



The Foundations of Pharmaceutical Compliance for Beginners

by Maxine K. Fritz and Austin Caudle of NSF International's Health Sciences Division

Whether you are just starting out in the pharmaceutical industry or an industry veteran transitioning into a new compliance or quality assurance role, it's critically important to understand the fundamentals of regulatory compliance and quality assurance.

The pharmaceutical and biotech environment today is changing quickly due to globalization, increased competition, cost constraints, demands for efficiency, development of international regulation, supply chain complexity, and product/process complexity. In this fast-changing environment, the people and companies that learn to adapt will prosper. But just knowing the regulations, following the standard operating procedures (SOPs) and focusing on compliance will not be enough. Successful companies need to develop high-calibre quality and technical professionals throughout their organizations — not just in traditional quality assurance roles. To succeed, we must understand how to interpret international regulations, understand processes and product technologies, make sound decisions, facilitate change, and drive business benefit.

For a beginner, it can seem like a dizzying amount to learn. But it's not so overwhelming if you focus on few foundational lessons.

- **Understand the difference between compliance and quality.** While the terms are often used interchangeably, there's a big difference between quality and compliance. Think of quality as the processes, procedures and culture that permeate an organization — enabling it to consistently develop and produce high-quality pharmaceutical products that will meet or exceed regulatory requirements. Quality is everyone's job, from production floor workers to



senior executives. Compliance, on the other hand, is a function that demonstrates and documents the quality of an organization's processes and products. You can have quality without compliance, but you can't have compliance without quality.

- **Investing in quality and compliance makes good business sense.** When it comes to quality and compliance, your company's reputation is at stake. Taking a proactive approach to quality assurance and compliance management is the key to maintaining your company's reputation and it is far less expensive than reacting to consent decrees, warning letters and product recalls. As a newcomer to pharmaceutical compliance and quality, you should seek out opportunities to continually enhance your knowledge and grow. Pharmaceutical companies and their people need to continually evolve and improve — or they will go extinct.
- **Know your role within your organization.** Most importantly, you must know the regulations as they apply to the products you are manufacturing. You don't need to be able to recite Title 21 of the U.S. Code of Federal Regulations (CFR), but you should understand the FDA's current expectations as they apply to your job, whether those are maintaining Good Manufacturing Practices (GMPs) or specific regulatory requirements. The expectations for your job will vary based on your role or function in your organization. For example, if your job is in document and change control, you will need to understand exactly what the FDA expects from a person managing or operating a document control and change control process and what is required for you to perform your job and maintain compliance.
- **Seek out appropriate training and support.** In the fast-changing pharmaceutical environment, no beginner can be expected to know everything there is to know about compliance and quality — even when the scope of knowledge is limited to a specific job or role within an



organization. Most organizations offer training programs for employees in compliance and quality assurance roles. Make the most of these training opportunities and, if needed, ask for additional training. Independent consulting firms like NSF-DBA offer quality and compliance training programs as well as audits and consulting support.

- **Find a mentor.** If you are new to a compliance or quality role, an experienced mentor can be invaluable in helping you identify your strengths and areas where you can improve. Talk to your supervisor about the best way to find a mentor within your organization. Or you may want to be mentored by an experienced professional from outside your organization. This can help you understand industry best practices. Professional organizations are good places to find mentors. Independent consulting firms like NSF-DBA also offer mentoring services for developing compliance and quality professionals.
- **Join professional organizations.** Professional organizations are a great way for beginners to develop in pharmaceutical compliance and quality assurance roles while also networking with others in the field. Depending on your role, consider joining professional organizations such as the Regulatory Affairs Professionals Society (RAPS), the Society of Quality Assurance (SQA) or the Parenteral Drug Association (PDA).
- **Work closely with manufacturing operations.** As a compliance or quality assurance professional, it's important to understand as much as possible about the manufacturing processes and challenges faced by production workers. Look for opportunities to cross-train in the manufacturing processes that are relevant to your role. Spend time on the production floor and build open relationships with manufacturing managers and workers. It will help you view the challenges of compliance and quality assurance through new eyes.



Whether it's through formal training programs or informal relationships, investing in compliance and quality always yields good returns. At NSF-DBA, we like to say that the most expensive test in any laboratory is the re-test. This is because re-testing can lead to manufacturing downtime, out-of-specification (OOS) investigations, increased manufacturing costs, product quarantines, increased waste, and product shortages. When companies invest time and resources into quality and compliance training programs as well as audits and consulting support, they are adding business value, improving compliance, enhancing improvement initiatives and developing employees – all good ways to adapt to our fast-changing industry.

Maxine K. Fritz is Executive Vice President of the Pharmaceuticals and Biologics Practice at Becker & Associates Consulting, Inc., which is part of NSF-DBA, a division of NSF International. She is a former U.S. FDA investigator with over 23 years of government and private sector experience in quality, training, and validation applications, quality system implementation and regulatory compliance. She can be reached at maxine.fritz@becker-consult.com.

Austin Caudle is a Business Development Manager at NSF-DBA, a division of NSF International with more than 30 years of experience in consulting, training and auditing services for the pharmaceutical and medical device industries. He can be reached at acaudle@nsf.org.