



650 Pleasant Street • Watertown • MA 02472

June 22, 2021

Via Electronic-Email

Simon Corson
Town Planner
Town of Boxborough
scorson@boxborough-ma.gov

Re: Arranta Bio Boxborough Facility is designed to operate at Biosafety Level 2

Dear Simon:

Arranta Bio is a Contract Development and Manufacturing Organization (CDMO) that provides services to clients for the development and manufacturing of therapies known as live biotherapeutic products (LBPs) associated with the human microbiome. The human microbiome consists of trillions of symbiotic microbial cells and are primarily bacteria in the gut.

Arranta Bio operates facilities in Gainesville, FL and Watertown, MA. The Gainesville site has been in operation for 10 years. Arranta Bio's Watertown site was completed in 2020, and provides LBP product development and manufacturing for clinical trials and, once the products are approved by regulatory authorities, will manufacture LBPs for commercial use. The Watertown site also provides plasmid DNA manufacturing services. Our future Boxborough facility, located at 1414 Massachusetts Avenue, will support clients with clinical trial and commercial production of LBP therapeutics.

All of Arranta Bio's facilities have been designed and built to be fully compliant with the Good Manufacturing Practice (GMP) of the U.S. Food and Drug Administration Code of Federal Regulations (Part 21) and the European Advanced Therapy Medicinal Products' regulations and relevant guidance for use with LBPs. All of Arranta Bio's facilities (and manufacturing processes) have been designed to be compliant with National Institutes of Health Biosafety Level 2 physical containment guidelines and biosafety levels for manufacturing of biological therapeutic products.

The process and facility design in Boxborough (just like in Arranta Bio's facilities in Watertown, MA and Gainesville, FL) leverages proven technology and standards including the use of closed systems and physical and temporal segregation of the process to ensure compliance with the governing regulations. A robust facility design further mitigates risks of operator safety and contamination by leveraging clean room processing, room pressurizations, standard operating procedures, and automation to ensure the process is in control.

Arranta Bio has a rigorous vetting process for incoming materials, which includes assessing incoming biological agents for occupational health and safety risks and contamination control. Arranta Bio's Watertown, MA, facility operates under a Biosafety Permit from the Town of Watertown. An Arranta Bio Institutional Biosafety Committee (IBC) assesses biological agent risk groups and biosafety levels and informs Watertown of new projects, risks, and controls. The biological agents that Arranta Bio works with are generally low risk, Risk Group 1 (RG-1) to RG-2 agents as they tend to be naturally occurring human gut bacteria. Therefore, Arranta Bio operates at a Biosafety Level 2 (BSL-2) as a standard,



which builds upon BSL-1. Arranta Bio does not work with RG-3 or RG-4 materials and therefore will not exceed BSL-2 practices and containment.

If you have any questions on Arranta Bio's Biological Safety Program, please do not hesitate to contact me by emailing Karisa.Hanson@ArrantaBio.com.

Sincerely,

A handwritten signature in black ink that reads "Karisa Hanson". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Karisa Hanson, CSP
Director, Global Environmental Health and Safety
Arranta Bio

Cc: Lana Gladstein, Chief Legal Officer and General Counsel
Richard Quinby, Vice President, Engineering and Facilities