality management and approval by several international authorities ensures regulatory compliance and patient safety for clinical and commercial development worldwide. You can trust us to make it right.

www.syncobiopartners.com

Innovation Partner

DNA Genotek Inc focuses on providing high-quality biological sample collection products and end-to-end services for microbiome. Our OMNIgene product line for gut, oral, vaginal and animal sampling and our GenoFIND™ services, a complete suite of microbiome services including wet lab and bioinformatics analysis, provide solutions for every step of your microbiome research, from sample to answer.

www.dnagenotek.com

Exhibition Partner

Since 1978 List Biological Laboratories, Inc. has been the leading manufacturer of bacterial products for research. With our extensive experience growing microorganisms, List Labs now offers GMP manufacturing of Live Biotherapeutic Products (LBP) for phase clinical trials with experience developing products for several microbiome companies from tech transfer through GMP production. With extensive experience with cultivation of aerobic and anaerobic bacteria, production of master cell banks, and lyophilization development, List Labs is your one-stop shop for your next microbiome project.

www.listlabs.com

Conference Partner

Jennewein Biotechnologie GmbH is a leading company specializing in the production of rare functional monosaccharides and oligosaccharides for nutritional, pharmaceutical, cosmetic and medical applications.The company produces rare monosaccharides such as L-Fucose and Sialic Acid. It also manufactures an extensive portfolio of HMO's such as 2'-Fucosyllactose, 3'-Fucosyllactose, Lacto-N-tetraose, Lacto-N-neotetraose and acidic HMO's like 3'-Sialyllactose and 6'-Sialyllactose.

www.syncobiopartners.com

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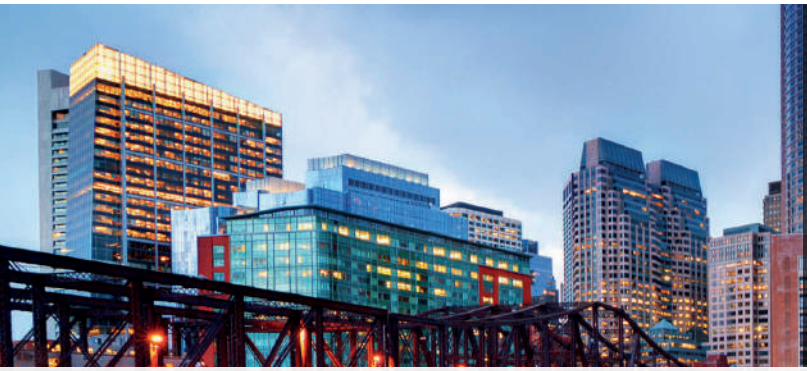
Jim Brown, Senior Fellow & Director in Computational Biology, GSK, Previous Speaker & Attendee



VENUE

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