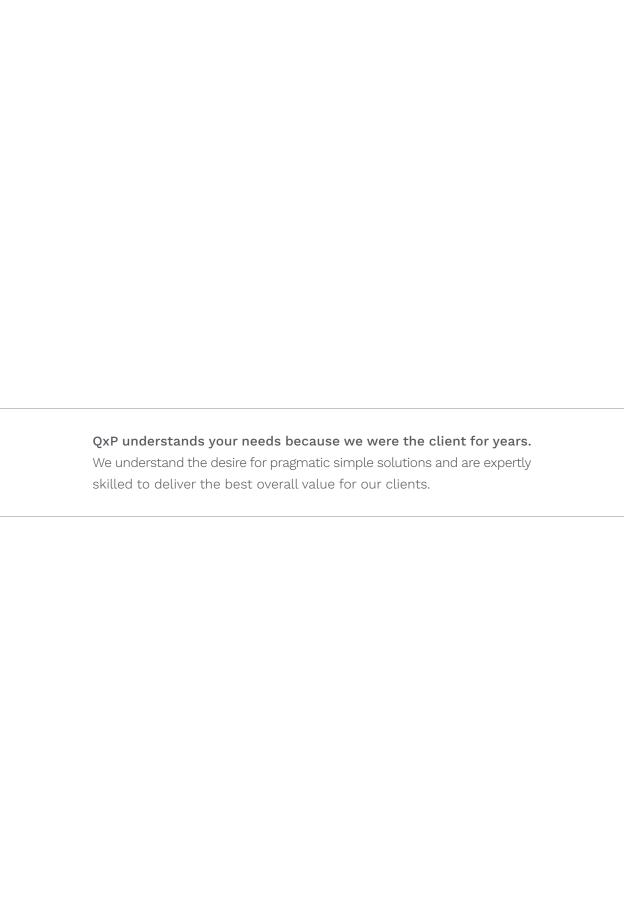


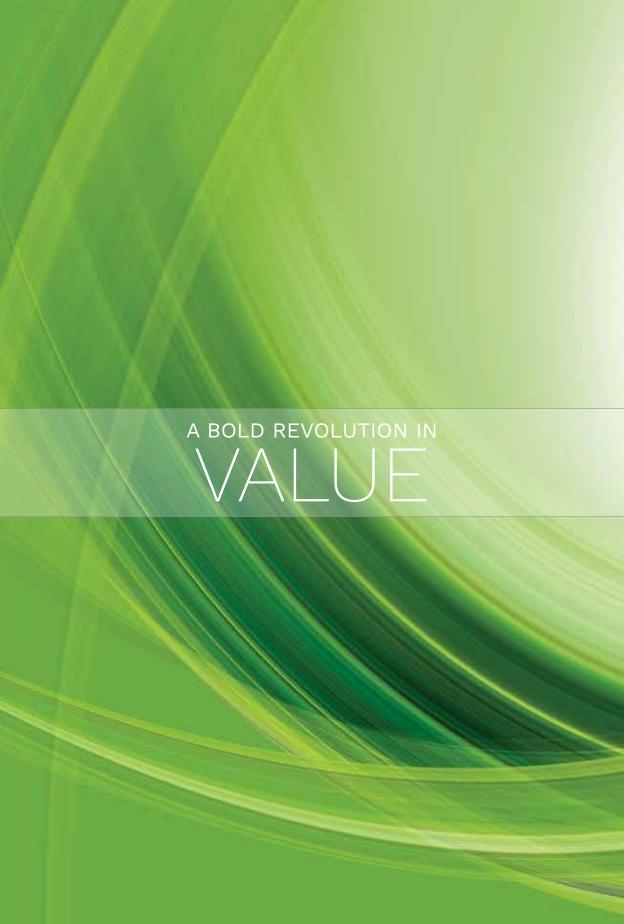


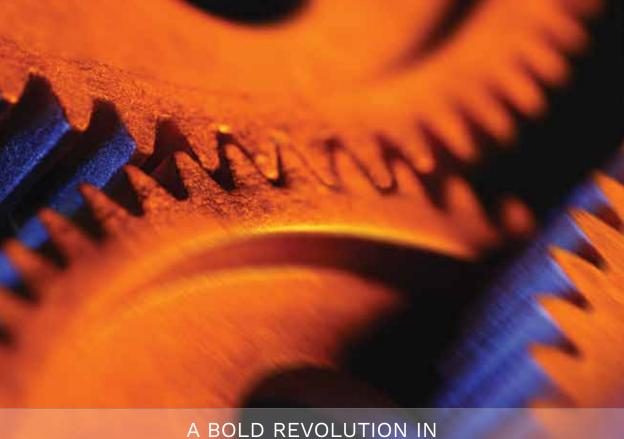
# THE BOLD REVOLUTION VALUE, INTEGRITY, PARTNERSHIP!

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 being the much needed disruptive innovation! 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.



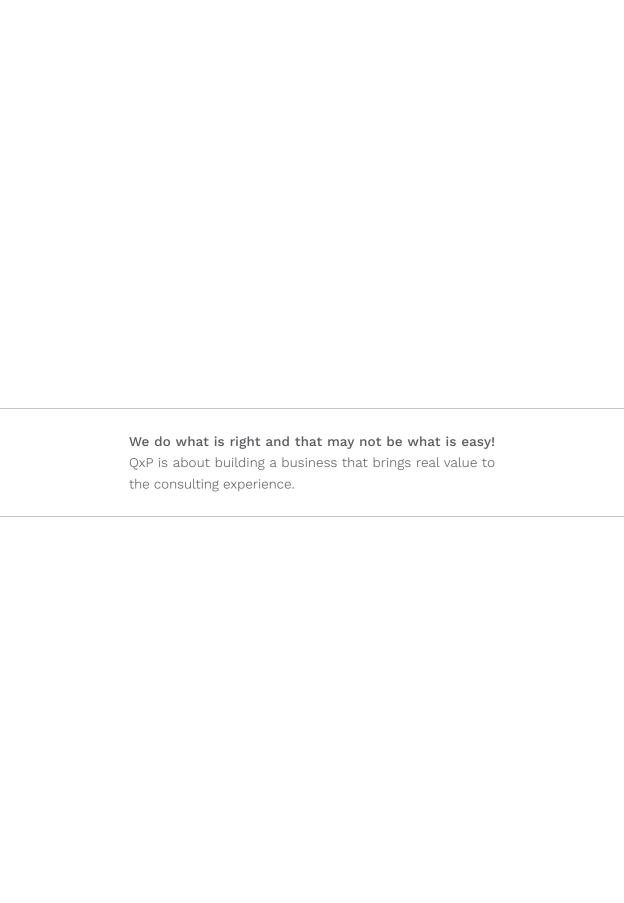






# A BOLD REVOLUTION IN INTEGRITY





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 issuesjust like we did when we sat in your seat.

# A BOLD REVOLUTION IN PARTINE RICHARD

# WHAT WE DO

### AREAS OF TECHNICAL AND REGULATORY EXPERTISE INCLUDE:

CLINICAL

ASEPTIC PROCESSING

SOLID DOSAGE

BIOTECH

**VACCINES** 

MEDICAL DEVICE

REGULATORY COMPLIANCE

REMEDIATION

INSPECTION PREPARATION

FDA NEGOTIATIONS

FDA FORM 483 / WARNING LETTER

RESPONSES

CONSENT DECREE STRATEGY/

**EXECUTION** 

ANALYTICAL CHEMISTRY

MICROBIOLOGY

STERILITY ASSURANCE

ENGINEERING

**OPERATIONS** 

PROCESS VALIDATION

CLEANING VALIDATION

COMPUTER VALIDATION

METHOD VALIDATION

DATA INTEGRITY

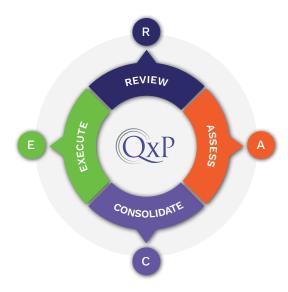


# HOW WE DO IT



# A QXP INNOVATION THAT

- 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 solutions



#### ONLY REAL EDUCATION BRINGS REAL RESULTS

Our "Teach & Do" approach ensures that knowledge is transferred and that change can be sustained over the long term.

