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ELEMENT PHARMACEUTICAL SOLUTIONS

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YOUR JOURNEY TO MARKET DEMANDS MORE THAN TESTING - IT DEMANDS CONFIDENCE

In today's pharmaceutical landscape, your path from breakthrough discovery to life-changing therapy faces numerous challenges. Behind every delayed submission, manufacturing setback, and quality concern lies a common need: the confidence that comes from trusted scientific partnership.

When you work with Element, you gain more than just test results. You secure the scientific backing to move forward confidently at each development stage. Your patients depend on your innovation reaching the market safely and efficiently. Your investors expect critical milestones to be met. Your reputation depends on unwavering quality standards.

With Element's network of FDA-registered and inspected, ISO-accredited laboratories spanning North America, you'll access testing services that provide fast and reliable results, support informed decision-making, and scale with your business needs. We transform potential obstacles into acceleration opportunities for your pharmaceutical, biologic, and advanced therapy medicinal products (ATMPs).

OUR COMMITMENT TO YOUR SUCCESS

At Element, we're driven by a simple but powerful purpose: Making tomorrow safer than today. This commitment guides everything we do for pharmaceutical and biotech innovators like you.

Our global scientific team brings deep expertise to your most complex analytical challenges, whether you need GMP/GLP compliant testing for regulatory submissions or exploratory analysis for early development. With our extensive network of specialized laboratories, we provide the scientific backbone for your critical decisions across the entire drug development lifecycle.

What sets us apart is our dedication to becoming a true extension of your team - understanding your unique challenges, anticipating your needs, and providing solutions that advance your business objectives, not just your analytical requirements.

HOW WE ACCELERATE YOUR SUCCESS

When analytical bottlenecks threaten your timeline, regulatory complexities challenge your submission strategy, and quality concerns emerge at critical moments—these aren't just technical problems. They're business challenges that directly impact your ability to deliver for patients and stakeholders.

With Element as your partner, you gain more than just testing services:

Insights That Drive Decisions, Not Just Data - You'll work with scientists who understand your challenges and provide context for results, helping you make confident decisions that balance scientific requirements with development realities.

Seamless Solutions to Complex Challenges - Your most difficult analytical problems are solved through our cross-disciplinary collaboration, giving you integrated solutions rather than fragmented testing results.

A Partnership That Adapts to Your Needs - Your program benefits from our flexible engagement models, responsive project management, and redundant testing capabilities, ensuring we're there when and where you need us, especially during critical development phases.

Working with Element means converting analytical challenges into strategic advantages. You'll navigate through demanding regulatory landscapes and technical hurdles with an expert partner that creates clear pathways forward.

AT A GLANCE: WHAT THIS MEANS FOR YOUR BUSINESS

- **Get to Market Faster -** Overcome analytical bottlenecks that threaten your timelines
- **Minimize Regulatory Submission Risks -** Present defensible data packages that satisfy reviewer requirements
- **Protect Your Manufacturing Operations -** Prevent contamination events that could halt production
- **Make Confident Development Decisions -** Access data that supports your most critical material and process choices
- **Maximize Your R&D Resources -** Utilize our expertise precisely when and where you need it most

YOUR CHALLENGES, OUR SOLUTIONS, YOUR BUSINESS IMPACT

YOUR CHALLENGE	OUR SOLUTION	YOUR BUSINESS IMPACT
Analytical bottlenecks delaying your critical milestones	Specialized expertise with priority handling capabilities	Get to market faster, preserving valuable patent life and competitive positioning
Regulatory complexity threatening your submission timelines	FDA-registered laboratories providing well-documented test results	Minimize regulatory risks with defensible, comprehensive data packages
Microbial contamination risks endangering your product integrity	Advanced environmental monitoring and surveillance systems	Protect your manufacturing operations and brand reputation through proactive prevention
Extractables & leachables uncertainties complicating your container selection	Advanced analytical capabilities for standardized testing	Make confident packaging decisions based on comprehensive data, avoiding costly changes
Resource constraints limiting your testing capacity during critical phases	Flexible engagement models that scale with your program	Maximize your R&D investment while maintaining testing quality
Evolving analytical requirements for your novel modalities	Continually adding new technologies in our arsenal of capabilities	Stay ahead of industry trends with testing approaches designed for your next-generation medicines

YOUR CHANGING LANDSCAPE: NAVIGATING WITH CONFIDENCE

Today's evolving pharmaceutical environment presents five critical challenges that require forward-thinking scientific support:

Regulatory Complexity – As scrutiny intensifies on your processes and data, you'll anticipate requirements rather than react to them.

