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.

- 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.
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

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