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ANN ARBOR

ACCELERATE YOUR PATH TO MARKET AND OVERCOME ANALYTICAL CHALLENGES

Regulatory delays, manufacturing issues, and unexpected analytical challenges can derail even the most promising pharmaceutical programs. When timelines are tight and quality standards are non-negotiable, you need a scientific partner who transforms these obstacles into opportunities for acceleration. Element's experts work alongside your team, delivering reliable results that ensure regulatory compliance while flexibly scaling with your pharmaceutical development needs. Partner with our Ann Arbor team to focus on your innovative therapies while we provide the expert analysis that helps bring life-changing treatments to patients faster.

TURN TESTING BOTTLENECKS INTO STRATEGIC ADVANTAGES

Partner with Element Ann Arbor to:

- Overcome analytical challenges that delay regulatory filings and threaten submission timelines
- Navigate increasingly complex regulatory requirements with confidence
- Transform method development from a time-consuming obstacle to a strategic asset
- Maintain reliable manufacturing supply with consistent lot release testing
- Convert stability challenges into data-driven insights for formulation decisions

GMP TESTING SERVICES THROUGHOUT THE PRODUCT LIFECYCLE

Navigate the complex journey of pharmaceutical development with flexible, comprehensive testing that adapts to your most challenging molecular and therapeutic innovations. Our testing capabilities cover a diverse range of pharmaceutical modalities:

- Small Molecule Pharmaceuticals
- Large Molecule Biologics
  - Antibodies & Bioconjugates
  - Gene Therapies

EARLY DEVELOPMENT

- Accelerate early-phase research with efficient analytical support
- Make data-driven decisions
- Characterize critical quality attributes

CLINICAL & REGULATORY

- Generate data for regulatory submissions
- Navigate complex regulatory requirements
- Meet strict regulatory timelines

COMMERCIAL

- Ensure consistent product quality
- Support continuous process improvements
- Maintain ongoing compliance

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COMPREHENSIVE CMC SOLUTIONS

Our Ann Arbor laboratory is FDA-registered and DEA-licensed, providing end-to-end analytical services for small and large molecules:

- **Method Development & Optimization -** Robust analytical methods that deliver reliable results
- **Method Validation per ICH/USP guidance -** Complete documentation for regulatory submissions
- **Lot Release Testing -** Consistent product quality assessment with comprehensive COA generation
- **Raw Materials Qualification & Testing -** Ensuring starting material quality for reliable manufacturing
- **Process Development Support -**Analytical expertise to optimize your manufacturing processes
- **E&L and Nitrosamines Analysis -**Advanced LC-MS/GC-MS capabilities for impurity identification
- **Forced Degradation Studies -** Comprehensive degradant profiling and identification
- **Stability Testing & Storage -** ICH-compliant programs

SPECIALIZED EXPERTISE FOR YOUR MOST DEMANDING CHALLENGES

NITROSAMINES SCREENING

Our specialized nitrosamines testing delivers:

- Ultra-sensitive LOQ (0.003 ppm) and LOD (0.0005 ppm) across common critical nitrosamine impurities
- Available methods for NDMA, NMEA, NDEA, NDPA, NDBA, NDPIP, NPYRR, and NMOR
- Efficient turnaround times to support your regulatory submissions

PROCESS IMPURITIES CLEARANCE

Our advanced process impurities testing capabilities include:

- Detection limits that satisfy regulatory guidelines
- Methods for common process impurities are available to test with your matrix
- Method validation packages for regulatory submissions
- Experience with complex biologics and challenging matrices

BIOLOGICS CHARACTERIZATION EXPERTISE

Our Ann Arbor team specializes in large molecule analysis with:

- Comprehensive characterization for regulatory filings
- Method transfer and validation capabilities
- Multiple orthogonal techniques for structural analysis
- Critical quality attribute (CQA) monitoring
- Experience with antibodies, bioconjugates, and gene therapy vectors

MAINTAIN PRODUCT INTEGRITY WITH ADVANCED STABILITY AND STORAGE SOLUTIONS

Our Ann Arbor facility offers multiple controlled-environment options for stability studies:

- ICH-compliant conditions (25°C/60%RH, 30°C/65%RH, 40°C/75%RH)
- Refrigerated (2-8°C) and frozen (-20°C, -80°C) cryogenic storage
- DEA licensed, Schedule I-V controlled substance capabilities
- Available capacity to accommodate your program needs

CUTTING-EDGE TECHNOLOGY DELIVERING SUPERIOR INSIGHTS

Our state-of-the-art instrumentation includes:

- Advanced chromatography systems (HPLC, UPLC, GC-MS)
- High-resolution mass spectrometry (LC-MS/MS, Orbitrap, QTOF)
- Specialized biologics analysis tools (Maurice CE, ddPCR)
- Comprehensive spectroscopy capabilities (FTIR, UV-Vis), UV, Fluorescence, Chemiluminescence plate readers
- Material characterization technologies
- Comprehensive tissue culture laboratory for bioassays

READY TO TRANSFORM YOUR ANALYTICAL CHALLENGES INTO OPPORTUNITIES?

Discover how Element Ann Arbor can help bring your therapies to patients faster. Our team of experienced scientists is ready to discuss your specific program needs and develop a customized solution.

Click or scan the QR code to learn more.

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