Accelerated Timelines – When speed to market is critical, you'll compress testing timelines without compromising quality.

Novel Modalities – Your advanced therapies require specialized capabilities for cell and gene therapies, bioconjugates, and beyond.

Supply Chain Security – Your manufacturing consistency demands thorough qualification and testing of raw materials.

Risk-Based Quality – Your success depends on identifying and mitigating critical risks before they affect your program.

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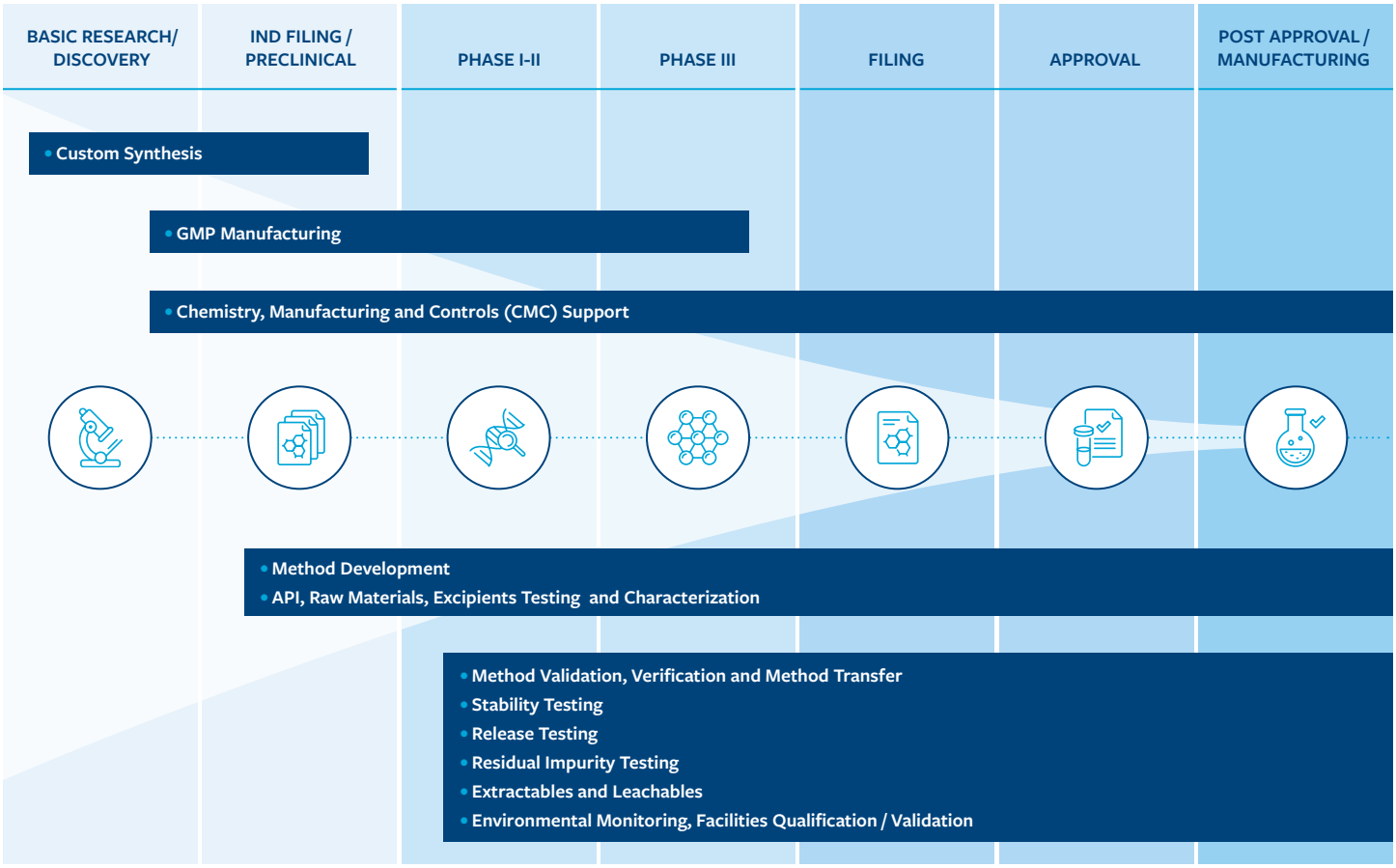
SUPPORTING YOUR COMPLETE PRODUCT LIFECYCLE

