QxP | QUALITY EXECUTIVE PARTNERS®

The Pharma Industry's Preferred Consulting Partner

VALUE | INTEGRITY | PARTNERSHIP

Quality Executive Partners is on a mission to ensure our clients meet their business, quality, and compliance goals, simultaneously. By engaging a unique partnering relationship strategy, we deliver technical expertise, educational tools, mentoring, and execution impact. Our success is defined by the transfer of knowledge to, and renewed capabilities of, our client's teams.

Consulting Service Specializations

- Development and Approval Through Commercialization
- Education and Training, Content and Platforms for Rapid Onboarding and Workforce Upskilling
- Advanced Therapies, Cell and Gene from Development to Commercialization
- Risk Modeling and Enterprise Supply Chain Management
- Regulatory Compliance and Quality Turnaround
- Inspection Readiness and Support

The Value We Add

QxP understands your needs because we've walked in your shoes. Our team members have worked the manufacturing lines, made the key decisions in leadership suites, and created winning strategies in response to regulatory scrutiny. Our solutions and tactics are crafted with a holistic approach to ensure simplicity, efficacy, and immediate impact.

The Integrity We Deliver

We are proud of the deep, practical, industry experience that each QxP team uses to enable our empathetic approach to the challenges our clients ask us to solve. We design with a long-term perspective for organizational health. That brings real value to the consulting investment you make.

The Partnerships We Create

On average, 72 percent of the projects we complete are from return clients. QxP becomes a partner of choice for additional projects because we do the work to stay ahead of the curve on regulatory affairs, organizational momentum, and executive coaching.

EXPERIENCE LEARNING.
EXPERIENCE RESULTS.

qualityexecutivepartners.com I info@qualityexecutivepartners.com I (+1) 678-496-7503

A Closer Look - QxP Consulting Service Specializations:

Development and Approval Through Commercialization

QxP can serve as your bridge to successful commercialization. By engaging our expertise in analytical methods, manufacturing, and regulatory filings, we ensure submissions meet regulators' tough standards. Our mentorship/partnership programs ensure your team develops the skills and capabilities needed to meet ongoing commercial demands.

Education and Training, Content and Platforms for Rapid Onboarding and Workforce Upskilling

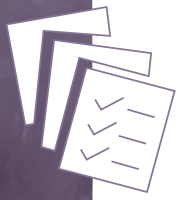
QxP partners with you to understand your unique set of cultural and organizational challenges. We synthesize this input through our expertise in adult training and education to develop and implement programs that educate and empower individual employees. In partnership with you, we efficiently catalyze rapid onboarding, workforce upskilling, and/or specific education and training requirements.

Advanced Therapies, Cell and Gene Development and Commercialization

The rapid development times of novel therapeutics mean increased scrutiny and risk for both early clinical work and technical CMC. Additionally, commercial GMP operations loom quickly, challenging our abilities in scale-up and aseptic operations. Our team has real-world experience across the cell and gene life cycle and in commercial aseptic operations. We will work with you to address these challenges and we can help you develop practical sustainable solutions to managing these risks, tailored for your product, your portfolio, your team, and your facilities.

Risk Modeling and Enterprise Supply Chain Management

QxP is a leader in quality risk management. We have created targeted risk assessment and risk modeling tools to deploy and help you quantify your specific business risks and implement effective risk mitigation plans. Additionally, we provide ongoing insights to maintain and improve your corporate quality standards.



Regulatory Compliance and Quality Turnaround

Regulatory compliance gaps must be addressed systemically, efficiently, and sustainably. We use our collective, industry-leading experience in remediation strategy to partner with your organization in developing and writing agency responses, creating structured remediation programs, and guiding the systemic execution of these plans to ensure rapid sustainable solutions.

Inspection Readiness and Support

QxP provides the expertise you need to quickly identify the key issues and logistical requirements that matter most in a regulatory inspection. We provide hands-on support for your Quality and Operations organizations to ensure inspection readiness. Our experts prepare your team, through coaching and mock audits to effectively interact with regulators and accurately represent the strategy and impact of the issues.

"What makes QxP unique is their expert talent and ability to augment your organization to accomplish your business objectives. They leave your organization stronger. I cannot recommend QxP highly enough."

Scott Canute, former President Global Manufacturing Eli Lilly and Company and Genzyme Corp., former Executive Board Director Immunomedics, Inc.

For decades, many of us in industry spent too much money and time on armies of consultants while receiving too little in the way of sustainable, high-impact results. This realization inspired us to launch a revolution. We recognized the critical need in compliance consulting for a value-based option and so QxP was born.

We are an organization fueled by the passion to do what is right and provide the pharma, biotech, and life sciences industries with the consulting talent it deserves. QxP is demonstrating to the industry that consultants can work with integrity and that our approach to partnering with your organization will bring impactful, long-term value.

Our team, composed of industry leaders and educators, administers practical operational experience. Our thought leadership enables the development of implementation processes for effective and consistent aseptic manufacturing, testing, and compliance tailored for your unique products.

VIRTUOSI® POWERED BY QxP | QUALITY EXECUTIVE PARTNERS®

Virtuosi is your validated, pharmaceutical education tool firmly rooted in Sterility Assurance, Microbiology and Cell and Gene Therapy content. Revolutionize your training program with our immersive Virtual Reality (VR) technology.

ACCREDITED IACET PROVIDER

As an IACET Accredited Provider, Quality Executive Partners offers IACET CEUs for its Virtuosi learning events that comply with the ANSI/ IACET Continuing Education and Training Standard.

WHO WE ARE:

- Executive quality leaders
- Compliance experts across all GMP aspects
- Technical experts in manufacturing, analysis, and engineering
- Successful change leaders
- Strategic experts with tactical solutions for significant compliance and product issues

(left to right) Brian Duncan, COO | **Crystal Mersh,** CEO and Founder
Nicole Monachino, Chief Legal and Head of Business Operations

info@QualityExecutivePartners.com | (+1) 678-496-7500

www.qualityexecutivepartners.com

Only real education brings real results.

Our "Teach and Do" approach ensures knowledge transfer that is synthesized and catalyzed to create long-term, sustainable change.

The QxP tool kit provides consistent, comprehensive, and robust delivery of services. We can also customize tools, including:

- Enterprise Quality and Compliance Risk Assessment and Remediation
- Support for FDA Inspections and Regulatory Actions
- Quality System Assessments and Maturity Ranking
- Development of Quality Standards
- Structured Gap Assessments
- Organizational Assessments, Design, and Development Management Controls Assessment
- Data Integrity Assessments

QxP Innovation:

- Quickly identifies the issues that matter
- Systematically works through these issues using a risk-based approach to create pragmatic solutions
- Ultimately delivers long-term meaningful results

Fast Company Award
Most Innovative Companies 2022

EDTECH Award
Cool Tool Finalist 2022

Laval Virtual Awards
2022 Nominee

Brandon Hall Group Gold Award
Excellence in Technology - 2020

Pharma Innovation Award
2019 Awardee

Areas of technical and regulatory expertise include:

Clinical
Aseptic Processing
Solid Dosage
Biotech
Vaccines
Medical Device
Analytical Chemistry
Microbiology

Sterility Assurance
Engineering
Operations
Regulatory Compliance
Remediation
Inspection Preparation
FDA Form 483/Warning Letter Responses

FDA Negotiations
Consent Decree Strategy / Execution
Process Validation
Cleaning Validation
Computer Validation
Method Validation
Data Integrity

 | www.qualityexecutivepartners.com I info@QualityExecutivePartners.com