Eight Strategies that Turn FDA Compliance into a Competitive Advantage

By Jan Warner, President, IQA Consulting Services

When it comes to FDA regulated industries, competition is fierce, and stakes are high. Compliance with regulations may sometimes be viewed as a "necessary evil" as FDA actions are complex, require effort and can be costly, imposing penalties with ranges of up to $500 million. Business expenses due to inadequate quality systems have run into the billions and can be potentially fatal to an organization's market share, reputational costs and shareholder value.

But the right program can offer a strategic advantage. With resourcefulness and agility, you can bring quality products to market faster and within budget.

Here are some proactive steps you can take to ensure full compliance and preserve your competitive edge in the manufacture and marketing of your products.

1. *Responsible Person:* Identify an experienced individual – be it a staff member, consultant or outsourced virtual quality department – who will be responsible for quality … and only quality. This is an FDA requirement and this role should report directly to executive management to avoid conflicts of interest.

2. *Gap analysis:* Audit your current quality system from its current state of compliance yearly. This verifies your operations are working as intended, exposes potential problems that may have arisen throughout the year and reveals opportunities for improvement.

3. *Documentation:* Prepare and implement documented procedures for all necessary operations. Documentation promotes consistency and avoids errors in interpretation.

4. *Employee Training:* Assess the current level of training and knowledge of your personnel yearly and educate them on the

current standards.

5. *Deviations:* Adopt the philosophy and ensure understanding among staff that exceptions from documented practices do occur, but documenting deviations is what's important.

6. *Adverse Events:* Implement a system for tracking and monitoring adverse events and complaints in the event of an injury.

7. *Management's Role:* Ensure management provides the right support – in both its culture and well as resources – for quality operations throughout the company.

8. *Quality Culture:* Adopt and instill a "Quality State of Mind," in which compliance is a shared effort and not the sole responsibility of any single member or department.

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Regulatory Review and Risk Assessment

Contact Jan at:
973-641-0063
Jan@IQAConsulting.com

Jan Warner is an accomplished, broad-based quality and compliance professional with over 30 years of experience in: cosmetics, pharmaceuticals, medical devices, OTC/Rx drugs, personal care, homeopathic drugs, and dietary supplements. He has had senior management responsibility at L'Oreal, Kiehls, Luitpold Pharmaceuticals, Axiom Pharmaceuticals and Nobel Biocare and has worked as a consultant for Johnson & Johnson, Merial, Wyeth, Merck, Pfizer, Proctor and Gamble, and Reckitt Benckiser, among others. Jan leads a team that understands how to work within the matrixed-management environment of Fortune 500 companies while offering a more streamlined and specialized approach for mid-sized firms and start-ups.