From early-phase discovery through commercial manufacturing, Element provides scientific expertise at every critical development stage:

PRODUCT LIFECYCLE VISUAL TIMELINE



ACCELERATE YOUR PHARMACEUTICAL JOURNEY

Ready to overcome analytical bottlenecks and strengthen your regulatory submissions? Our pharmaceutical testing experts are standing by to help you navigate complex testing requirements and accelerate your product development timeline. Whether you're in early development, preparing for clinical trials, or supporting commercial production, we're here to provide the scientific expertise that transforms challenges into opportunities for advancement.

YOUR TESTING SOLUTIONS: EXPERTISE THAT DRIVES RESULTS

The capabilities below directly address the challenges we've discussed, transforming testing requirements into strategic advantages that accelerate your programs and reduce risk.

While others may offer testing services, Element's integrated approach ensures these capabilities work together across your product lifecycle, providing the comprehensive support needed to turn analytical challenges into market success.

ANALYTICAL CHEMISTRY

KEY BENEFIT: Accelerate your development timeline while ensuring regulatory acceptance with reliable, defensible analytical methods and data.

YOUR CHALLENGE: Analytical uncertainties can delay your critical milestones and threaten approvals. When timely, reliable data is non-negotiable, you need advanced capabilities that deliver reliable results.

HOW WE HELP YOU SUCCEED: You'll receive the precise analytical data needed to support decision-making throughout your product lifecycle, from early development through commercial production.

KEY CAPABILITIES YOU'LL ACCESS:

- Method development, validation, and verification
- API, raw materials, and excipients testing
- Container closure testing
- Extractables and leachables testing, including complete compendial testing (USP, EP, JP, BP, ACS, FCC)
- Trace metal and elemental impurities testing (ICH Q3D)
- Nitrosamines testing
- Impurity identification and forced degradation studies
- GMP NMR testing
- Solid state characterization, including X-ray diffraction and polymorphism
- Particle size and morphology analysis
- Glass delamination studies
- ICH stability storage and testing
- Residual solvent analysis
- Lot release testing

MICROBIOLOGY & ENVIRONMENTAL MONITORING

KEY BENEFIT: Protect your manufacturing operations and product quality through proactive contamination prevention that identifies microbial risks before they impact production.

YOUR CHALLENGE: Microbial contamination can devastate your production schedules, compromise product quality, and potentially harm patients. You need rigorous monitoring that identifies threats before they impact operations.

HOW WE HELP YOU SUCCEED: You'll establish and maintain controlled environments critical to product quality, with advanced microbial identification that protects your manufacturing processes.

KEY CAPABILITIES YOU'LL ACCESS:

- Complete environmental monitoring services
- USP <797> and <1116> microbiological monitoring
- ISO 14644-1 classification and cleanroom validation (IQ, OQ, PQ)
- USP microbiology testing (USP <51>, <60>, <61>, <62>, <85>)
- Sterility testing and rapid sterility methods, including USP <71>, USP <72>, and BacT/Alert
- Water system sampling, analysis, and bioburden testing
- Compressed gas sampling and testing
- Gowning qualifications
- Advanced microbial identification with MALDI-TOF
- Disinfectant efficacy studies across bacteria, fungi, and viruses
- Particulate matter testing (USP <787>, <788>, <789>)
- Custom protocol development for unique challenges
- Method suitability

BIOLOGICS AND ATMP TESTING

KEY BENEFIT: Advance your complex biologics and cell/gene therapies confidently with specialized testing methods designed specifically for these challenging modalities.

