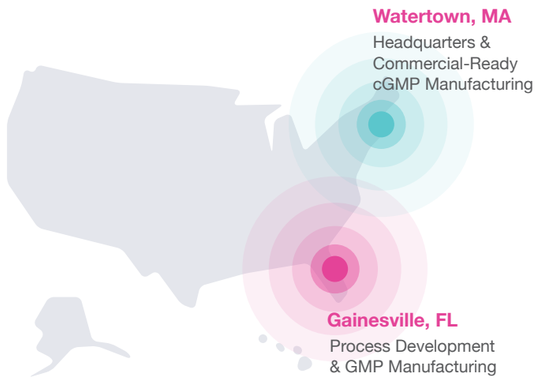
Facilities Purpose Built For Microbiome

Arranta Bio is exclusively dedicated to providing process development and cGMP manufacturing services for natural isolates and engineered live biotherapeutic products (LBPs) targeting diseases linked to the human microbiome.

Our Center of Excellence for Process Development & Early Clinical Supply is an expansion of the former Captozyme facility in Gainesville, Florida, where our expert team continues a legacy of 10 years dedicated to developing and scaling up processes for aerobic, anaerobic and spore-forming organisms.

The commercial-ready cGMP facility in Watertown, Massachussetts willl be operational by late 2020, which will offer large-scale manufacturing using state-of-the-art equipment and facilities, enabling Arranta Bio to take your microbiome projects from concept to commercial supply.



