REMEDIATION OF PHARMA QUALITY SYSTEMS
IT’S ALL ABOUT THE PEOPLE
by Maxine Fritz

MUCH OF NSF PHARMA SERVICES 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 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 | Global Vice President**  
Over 35 years’ experience in operations, QA, troubleshooting and due diligence. Now committed to helping clients do better with less.

**John Johnson | Vice President**  
Expert at GMP remediation and passionate about education, continuous improvement tools and mentoring of senior managers.

**Lynne Byers | Vice President**  
Over 35 years’ extensive pharmaceutical manufacturing management and QA experience, and fully conversant with current EU and FDA GMP regulations and requirements.

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

**Peter Gough | Vice President**  
45 years’ experience in pharmaceutical law, manufacturing, QC and quality systems.

**Mike Halliday | Executive Vice President**  
With his unique training style and over 30 years’ experience, Mike oversees our world-class QP and CQI and IRCA education programs.

**Catherine Kay | Executive Director**  
Over 22 years’ pharmaceutical operations management, technical and QA experience, passionate about developing people and creating learning organizations, with continuous improvement embedded in daily operation.

**David Waddington | Executive Director**  
Broad experience in QA and manufacturing management gained through working with a wide range of dosage forms for global supply including solids, liquids, sterile products, food supplements and natural products.

**Nick Burmester | Managing Consultant – TechFile Factory**  
Expert in projects concerning the review and remediation or compilation of technical documentation of medical devices. He has been involved in numerous conformity assessment projects in Europe, the USA and Asia and is also a certified Lead Auditor for ISO 13485 with extensive expertise in the MDSAP program.

**Robyn Meurant | Executive Director**  
IVD regulatory expert with over 30 years’ experience in the field of IVDs – former regulator with the Australian Therapeutic Goods Administration (TGA) and with World Health Organization (WHO) Prequalification.

**Nicholas Markel | Executive Director**  
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.

**Jim Morris | Executive Director**  
Over 25 years’ pharmaceutical management experience in both plant operations and corporate offices.
Jesse Ahrendt | Executive Director
Quality assurance and manufacturing improvement innovation leader who optimizes organizational resources to exceed business quality goals.

Maria Tellier | Director
10 years’ experience in pharmaceuticals and biologics. Areas of expertise include regulatory affairs, clinical trials and FDA submissions.

Andrew Papas | Vice President of Regulatory Affairs
30 years’ experience in the industry, providing leadership and guidance on global regulatory affairs, quality and drug development programs.

Tom Dzierozynski | Executive Vice President
20 years’ experience in the pharmaceutical, medical device and biologics industries, developing and implementing risk-based strategies that integrate varying business functions to drive ownership and improve operational and quality performance.

Oliver Christ | Executive Vice President
Active in international standardization efforts for more than 25 years. Served as chair or co-chair of national committees including Human Factors/Usability for Medical Devices, Risk-Management for Medical Electrical Equipment, and Software for Medical Devices and Networked Medical Systems.

Kimberly Trautman | Executive Vice President
30 years of experience in medical device quality systems and international regulatory affairs - leading international initiatives for the U.S. FDA to include the conception and development of the International Medical Device Single Audit Program.

Maxine Fritz has 30+ 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.

For more information, contact healthsciences@nsf.org or visit www.nsfhealthsciences.org

Copyright © 2020 NSF International.
This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

NSF INTERNATIONAL
789 N. Dixboro Road, Ann Arbor, MI 48105, USA | T +1 (202) 822 1850
The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF | T +44 (0) 1751 432 999
Beim Strohhause 17, 20097 Hamburg | T +49 40 66 87 88 -100
E healthsciences@nsf.org | www.nsfhealthsciences.org | Follow us on LinkedIn, Twitter, YouTube