The Pharma Industry's Preferred Cell and Gene Therapy Partner

VALUE | INTEGRITY | PARTNERSHIP

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 solutions to managing these risks, tailored for your product, your team and your facilities.

Consulting Service Specializations

- Leveraging Data Integrity Controls in R&D to enable accelerated BLA filings
- Preparation for Approval Inspections in Accelerated Timeframe
- Overcoming the Challenges and Complexities of Commercial Launch
- Optimizing Clinical Design and Data Management to yield Maximum Clinical Data Value
- Technical Consulting to ensure Analytics tell full story for manufacturing
- Presenting a robust data set to attract potential investors
- Preparing the workforce for Cell and Gene at commercial scale

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.

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QxP | QUALITY EXECUTIVE PARTNERS®

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

Laval Virtual Awards
2022 Nominee

Brandon Hall Group Gold Award
Excellence in Technology - 2020

Pharma Innovation Award
2019 Awardee

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.

Areas of technical and regulatory expertise include:

Clinical	Sterility Assurance	FDA Negotiations
Aseptic Processing	Engineering	Consent Decree Strategy / Execution
Solid Dosage	Operations	Process Validation
Biotech	Regulatory Compliance	Cleaning Validation
Vaccines	Remediation	Computer Validation
Medical Device	Inspection Preparation	Method Validation
Analytical Chemistry	FDA Form 483/Warning	Data Integrity
Microbiology	Letter Responses	