

The Windshire Group, LLC

Comprehensive CMC and Management Consulting®

Company Overview

The Windshire Group is a global consulting firm that provides comprehensive CMC (Chemistry, Manufacturing, Controls) and management services to pharmaceutical (oral and parenterals), cell therapy, and medical device companies, and industry investors.

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.



Our Consulting Expertise

- Process, product, analytical and formulation development
- Quality and regulatory requirements and systems
- Operational excellence, including Lean, EVA portfolio analysis and program management
- Data and automation integration
- Manufacturing and technical operations
- Technology and analytical method transfer
- Outsourcing and supply chain: CMO selection/oversight
- Packaging and shipping
- Due diligence and auditing
- Product and technology assessments
- Facility conceptual design; owner representation

Why Go It Alone?

The Windshire Group's is ready to assist you at any stage and our team is prepared to tackle the most challenging demands.

Products and Services

- *Stabilityshire*SM service for drug product stability and shelf-life assessments, data analysis, reporting, and management using validated software backed by a quality system for audit ready reports and regulatory filings
- Continued Process Verification and Data Integrity: data analytics and auditing, monitoring, and reporting for process and manufacturing data including manufacturing, quality, stability, and shipping data throughout the lifecycle
- *ARCC*SM (Audit Ready Compliant Cloud) is the industry leading 21 CFR Part 11 compliant hosting solution for quality related software to regulated life science industry for QMS (e.g., SharePoint, ComplianceSP, Documentum), eDMS, e-CTD submissions
- Commercial launch: strategy; tactics; regulatory readiness; launch support
- Operational Excellence – organizational transformation in: quality, supply chain, EVA (earned value analysis) implementation and portfolio optimization
- Value transformation of “unwanted” products: connecting to investors and executing commercial and CMC strategy

