



## Company Profile

### Windshire Group, LLC Overview

We are a CMC strategy, management, and tactical execution consulting firm exclusively serving the regulated life sciences industry- Boston based but global reach

- Offices in Boston, MA (US)  
Melbourne, Australia (APAC)
- Our clients include pre-clinical, emerging, established and mature global companies.

We help companies achieve important business objectives by bridging the gap between sound strategy and reliable execution

We assist clients with the transition from scientific and technical excellence to business and commercial success

### Our Clients Benefit From...

- The experience and capabilities of our practitioners
- Direct interaction with our senior team
- Our commitment to delivering superior service and exceeding client's expectations.

### Areas of Expertise:

- All therapeutic classes
  - CGT, oral, parenteral, vaccine, combo
- All stages of the product life-cycle
- Product and process development
- Process Validation and PPQ
- Analytical development and QC
- Commercialization and supply chain strategy
- Technical operations and operational excellence
- Quality, compliance, and regulatory requirements and submissions
- PAI Preparedness
- Due diligence, product and technology assessments
- Facility conceptual design and owner's representation

### Systems and Infrastructure:

- ARCC – Audit Ready (21CFRPart11) Compliant Cloud
- RegDocs365 eTMF / eCTD Submissions, EDMS, QMS
- StabilityShire – stability testing/ data analysis
- Process data management and reporting/dashboards

### Excellence: Strategies and Solutions Delivered

We help our clients stay on track to meet their milestones by providing CMC strategy and key subject matter expertise to complete initiatives

### Our Consulting Expertise

Our expert consultants are industry veterans with broad, global experience within product companies and as consultants. Our team has worked with virtual companies to global conglomerates during all phases of the product life cycle

#### Strategy Development:

- Strategic roadmaps: CMC, regulatory, clinical, quality
- Product, process, analytical strategy
- Regulatory strategy
- Buy vs. Build decision making
- COGS analysis
- Product due diligence and technology assessments –
- Quality system design
- 505(b)(2)

#### Operational & Functional Support:

- Analytical development
- Formulation and characterization
- Quality system and operations- QA, QC
  - PAI preparedness
  - Warning Letters
  - Investigations/CAPAs
- Compliance audits
- Labshire – laboratory consulting (labshire.com)
- Process and product development
- Program/project management
- Hireshire - temporary and retained search
  - Interim leadership
  - QA support- virtual, on-site
- Stability data and shelf life
- Continued process verification
- IND/BLA/NDA/SOP technical writing
- Training

**Why go it alone? Windshire Group is ready to assist you at any stage and our team is prepared to tackle the most challenging demands**