REMEDIATION OF PHARMA QUALITY SYSTEMS

IT'S ALL ABOUT THE PEOPLE

by Maxine Fritz

MUCH OF NSF PHARMA BIOTECH CONSULTING'S WORK INVOLVES HELPING COMPANIES REMEDIATE FLAWED QUALITY SYSTEMS.

This is usually done as a result of threatened or actual enforcement action by regulatory agencies. In these circumstances, companies are desperate and willing to do 'whatever it takes' without a full understanding of what that means. While expansive in concept, 'whatever it takes,' for many, means simply deploying internal and external resources to design and document a new quality management system. This is a significant commitment by management in resources, but unless the cause (how did this happen?) is also considered, the effort is doomed to fail.

IN OUR EXPERIENCE, ONE OF THE ANSWERS TO 'HOW DID THIS HAPPEN?' IS ALMOST UNIVERSALLY ORGANIZATIONAL QUALITY CULTURE.

Most companies are surprised by this answer and find it difficult to imagine. Most companies will tell you and truly believe that they are committed to quality; and in fact most companies make the pursuit of quality part of their corporate mission statements. However, failing to address organizational culture as a root cause during the remediation initiative will foretell an unsuccessful outcome. We often meet senior leaders of pharmaceutical firms who are willing to invest in quality systems and processes, but we find that they do not understand that there is an underlying issue in the organizational culture and the change that is necessary to support quality initiatives. Unfortunately, without a true culture of quality built into the DNA of your

organization, most quality improvement projects will fail. Worse still, such a failure could lead to even more aggressive and difficult regulatory enforcement action.

We possess the experience, skills and methodology needed to help a company design and document a world-class quality system. We also learned very early that this methodology must address the imperative of organizational cultural alignment and this is the most difficult part of a remediation project. Many individuals are drawn to the healthcare industry by altruistic desires to help people. Consequently, healthcare companies are bewildered and aghast at the suggestion that their cultures may not support quality principles. After all, what healthcare company doesn't want to produce high-quality products? It is no wonder that a company would challenge a consultant's suggestion that attention to the corporate culture is necessary.

One aspect of the NSF process is to encourage a self-assessment by company management of its policies and practices that influence employee behaviors. While most companies have stated values supportive of quality objectives – the easy part – it is management's

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compliance with them that is determinative in influencing employee behaviors. Does management override the quality assurance unit's decision to withhold product release? Does management cut funding of the quality function before, or to a greater extent than, others? Does management recognize and reward quality achievements as it does financial ones? Does management effectively balance its capital needs and initiatives with its commitment to quality? An integral element of the NSF methodology addresses management's responsibility to 'walk the talk' and model the company's quality values. Among other things, we encourage the most senior executive managers to have at least one performance element related to quality. Our goal is that each member of the company's senior executive management team has as intimate a knowledge of the state of the company's quality system as he or she does its financial condition.

During a remediation project, NSF consultants are on site working collaboratively with the company to create a new system, coaching and mentoring throughout the project. Organizational values and principles, as well as an effective means to communicate them, are established by the top of the organization. Does your company have a communication plan? Does the company communicate collaboration, openness and transparency? Does the communication plan clearly define process ownership and who owns the process? During the planning process, we can be effective in counteracting the negative impacts of organizational culture through open collaboration and communication. Recognizing that an antagonistic corporate culture can have its greatest negative impact at this point, our overall approach is designed to address cultural issues early in the process. This enables the company to operate in a quality-supportive coaching and mentoring environment, assuring ultimate success.

NSF HEALTH SCIENCES QUALITY SYSTEM REMEDIATION EXPERTS:

Martin Lush
President

Over 35 years' experience in operations, QA, troubleshooting and due diligence. Now committed to helping clients do better with less.

Maxine Fritz
Executive Vice President

A former US FDA investigator and industry expert with over 25 years of pharma, biologics and biotech quality systems, compliance and regulatory experience specializing in strategic pragmatic solutions to customer needs.

George Toscano
Vice President of Quality Systems

Over 16 years' experience with a proven record in providing clients with strategies for the implementation and remediation of quality systems to comply with FDA regulations.

John Johnson
Executive Director

Expert at GMP remediation and passionate about education, continuous improvement tools and mentoring of senior managers.

Rachel Carmichael
Executive Director

Over 20 years' experience of pharmaceutical manufacture, control and quality management including nearly 11 years as a GMDP Inspector for the MHRA.

Rocco Duran
Executive Director

Over 33 years' experience in pharma production, technical services and quality. A passionate leader who champions pragmatic approaches in quality.

Peter Gough
Executive Director

40 years' experience in pharmaceutical law, manufacturing, QC and quality systems.

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With his unique training style and over 30 years' experience, Mike is responsible for our world-class QP and IRCA education programs.

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25 years' experience in biopharmaceuticals and 15 years' experience providing general and strategic consultation to domestic and foreign clients in the biotech, biologic and pharmaceutical industries.

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Shritin Shah
Executive Director

Over 25 years' experience in regulated industries with a successful record of helping companies address regulatory compliance with USFDA, DEA and NRC.

ABOUT THE AUTHOR

Maxine Fritz has 25+ years of combined FDA, industry and consulting expertise and is responsible for overseeing the Pharma Biotech practice at NSF Health Sciences, serving in both a technical and management role. Ms. Fritz works with clients in the pharmaceutical, biologics, biotech and medical device industries to develop quality assurance, manufacturing and regulatory strategies for compliance with FDA regulations. She conducts and oversees regulatory gap analyses, assists with the development and implementation of quality systems, and develops and implements corrective action plans to address deficiencies identified by regulatory agencies. Ms. Fritz has successfully managed, resolved and consulted on large complex compliance projects including corporate warning letters, mass seizure, consent decree(s), Application Integrity Policy (AIP) prosecution and import detentions.

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