



Windshire Profile

Windshire Group, LLC Overview

Since 2011: 10+ multi-national and 80+ satisfied clients

More than 250 successful projects

- » 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
- An integrated team that works seamlessly
- Our commitment to delivering superior service and exceeding client's expectations
- Efficient commercialization

Our Broad Areas of Expertise Including:

- All therapeutic classes: CGT, oral, parenteral, vaccine, combo, biotech, 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 Support Including:

- ARCC – Audit Ready (21CFRPart11) Compliant Cloud
- RegDocs365 eTMF / eCTD Submissions, EDMS, QMS
- StabilityShire – stability testing data analysis/reporting
- 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 Depth Delivers Results...

- » Our expert consultants are industry veterans with broad, global prior experience within development and product companies
- » Our team has worked with virtual 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

For laboratory consulting services, visit labshire.com

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