# OUR SERVICES

## **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

#### WE OFFER

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 Assessment and Maturity Ranking
- · Development of Quality Standards
- Structured Gap Assessments
- Structured Product Assessments
- · Organizational Assessments, Design, and Development
- Management Controls Assessment
- · Data Integrity Assessments





"The selection of QxP as the third party expert for our Warning Letter remediation was the best decision we made."

Senior VP of Operations for a global pharmaceutical company

"The money we spent with QxP was the most worthwhile consulting dollars we have ever spent!"

Site QA Head for a mid-sized pharmaceutical company speaking about comprehensive data integrity assessment and forensic audit

"QxP performed the most valuable audit we have ever had. They were able to quickly identify issues we had not previously uncovered and provide us with practical, risk-based solutions."

VP of Quality Control for a global biologics company speaking about a Chemistry Laboratory audit

"Individualized mentoring by QxP supported my promotion to Site QA Head."

Site QA Head for a pharmaceutical company under a consent decree speaking about QxP's mentoring and teaching

"Thank goodness we've had QxP present at (the site) for the past month. We are much better prepared now than we ever would have been on our own. We are not only aware of the issues, but your recommendations for addressing them have been spot on."

Head of Global Compliance for a global company speaking about a Warning Letter remediation support program

## "STRATEGY WITHOUT EXECUTION IS WORTHLESS ...

# OUR TEAM

#### Crystal Mersh

CEO and Executive Partner

### Dale Robson

COO and Executive Partner

#### Brian Duncan

V.P. of Engagement Operations

#### Nicole Monachino

General Counsel and V.P. of Business Operations

#### Rebecca Brewer

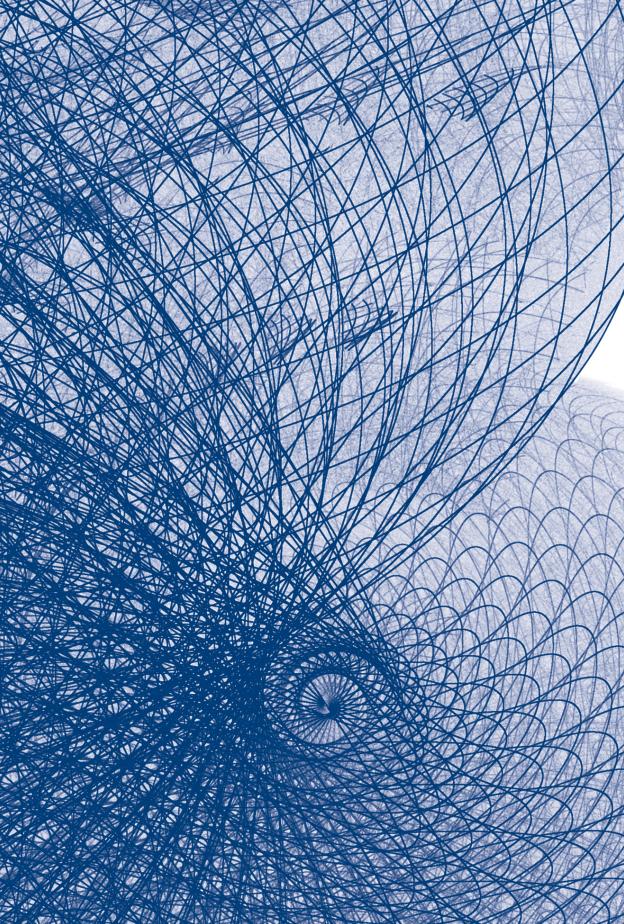
Strategic Practice Lead

#### **Bob Ferer**

Strategic Practice Lead

# BUT EXECUTION WITHOUT STRATEGY IS HOPELESS." - C. Mersh





# THE BOLD REVOLUTION

"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, Quality Executive Partners 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.

CONTACT NICOLE MONACHINO: nmonachino@qualityexecutivepartners.com 216.538.6001







QUALITYEXECUTIVEPARTNERS.COM