



Windshire 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

10+ multi-national and 80+ satisfied clients

Since 2011, 250+ successful projects

Our Clients Benefit From...

- The experience and capabilities of our practitioners
- Direct interaction with our senior team
- An integrated team that works seamlessly
- Our commitment to delivering superior service and exceeding client's expectations
- Efficient commercialization

Areas of Expertise:

- All therapeutic classes: CGT, oral, parenteral, vaccine, combo, biome, veterinary
- 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 in 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 prior experience within development and product companies

» Our team has worked with virtual companies to multinationals 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, including
 - 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 is ready to assist you at any stage and our team is prepared to tackle the most challenging demands