

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, 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 EVA portfolio analysis and program management
- Manufacturing and technical operations
- Technology and analytical method transfer
- Outsourcing and supply chain
- Packaging and shipping
- Auditing, due diligence
- 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. Please contact us to explore how!

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
- *ProcessPad*TM data analytics, monitoring, and reporting (continued process verification) software for process and manufacturing data including 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 Process-Pad, QMS (e.g., SharePoint, ComplianceSP, Documentum), eDMS, e-CTD submissions
- The *Informashire*SM service provides information research for organizations who do not have their own internal information research specialist and digital librarian, and access to industry databases
- 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

