

## OUTSOURCED PHARMA EAST COAST

Originally set to take place May 20; Outsourced Pharma East Coast has been canceled for this year.

We think it is unfortunate that we will not be able to meet you all in person at the conference, but we do want to 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 Brian or Theresa to start your partnership with us today. At the end of this virtual conference you will also find a link to join our webinar on Analytical Support in the Development of Biologics set to take place on May 20th, 11:30am (EST). We look forward and hope to having you join us on wednesday!

### meet our team!



**BRIAN KIRSCH**  
Account Executive



**THERESA EDICK**  
Account Executive

## SNAPSHOT OF OUR SERVICES

CLICK ANY SERVICE FOR FURTHER INFORMATION

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### 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**

Offering 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](#)

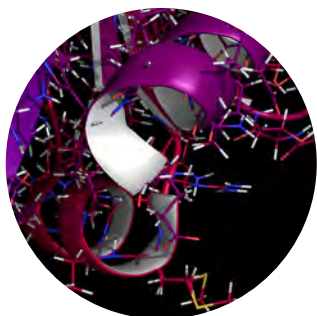
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### E&L SERVICES

#### **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**

Offering 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

**Q: Do you offer protein characterization?**

**A:** Yes we offer methods needed for full characterization of a protein product, including evaluation of primary structure, post translational modifications and potency of proteins by a variety of techniques, including LCMS, capillary electrophoresis, ELISA, qPCR and UPLC with UV, MALS and fluorescence detectors.

**Q: How would you approach a method development through validation project in your large molecule lab?**

**A:** We would work closely with the sponsor to first understand the product and goals of the analysis to be developed. The type of test and the specifications would be determined, then the appropriate technology applied. Development projects may have different starting points in our lab depending on whether there has been any R&D analysis performed that can serve as a launch point. But whether there is a basis to begin with, the development focuses on the end goal for what the method will be analyzing. We'll take into account the particular circumstances surrounding the project and keep the end point in mind. Once begun, we work to establish conditions for the method that will produce the appropriate accuracy, precision and specificity. For validation, we work from protocols written by our staff or by our sponsors, following ICH validation principals. We can tailor the validation for the current stage of development.

**Q: What type of drug products does Boston Analytical have the most experience working with?**

**A:** We have experience with a wide range of small and large molecule products in several formulations, including oral, sterile injectable, patches, implantable medical devices, lyophilized powders, creams and ointments.

**Q: Does Boston Analytical have experience working with compounding pharmacies?**

**A:** Yes we do method development and stability testing on many products for several 503(B) compounding pharmacies.

**Q: What type of biological macromolecule characterization does Boston Analytical you offer?**

**A:** We analyze proteins, peptides, oligonucleotides and polymers, including monoclonal antibodies, drug-antibody conjugates, peptide-polymer conjugates.

**Q: Can BA perform Disinfectant Efficacy Studies (DES)?**

**A:** Yes BA performs disinfectant efficacy studies routinely. We have been executing Disinfectant Efficacy Studies for over 10 years.

**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: Full E&L studies tend to be expensive, what is BA's recommendation to start? ( ie Risk Assessments)**

**A:** We recommend starting with a Materials Risk Assessment. This will evaluate 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 within 1-2 weeks of the approval of a quotation.

**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 components. 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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**JOIN OUR WEBINAR**

MAY 20TH | 11:30AM EST | 10:30AM CDT | 9:30AM MDT | 8:30AM PDT

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Analytical Support in the Development of Biologics

Life-saving protein-based therapeutics are becoming an increasingly important therapeutic option. Analytical methods are deployed from the earliest moments of discovery up through delivery of approved protein therapeutics to patients, ensuring a safe and effective supply of drugs. So what is the role of analytical chemistry in the evaluation of protein drugs? When are certain approaches first engaged and what are the tools needed and methodologies employed? We'll look at some of the key analysis techniques for proteins.



FEATURING  
**MIKE MOLLOY**  
TECHNICAL DIRECTOR

**CLICK HERE**  
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