5TH MICROBIOME MOVEMENT DRUG DEVELOPMENT | BOSTON

Originally set to take place June 8 - 10, the ***5th Microbiome Movement Drug Development - at the Park Plaza Boston,*** has been rescheduled for October 19 - 21. Boston Analytical is looking forward to meeting all conference attendees in person at this later date.

In a better effort to get to know the team that will be on site October 19 - 21, we invite you to attend our virtual conference series. Whether you were planning to attend the conference or are simply looking for a testing facility, our goal is to provide you with the ability to make an educated and informed decision as to why Boston Analytical is the best testing facility for your project.

At Boston Analytical we continuously pride ourselves in our ability to help you find the right service for your business. The following pages provide a snapshot of the services we offer, including links to our website that contains further information for your individual or business needs. This also includes ways to get in touch with our team of business development representatives - please reach out to Kristin, Eileen or Theresa to start your partnership with us today.

We'll see you in October!

meet our team!

KRISTIN DANGELO
Director Of Business Development

EILEEN HEFFERNAN
Senior Account Executive
New England Territory

THERESA EDICK
Account Executive
New England Territory

Boston ANALYTICAL

VIRTUAL
CONFERENCE SERIES

A SPECIAL **PRESENTATION BY**

JEFF HEISER
Director of Microbiology

LBP CGMP CHARACTERIZATION AND STABILITY:
Designing an Effective Testing Program on the Road to Commercialization

Once the science has determined the production strains targeting to treat the disease indication, there are many regulatory hurdles that must be overcome on the path towards clinical trials, and ultimately commercialization. Setting up an effective, compliant release testing and stability regimen are paramount.

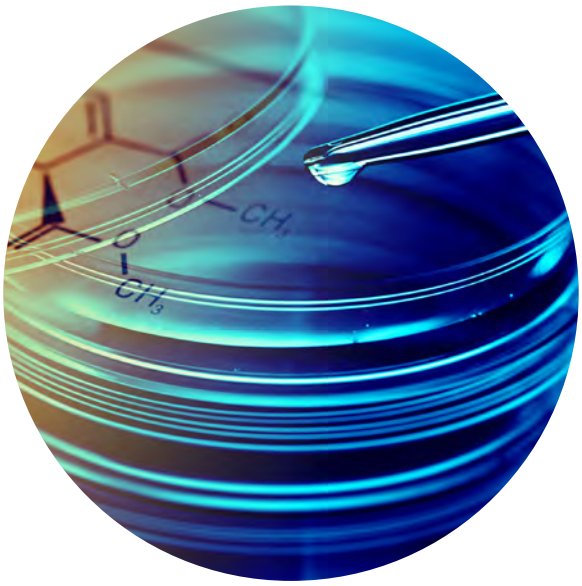
This talk provides detailed background on the following:

- Evaluation of successful clean room commissioning, with both microbial ingress and egress considerations specific to LBP manufacturing.
- Cell culture and raw material characterization programs
- Assay design and validation of viability-based titer and identification assays with molecular technologies.
- Cold Chain Transport stability program design and execution; ensuring testing regimens are timely and accurate when dealing with a living product.
- Release testing in support of clinical trials and IND filings
- Building upon biologic manufacturing and testing practices to characterize LBP drug substance and drug product.

PRESENTATION TO TAKE PLACE
Tuesday October 20, 9:30 - 10AM | Park Plaza Boston

SNAPSHOT **OF OUR**
MICROBIOLOGY TESTING SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

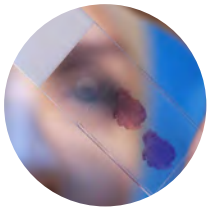


MICROBIOME SERVICES

Boston Analytical has a proven track record on a variety of microbiome programs, including spore fraction and defined drug product manufacturing processes. We can provide you with the assistance needed to help your gut microbial imbalance drug advance on its development path. ***Learn More.***

SNAPSHOT **OF OUR MICROBIOLOGY TESTING SERVICES**

CLICK ANY SERVICE FOR FURTHER INFORMATION



MICROBIAL IDENTIFICATION

We can accurately identify a microbial contaminant the same day the isolate is submitted, using either a 3130XL Genetic Analyzer or the Bruker Biotyper® MALDI-TOF system. With this information quickly in hand you can make adjustments to your manufacturing process to avoid contamination. ***Learn More.***

PHARMACEUTICAL TESTING

Providing a complete spectrum of microbiological testing for pharmaceuticals, including bacterial endotoxin testing, biological indicator testing, VHP sterility testing, and in vitro microbial kill rate studies. These tests can help you verify there are no endotoxins present in your manufacturing process stream. ***Learn More.***

MEDICAL DEVICES TESTING

We help you ensure medical devices are sterile, offering sterility testing, bioburden validation and testing, and bacterial endotoxin testing. We can assist you by providing information that will indicate if there are any sterility issues with your medical devices. ***Learn More.***

