

CDMO • CMO • CRO Advisory Services

Accelerating Performance and Value Creation

Risecor helps CDMO, CMO and CRO businesses accelerate growth, improve operating performance, and create enterprise value. Our work is guided by Current Good Manufacturing Practice (cGMP) regulations and global compliance requirements, keeping quality and patient safety at the forefront. Our senior industry operators and technical experts partner with management teams to solve complex challenges in manufacturing, quality, CMC, supply chain, technology transfer, and commercial operations.

We also assess your GTM and operational strategies, processes, and technology to identify opportunities for improvement designed to help you operate at the highest levels and support growth, business performance, revenues and profitability.

From M&A due diligence and integration through remediation, capacity expansion and process optimization, we translate operational improvements into measurable results such as higher utilization and throughput, stronger customer performance, CapEx avoidance, improved margins and cash flow, and sustainable EBITDA growth.

Unlock your potential with Risecor as your strategic partner.



Network, Site & Asset Strategy

Site buildout and consolidation, external manufacturing transfer, and network footprint decisions. Production asset utilization, manufacturing oversight and capacity modeling, capital equipment purchase and transfer, IT and indirect spend assessments, planned around supply continuity. Designed to unlock capacity and support growth while minimizing incremental capital requirements.



Technology Transfer & Product Development

Launch readiness, speed to revenue, and transfer cycle time reduction, including cross-border programs — site and operational readiness, capital and raw material workstreams, and supply chain management. Integrated plans, critical path monitoring and remediation activities. Application of Quality by Design (ICH Q8), Quality Risk Management (ICH Q9), Pharmaceutical Quality System (ICH Q10) and post-approval lifecycle management (ICH Q12), built into stage-gate governance. Late-stage product and process qualification, and scale-up troubleshooting from lab to pilot to commercial scale.



Commercial Growth & Business Development

Building and scaling business development and inside-sales organizations — coverage models, performance metrics, and disciplined opportunity progression. Portfolio positioning, pricing and value articulation, strategic contracting and negotiation, expansion into adjacent offerings and customer segments, and engagement models designed to carry a sponsor from early phase into commercial supply.



M&A Due Diligence & Integration

Due diligence support, integration management — planning, delivery, steering committee leadership, Day 1 readiness, and risk, issue and dependency management. Designed to support post-close growth, EBITDA expansion, and synergy capture.



Quality Strategy, Compliance & Remediation

Pre-Approval Inspection and inspection-readiness risk assessment across global sites. QA, QC, validation and engineering assessment. FDA 483, OAI, and Warning Letter remediation. Global QMS design and site alignment, and compliance culture development.



Operations & Performance Improvement

Lean manufacturing and operational excellence to drive Overall Equipment Effectiveness (OEE), throughput, cycle time, labor productivity and asset utilization — improved through disciplined quality and operating systems. Bottleneck resolution across manufacturing, laboratories and support functions to unlock capacity with minimal incremental capital expenditures. S&OP, tiered daily management, asset reliability, and KPI accountability, designed to deliver sustainable production, margin, cash and EBITDA improvement.



CMC Strategy & Technical Support

End-to-end CMC for drug substance and drug product from preclinical through commercial — advanced therapies, small molecules, large molecules, ADCs and oligonucleotides. Analytical and formulation development, stability, extractables and leachables, bioequivalence and PK program design, IND/NDA/BLA/ANDA CMC sections, and high-potency lab design.



Audit Readiness

Regulatory updates and awareness, continuous internal monitoring and compliance, documentation and record keeping, data integrity, training, supplier qualification, and quality and technical agreements. Internal mock audits to assess compliance and readiness, and to identify gaps and necessary remediation.

