



## NAVIGATE COMPLEX EXTRACTABLES & LEACHABLES CHALLENGES AND ACCELERATE YOUR REGULATORY SUBMISSIONS

Extractables and leachables complexities, regulatory hurdles, and materials compatibility issues can play a critical role in even the most promising pharmaceutical and medical device programs. When patient safety depends on thorough chemical characterization and regulatory expectations are increasingly stringent, you need a scientific partner who transforms these obstacles into manageable processes. Element’s experts deliver reliable E&L analysis that provides the data needed for regulatory compliance while flexibly scaling with your product development requirements. Partner with our Bend team to focus on your innovative therapies while we provide the specialized testing that helps identify risks, generate data for regulatory submissions, and protect patients.

### TRANSFORM E&L TESTING TO A STRATEGIC ADVANTAGE

#### PARTNER WITH ELEMENT BEND TO:

- Overcome extractables and leachables challenges
- Meet rigorous regulatory requirements with comprehensive, well-designed E&L studies
- Convert unknown chemical identification challenges into precise analytical solutions
- Maintain consistent quality documentation with reliable analytical methodologies
- Meet regulatory expectations with precise, well-documented testing services

### COMPLIANT TESTING THROUGHOUT YOUR PRODUCT LIFECYCLE

Protect your products and patients with specialized extractables and leachables testing designed to identify risks and support regulatory submissions. Our expert laboratory services help you navigate complex material compatibility challenges from development through commercialization:

- Extractables & Leachables Studies
- Unknown Identification
- Method Development & Validation
- Toxicological Data Generation
- Chemical Risk Analysis



#### EARLY DEVELOPMENT

- Accelerate development with screening studies
- Make data-driven material selection decisions
- Establish extractables profiles

#### REGULATORY SUBMISSION

- Generate comprehensive E&L documentation
- Address complex regulatory requirements
- Meet critical timelines

#### COMMERCIAL SUPPORT

- Ensure ongoing material compatibility
- Support manufacturing changes and product improvements
- Maintain safety documentation throughout product lifecycle



## COMPREHENSIVE E&L AND ANALYTICAL SOLUTIONS

Our Bend laboratory is cGMP compliant, FDA registered and inspected, and DEA licensed, providing specialized testing services:

### EXTRACTABLES & LEACHABLES

- **Industry Leader in Compliant E&L Studies** - Reliable documentation for regulatory submissions
- **Customized and Standardized Study Designs** - Tailored approaches for unique product challenges
- **Comprehensive Analytical Methodologies** - Multi-technique approach for complete characterization
- **Pharma and Medical Device Expertise** - Experience across diverse product categories
- **Unknown Identification Experts** - Advanced structural elucidation capabilities
- **Method Development and Validation** - Robust methods supporting regulatory compliance
- **Toxicology Data Generation** - Comprehensive chemical characterization for safety evaluation
- **Risk Assessment Documentation** - Comprehensive data to support your regulatory interactions

### EXTRACTION DESIGN

- **Wide Array of Accommodation** - Flexibility for diverse material types
- **Controlled Storage, Temperature and RH** - Precision environmental control
- **Bioprocessing Materials** - Including ultra/ diafiltration configurations
- **Medical Devices** - Specialized protocols for device components
- **Drug Final Container/Closures** - Critical container closure system assessment
- **Long-term, Multi-timepoint Studies** - Comprehensive leachables evaluation
- **Accelerated/Exaggerated Conditions** - Efficient extractables screening
- **Simulation Studies** - Application-specific extraction conditions
- **Leachables Studies with Targeted Compounds** - Focused analytical approaches

### ANALYTICAL CAPABILITIES

- **LC-UV-MS** - Comprehensive organic compound identification
- **LC-QTOF (Accurate Mass)** - High-resolution compound characterization
- **GC-MS/FID** - Volatile and semi-volatile compound analysis
- **GC-QTOF** - Advanced volatile compound identification
- **HS-GC-MS/FID** - Specialized headspace analysis
- **ICP-MS** - Elemental impurity characterization

## READY TO TRANSFORM YOUR E&L CHALLENGES INTO REGULATORY SUCCESS?

Discover how Element Bend's specialized extractables and leachables expertise can help ensure the safety and regulatory compliance of your pharmaceutical and medical device products. Our experienced scientists are ready to discuss your specific testing requirements and develop a customized solution.

Click or scan the QR code to learn more.

