



## YOUR FOURTH EMERGENCY SERVICE: SUSTAINABLE REMEDIATION

In an ever-changing world even the best can take their eye off the ball and, before they know it, get into regulatory trouble. If this happens, please remember we are here to help. We have considerable success helping clients in pharmaceuticals, biotech and medical devices through very difficult times. Whether it be consent decrees, warning letters, importation alerts, Inspection Action Group (IAG) remediation or WHO “decertification,” we can help. What we do and how we do it are driven by our CORE BELIEFS:

### We cultivate partners, not clients

- We want to cultivate a lasting relationship based on mutual respect and “return on investment.” In short, we will stick with you no matter what
- Our team members are some of the best available. Most have in excess of 30 years’ hands-on experience. They are seasoned professionals who have walked in your shoes

### We are driven by YOUR SUSTAINABILITY

- We don’t believe in quick fixes
- We believe success depends on what you STOP doing. Disaster awaits those who try to do everything... and do nothing properly
- We work with you to identify and implement simple and sustainable solutions. We believe introducing unworkable levels of complexity is wrong. We are driven by helping you identify and implement SIMPLE, practical and sustainable solutions
- As painful as remediation can be, we believe that it must be used as an opportunity to change mind-sets and culture, simplify systems and procedures, and improve business performance. Our objective is to leave you better off than when we found you!

### We help you CHANGE YOUR CULTURE

- You can’t change culture without changing the way people think
- Our customized approach to education (using the 10/20/70 approach) will help change attitudes and behaviors in the workplace
- Our workplace coaching and mentoring programs, combined with our customized education workshops, focus on your people, your products, your processes and your systems
- Our unique approach to education is designed to improve skills in areas vital to your long-term success such as decision making, problem solving, change management, error reduction, quality ownership, leadership behaviors and more
- In short, we leave your people better informed and educated, and equipped with the skills needed to take your business to the next level

### We help our partners plan for the future, not the past; to think beyond remediation

- Even in the thick of remediation, we believe in solutions fit for the future, not the past
- Our excellent connections with industry and regulators mean that the advice we provide is current and reflects best-in-class practices
- We will help you set standards that are fit for purpose, based on your ways of working and good science and common sense, not ones that are over complicated and unattainable

## We are driven by you getting a “return on investment”

- After remediation has been completed, we don't abandon you. We stay in contact, either by phone, face to face or by email. Whatever it takes. Remember, we focus on building lasting relationships
- We get immense satisfaction when our clients tell us that the regulatory action and remediation have improved their business by allowing them to create simpler systems, robust processes, and better educated and more motivated people

So, when faced with the threat of regulatory action, please give us a call at **+1 857-277-0060** in the US or **+44 (0)1751 432999** in Europe. We have the right people, driven by the right beliefs, to provide the solutions you need...the first time.

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