

Windshire Group, LLC

Your Valued Partner in CMC Strategy, Management, and Execution

Overview

Since 2011, Windshire Group has provided strategic, management, and tactical execution consulting to the regulated life sciences industry. Headquartered in Boston, Massachusetts, with a global reach, we have:

- Served 10+ multinational and 80+ satisfied clients
- Executed more than 250 successful projects with many repeat clients

We help pre-clinical, emerging, established, and mature global companies, their investors and service providers, achieve critical business objectives by bridging the gap between sound strategy and reliable execution for business and commercial success.

Why Windshire?

- **Experienced Practitioners:** Our consultants are industry veterans, bringing extensive global experience across various therapeutic classes (CGT, oral, parenteral, vaccine, combination products, biome, RNA, and veterinary)
- **Direct Senior-Level Collaboration:** We believe in hands-on engagement with our senior experts, ensuring high-value insights and seamless teamwork
- **Proven Track Record:** With hundreds of projects successfully completed, we pride ourselves on exceeding client expectations with efficient commercialization pathways
- **Comprehensive Service Range:** From early product development to commercial-scale operations, we offer an integrated approach to CMC strategy, quality, and regulatory compliance
- **One-Stop Shop:** We provide individual SMEs/practioners to cohesive teams, to seasoned fractional leadership

Core Areas of Expertise

- Product, Analytical, and Process Development
- Technical Operations and Operational Excellence
- Quality (QA and QC), Life-cycle Risk Management, Compliance, and Remediation
- Regulatory Submissions and PAI Preparedness
- CMC Due Diligence, Product and Technology Assessments
- Facility Conceptual Design and Owner's Representation
- Industry Service Provider Support for Revenue Growth
- For Laboratory Consulting Services Visit www.labshire.com

Why Go It Alone?

Windshire stands ready to assist at any stage, equipped to tackle even the most complex demands. We are here when you need us, and not when you don't.

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