PDA ANNUAL MEETING 2020

Originally set to take place March 30 - April 1, the PDA Annual Meeting has been rescheduled for July 20 - 22. 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 July 20-22, 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, Christine or Rebecca to start your partnership with us today.

We'll see you in July!

meet our team!

KRISTIN D'ANGELO
Director Of Business Development

CHRISTINE JAMPO
Account Executive
Mid-Atlantic (PA, DE, MD) Territory

REBECCA IVEY
Account Executive
SouthEast Territory

SNAPSHOT OF OUR SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

ANALYTICAL DEVELOPMENT & VALIDATION

FEASIBILITY / OPTIMIZATION / DEVELOPMENT / VALIDATION / TROUBLESHOOTING

Whether you need to develop and validate a new method, or you're seeking to refine and streamline existing methods to meet specific requirements, Boston Analytical offers the expertise you are looking for. Following USP guidelines USP <1224> Transfer of Analytical Procedures, USP <1225> Validation of Compendial Procedures, and USP <1226> Verification of Compendial Methods, our experienced analysts will work with you to create the methods that are right for you.

ANALYTICAL TESTING

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

Reliable data for the pharmaceutical industry

MICROBIOLOGY TESTING

MICROBIOME / MICROBIAL IDENTIFICATION / PHARMACEUTICAL TESTING / MEDICAL DEVICES TESTING / CLEANROOM UTILITIES TESTING / CONTAMINATION RESPONSE INVESTIGATION

Offerring a widespread, comprehensive cGMP compliant microbiology testing services of pharmaceuticals, biopharmaceuticals and medical devices. Our FDA/DEA registered, cGMP compliant, and ISO/IEC-17025:2005 certified laboratory is well equipped with the latest technology and instrumentation, ensuring timely and accurate testing results.

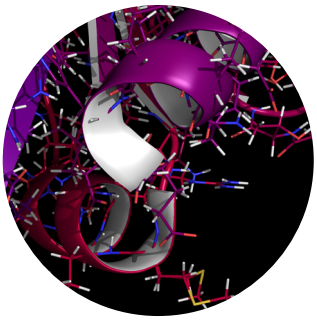
SNAPSHOT OF OUR SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

E&L SERVICES

EXTRACTABLE STUDIES / LEACHABLES STUDIES / BPOG PROTOCOL TESTING

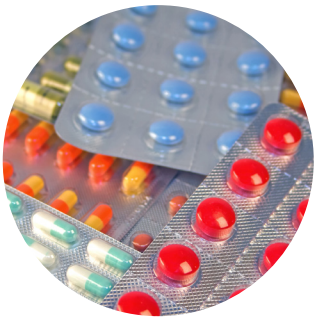
We offer full Extractables & Leachables testing for the Pharmaceutical, Bio-Pharmaceutical, Medical Device, and Consumer Products industries. Extractables & Leachables in drug products have become an area of concern to patient safety and to the FDA. We have staff with vast experience working directly with the FDA to address concerns and demonstrate drug product safety. Our processes adhere to ISO 10993, USP <661.1>, <661.2>, <1663>, <1664>, <1664.1>, as well as industry best practices from the Product Quality Research Institute (PQRI) and BioPhorum Operations Group (BPOG).



BIOLOGICS

PROTEIN ANALYSIS / PROTEIN CHEMISTRY CHARACTERIZATION

We have a team of knowledgeable scientists in this area of study who are ready to help with even the most complex projects. We have the expertise needed to identify and address scientific or regulatory concern with the latest instrumentation and technology. Boston Analytical can analyze your proteins and establish their characterizations to provide the information needed for your product development.



STABILITY & STORAGE

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

Offreing a comprehensive line of stability testing and storage capabilities to meet ICH and FDA guidelines for drug development and follow-up stability studies. We offer ICH storage for both standard and semi-permeable packaging.

OUR **FAQ'S**

HERE ARE SOME OF THE MOST FREQUENTLY ASKED QUESTIONS FROM LAST YEAR'S PDA ANNUAL MEETING

Q: Full E&L studies tend to be expensive, what is BA's recommendation to start? (ie Risk Assessments)
A: We recommend starting with a Materails Risk Assessment. This will evalute and document the leachables risk for the study, and recommend an appropriate study to mitigate this risk to ensure patient safety & compliance. This approach also assures unnecessary tests are not performed.

Q: What is BA's experience and lab capacity regarding E&L testing?
A: The E&L team at BA has an average of 8+ years of experience. The director of the group has 21 years of experience in polymer material characterization and E&L testing. We recognize the growing need for E&L testing, and are maintaining resource levels (both personnel and instrumentation) to allow us to start studies withing 1-2 weeks of the approval of a quotation.

Q: How can BA help support cell and gene therapies? What type of testing does BA offer?
A: We can support characterization of AAV or other delivery vehicles with SEC-MALS, qPCR and LC-MS, to get reads on such components as viral capsid count, percent full vs empty particles, aggregation and percent monomer.

Q: BA has a MALDI-TOF, when would BA recommend using MALDI vs. Microseq?
A: MALDI-TOF is preferred for a quick readout, and is the first choice approach for most id work. However, since MALDI-TOF is a protein based approach, it's necessary to have intact proteins, which usually requires live cells, while the Microseq uses oligonucleotides as the target for analysis, so is more robust and does not require active culture.

Q: Can BA perform Disinfectant Efficacy Studies (DES)?
A: Yes BA performs disinfectant efficacy studies routinely.

Q: How does BA approach an E&L Study?
A: BA takes a materials based approach to all E&L studies. We follow PQRI and USP guidance for container closure systems and manufacturing componets. For medical devices, we follow ISO 10993.

Q: Are E&L studies similar for different product types, medical device, sterile syringe etc?
A: No, the risks and requirements for these different types of products are quite different. We tailor all E&L studies to the product type, the risk, and regulatory expectations.

Q: Do you have experience with all of these product types?
A: Yes, we have experience conducting E&L studies on drug products, combination products, transdermal patch products, medical devices, implantables, and manufacturing equipment.

Q: For capabilities:

- **do you have PCR? (which kind: qPCR)**
  A: We have endpoint RT-PCR and qPCR instrumentation.

- **do you have ELISA?**
  A: We have ELISA capability with microplate readers for UV-Vis spectroscopy along with fluorescence, FRET and luminescence.

REACH OUT

ASSISTING YOU & YOUR TESTING NEEDS!

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