Microbiome by the Numbers

Human Microbiome
~3,300,000 genes

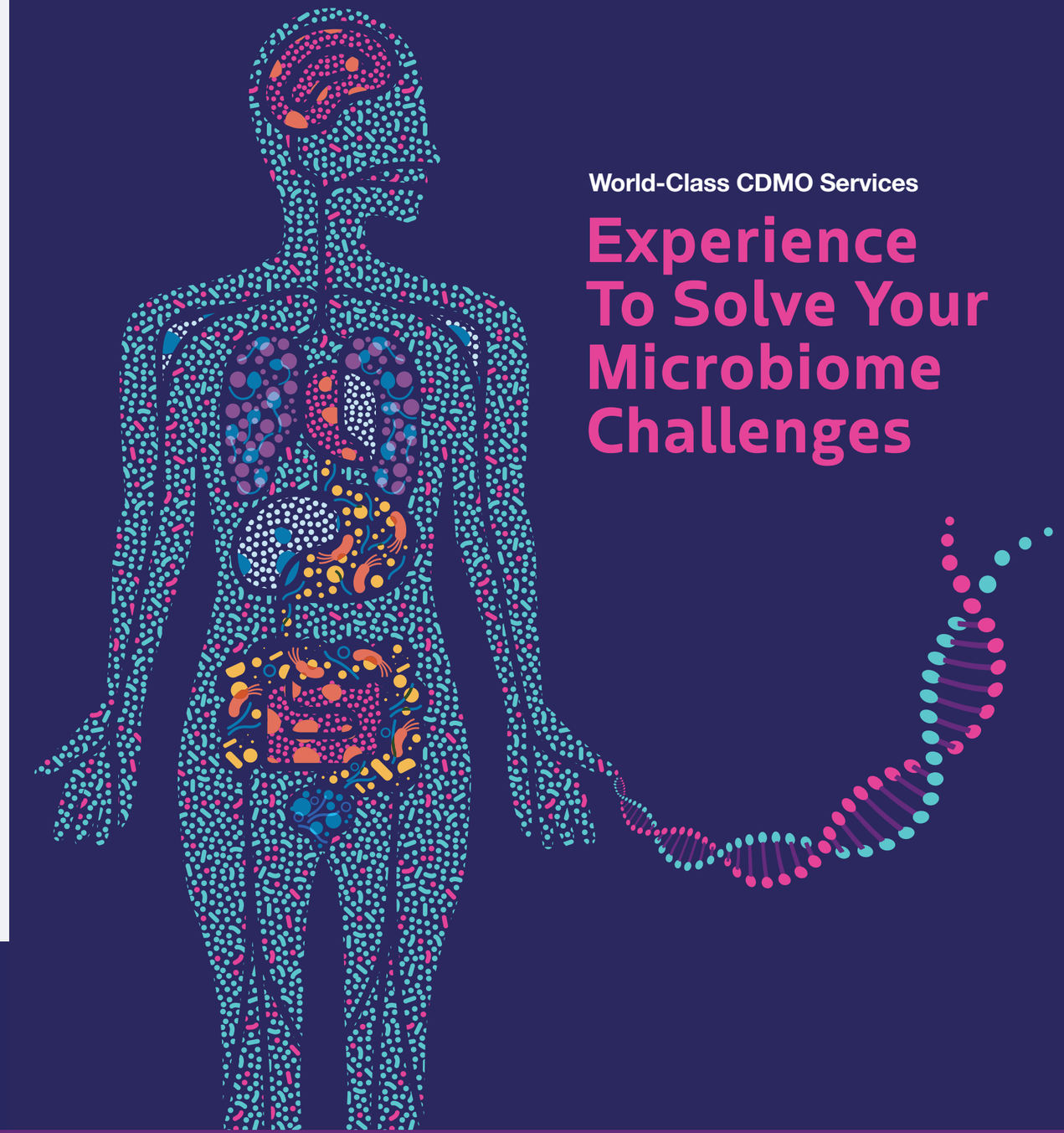
Human Genome
~22,000 genes

37 trillion
estimated average number of cells in a human

10-100 trillion
number of symbiotic microbial cells in one person

1,200
species of microbes found in human intestines

>100
species of microbes living in a human stomach



ARRANTABIO

World-Class CDMO Services

Experience To Solve Your Microbiome Challenges

ARRANTABIO

Admin Office & Commercial-Ready Manufacturing & cGMP Manufacturing
480 Pleasant St. Ste. C300
Watertown, MA 02472

Process Development & cGMP Manufacturing
1622 NW 55th Place
Gainesville, FL 32653

T. +1 833 ARRANTA
E. info@arrantabio.com

www.arrantabio.com

Unlocking Your Microbiome Potential

Arranta Bio is delivering on its vision to build the best-in-class microbiome contract development and manufacturing organization (CDMO).

Our merger with veteran CDMO, Captozyme in November 2019, and subsequent investment in expansion of the Gainesville, Florida facility, provides the dedicated manufacturing focus and expertise to deliver active pharmaceutical ingredients (APIs) for first-in-human Phase I/II clinical studies.

Arranta Bio is committed to investing $100,000,000 in building its capabilities to help support microbiome pioneers - a project on track for completion in 2020. Our Florida facility, combined with construction of a commercial-ready manufacturing facility in Watertown, Massachussetts, establishes 100,000 square feet of facilities purpose built for aerobic, anaerobic and spore-forming organisms, and an experienced team ready to solve your challenges and take your project all the way from concept to commercialization.

Over a 10-year period, our Gainesville team has produced **more than 135 species spanning 80 genera**, amassing an unrivaled understanding of the manufacturing needs for natural isolates and engineered live biotherapeutic products (LBPs).

Arranta is the market-leading CDMO dedicated to supporting pioneering innovators in the development of healthcare therapies based on LBPs targeting gut health and other microbiome-related diseases.

10+
years of expertise

>125
species produced

100,000
sq.ft. of facilities

Microbiome CDMO Services

Types of Microorganisms

Aerobic

Anaerobic

Spore-forming

Media Screening

- Proprietary panel of 22 Arranta media blends (AMB™)
- Screening of up to 22 different animal-component-free media blendsfor optimal growth of your microorganism

Process Development & Scale-Up

- Cell banking optimization
- Research Cell Banks
- 3 L, 5 L, 14 L fermenters
- Optimization of fermentation parameters
- Optimization of cell harvest and isolation
- Proprietary panel of 16 pre-formulation Arranta cryoprotectants (ACP™)
- Lyophilization and formulation development

Analytical Development, Qualification and Validation

- Assay development
- Appearance
- pH & OD
- Moisture content (Karl Fisher)
- Potency
- Total cell count
- Viable cell count
- Non-viable cell count
- Live / dead staining
- Gram staining
- Sequencing (16S)
- Colony morphology
- Endospore staining (spore forming test)
- Bioburden
- Antibiotic sensitivity screen
- Capsule weight
- Disintegration
- Uniformity of content

cGMP Drug Substance Manufacturing

- cGMP Master and Working Cell Banks
- 500 L cGMP fermenter
- Addition of 2x 2,000 L GMP fermenters (Q4, 2020)
- Cross contamination control with 100% isolated rooms
- QC testing and QA release

cGMP Drug Product Manufacturing

- Formulation
- QC testing and QA release
- Lyophilization
- Encapsulation (Q3, 2020)
- Primary packaging (bottles and sachets)

Quality Assurance & Regulatory Support

- Compliant with cGMP (US FDA)
- Support package available for IND documentation
- Commercial ready facility and cGMP systems

Stability Studies

- Stability studies conducted according to ICH Q1 and ICH Q5 guidelines
- -70ºC, -20ºC, +5ºC, +25ºC/60% RH, +30ºC/65% RH and +40ºC/75% RH conditions available for stability studies

Long-Term Storage (cGMP)

- Temperature-mapped cGMP storage of MCB and WCB
- Temperature-mapped cGMP storage of Drug Substance or Drug Product
- All storage on an alarm system