

THE BOLD REVOLUTION. VALUE. INTEGRITY. PARTNERSHIP.

At Quality Executive Partners, Inc. (QxP), our mission is to bring bold revolution to quality consulting. We are fueled by the passion for doing what is right and bringing bold disruptive innovation to consulting. There may be nothing revolutionary about passion, but we turn that passion into real value, built on integrity and long-term client partnerships. And, in our industry, that is revolutionary!

The Bold Revolution in Value

QxP understands your needs because we were the client for years. We understand the desire for pragmatic, simple solutions and are expertly skilled to deliver the best overall value for our clients.

The Bold Revolution in Integrity

We do what is right and that may not be what is easy! QxP is about building a long-term organization that brings real value to the consulting experience.

The Bold Revolution in Partnership

We partner with our clients to own the issues and to bring the solutions. We take great pride in helping our clients fully resolve these issues, just like we did when we sat in your seat.

“If you keep doing the same thing and expect different results ... ”

We are all familiar with the definition of insanity, yet so many of us in industry did just that for decades. We spent too much money and time on armies of consultants and received too little in the way of sustainable results.

The revolution began a few years ago. Recognizing the critical need in compliance consulting for a value-based option, QxP was born. We are an organization fueled by the passion to do “what is right” and provide industry 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 can bring impactful, long-term value.

If you're looking for "cheap" hourly rates, you will find them. If you're looking for the results you want, done once, done right, and built to sustain over the long term, let's talk soon.

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Only real education brings real results. Our “Teach & Do” approach ensures that knowledge is transferred, such that change can be sustained over the long term.

QxP’s extensive tool kit provides consistent, comprehensive, and robust delivery of services. We can also customize tools for your use 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

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

Areas of technical and regulatory expertise include:

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