YOUR CHALLENGE: Your biologics and advanced therapies present unique analytical challenges that conventional testing approaches cannot address. Complex modalities require specialized expertise designed specifically for your product type.

HOW WE HELP YOU SUCCEED: You'll characterize, validate, and release complex biotherapeutics with specialized capabilities that ensure quality throughout development.

KEY CAPABILITIES YOU'LL ACCESS:

- Cell-based bioassays and potency testing
- Comprehensive viral safety testing:
  - Adventitious virus detection
  - Viral clearance studies
  - Viral surrogate testing
- Protein, peptide, and glycoprotein analysis
- Post-translational modification analysis
- Host cell impurity testing (DNA, protein)
- Residual impurities testing
- Mycoplasma testing (USP <63>/EP 2.6.7)
- Process and product-related unknown analysis
- Custom assay development
- Method development, optimization, and validation
- ICH stability storage and testing
- Biopharma release testing

EXTRACTABLES & LEACHABLES

KEY BENEFIT: Confidently evaluate final packaging or manufacturing equipment E&L data to evaluate potential risks early and quickly, helping you avoid unnecessary costs and delays.

YOUR CHALLENGE: Container closure systems and manufacturing components can introduce unexpected impurities into your products. You need comprehensive E&L characterization, but this often becomes a complex, time-consuming obstacle.

HOW WE HELP YOU SUCCEED: You'll make confident material selection decisions and satisfy requirements with industry-leading extractables and leachables testing, helping you avoid costly delays.

KEY CAPABILITIES YOU'LL ACCESS:

- Risk assessments
- Single-use systems evaluation
- Packaging systems evaluation
- Efficient extractable studies
- Accelerated or real-time leachables studies
- Simulation studies under application-specific conditions
- Thorough compound identification and quantification
- Unknown or impurity identification capabilities
- Toxicology partner
  - Medical device or combination product chemical characterization

CUSTOM SYNTHESIS & MANUFACTURING

KEY BENEFIT: Eliminate critical path delays caused by material sourcing challenges with custom-synthesized compounds from milligram-scale reference standards to kilogram quantities.

YOUR CHALLENGE: Obtaining specialized compounds, reference standards, and small-scale APIs for early development can create significant sourcing challenges that become critical path bottlenecks for your program.

HOW WE HELP YOU SUCCEED: You'll bridge the gap between testing and specialized manufacturing needs with custom synthesis capabilities that produce challenging compounds from milligram-scale reference standards to kilogram quantities for your early clinical trials.

KEY CAPABILITIES YOU'LL ACCESS:

- Small-scale APIs for early-stage clinical studies
- Process development and optimization
- Clinical supply manufacturing with QA release
- Multi-step custom synthesis
- Chiral compounds synthesis
- Peptide-drug or polymer-drug conjugate synthesis
- Custom HPLC purification
- Reference standard generation and qualification

READY TO TRANSFORM YOUR ANALYTICAL CHALLENGES?

Your patients depend on your innovation. Your success depends on scientific reliability. Partner with Element to achieve both.

With Element, you'll confidently advance the development of your pharmaceutical, biologic, and advanced therapy medicinal products, accessing testing services that provide fast and reliable results, address development hurdles, and scale with your business needs.

Our team of experienced scientists is ready to discuss your specific program requirements and develop a customized testing solution that accelerates your path to patients while ensuring the highest quality standards.

START THE CONVERSATION TODAY

Connect with us through the QR code, by phone, or via email. Whichever method you choose, our team is ready to discuss your specific testing requirements and provide a tailored solution that meets your unique needs.

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