CLEANROOM

Providing on-site microbial air and surface environmental monitoring services for cleanrooms, USP <797> compliant laboratories, ISO cleanrooms, and other controlled environments. If you perform environmental monitoring in-house we can help you ensure your site is properly maintained. ***Learn More.***

UTILITIES TESTING

Offering a complete line of compressed air and purified water testing services, with a rapid turnaround time. Our experienced staff can help you determine the specific tests you need and assist with sample collection. ***Learn More.***

CONTAMINATION RESPONSE INVESTIGATION

We have worked with clients to respond to biofilm formations, disinfectant neutralization, efficacy validation, cleanroom validation, and water system specification failures. Providing expert root-cause analysis and on-site consultation. ***Learn More.***

OTHER SERVICES WE PROVIDE

CLICK ANY SERVICE FOR FURTHER INFORMATION

ANALYTICAL DEVELOPMENT & VALIDATION

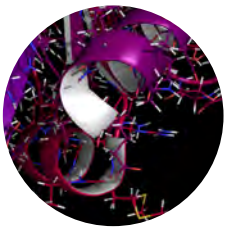
FEASIBILITY / OPTIMIZATION / DEVELOPMENT
VALIDATION / TROUBLESHOOTING

ANALYTICAL TESTING

ELEMENTAL IMPURITIES / DISSOLUTION TESTING
IN-PROCESS & LOT RELEASE TESTING / RAW MATERIAL TESTING
PRODUCT CHARACTERIZATION

EXTRACTABLES & LEACHABLES

EXTRACTABLES AND LEACHABLES / EXTRACTABLE STUDIES
LEACHABLES STUDIES / BPOG PROTOCOL TESTING / RISK ASSESSMENT



BIOLOGICS

PROTEIN ANALYSIS / PROTEIN CHEMISTRY CHARACTERIZATION

STABILITY & STORAGE

STABILITY STORAGE / THERMAL CYCLING STABILITY TESTING
PHOTOSTABILITY TESTING & PHOTODEGRADATION STUDIES
CLINICAL REGISTRATION & ANNUAL STABILITY STUDIES
BLIND COMPARATOR STABILITY STUDIES

OUR **FAQ'S**

HERE ARE SOME OF THE MOST FREQUENTLY ASKED QUESTIONS

Q: What type of identification technologies do you use for identification of LBP production strains at Boston Analytical?
A: We employ both 16S genetic sequencing and MALDI-TOF proteomic ID testing. Both systems result in a cGMP result. One of our specialties is the creation of production strain specific libraries to differentiate between drug substance strains in consortia drug product matrices. We do not offer Next Gen Sequencing, but have recommendations for it when the need arises.

Q: Does Boston Analytical have anaerobic testing environments?
A: We have 3 anaerobic chambers. We use Anaerobe Systems AS-580 systems and they're great because they provide both an ambient work space and incubator all in one. Materials can be pre-reduced in the days prior to plating events and following addition to the agar plates, they are placed directly into the environment, without ever leaving the anaerobic environment. We also chose this system because it is hard-walled (easy to disinfect) and has an auto-catalyst regeneration cycle that eliminates the need for our analysts remove the catalyst and bake it on a daily basis.

Q: What type of experience does Boston Analytical have with LBP products?
A: Over the past three years, we have led the QC and stability testing design for our clients from throughout the world. Our client's products include spore fraction, defined Drug Product (both single strain and consortia) and even injectable LBP products.

Q: What are some of the challenges that Boston Analytical has encountered when working with LBP products?
A: Believe it or not, some of biggest challenges we run into deal with traditionally simple tests, like USP <61> and <62>. In these assays, we are looking to see that extraneous contamination is below a quantitative threshold (USP <61>) and that target pathogens are not present (USP <62>). When LBP production strains are strict anaerobes, these tests are easy. When productions strains are aerobic, or facultative, it can be difficult to decipher the presence of potential contaminants from production strain growth. Over the past three years, Boston Analytical has developed approached to rule out production strain growth, in terms of contribution to bioburden, through a variety of methods.

Q: Does Boston Analytical offer activity assays for LBP?
A: Yes, we have worked on the development and validation of a number of these assays over the last 3 years. In these assays, production strains are spiked into a nutrient broth with the intention of stimulating them to consume a metabolite/ make a byproduct. The byproduct is subsequently measured through a traditional HPLC assay to determine the ability of the production strain to do it's intended job (e.g. Activity).

REACH OUT

ASSISTING YOU & YOUR TESTING NEEDS!

KRISTIN DANGELO
Director Of Business Development

KDANGELO@
BOSTONANALYTICAL.COM

(603) 489-8692

EILEEN HEFFERNAN
Senior Account Executive
New England Territory

EHEFFERNAN@
BOSTONANALYTICAL.COM

(781) 883-9452

THERESA EDICK
Account Executive
New England Territory

TEDICK@
BOSTONANALYTICAL.COM

(603) 475-7392