



# PHARMA COMPLIANCE BUILD IT IN FROM THE START WITH A QUALITY MINDSET

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Regulatory action can cost pharmaceutical companies millions of dollars, as can enforcing quick fixes to keep up with the latest rule changes.

One way to avoid both is by building quality in at the outset, with regulatory compliance a happy by-product of what NSF International's Maxine Fritz describes as having a "quality mindset".

The former FDA investigator heads up NSF's pharmaceutical services team, which provides compliance, consulting and training services to the pharmaceutical and biotech industries.

According to Fritz: "Being in compliance does not equal good quality. There is a difference and that's the challenge."

She adds that by "tackling the individual building blocks of a quality mindset" companies can ensure they are "never out of compliance to begin with ... Regulations are the minimum requirements, not where your bar should be set."

This is the approach which NSF advocates when its consultants look at how health care companies can improve their systems.

Asked what the broader benefits are to a company of adopting this approach, Fritz replies: "If you choose a quality mindset you will build it in to begin with. You will build your systems with always having quality in mind. You will build your facilities, you will buy your equipment, you will bring people in who have the same common goal.

"If you approach it from a compliance mindset your goals are different. Your goals are not always quality minded. It's only meeting the letter of the law. Sometimes that conflicts with if you'd just done it right to begin with, you would be naturally in compliance.

"There are many reasons why companies don't take this approach to begin with. They're worried about



getting products out the door but sometimes quality gets left behind. And then they have to retrofit it back in and sometimes it's not a clean fit.

**"Going through and self-assessing and seeing where you're at with quality systems is a much better model than trying to build a compliance model that doesn't always fit very well."**

"For companies that practice this at the outset, they have a much better outcome than those companies that worry about the letter of the law when it comes to regulation."

Fritz believes that a quality mindset approach also leads to more efficiency.

"The broad benefit is that everybody has the same goals. Everybody wants to make quality products, so everybody follows the same mindset," she says.

"That's one of the big benefits, it does lend towards efficiency. It doesn't tend to build overly complex systems, but it makes sure you have the requisite



pieces in place to make sure that the product you are producing is produced with quality always intended.”

What about customers who haven't built this in from the outset? What do they need to change if they want to adopt a quality mindset approach?

“We would advise them to take a quality systems approach which in the US is the six-systems model,” says Fritz. “We would advise them to go through and evaluate are the systems in place. They look for gaps where there may be gaps. Not necessarily gaps in regulation, but gaps in your system.

“Do you have procedures in place? Do you have records? Do you have training?

“Going through and self-assessing and seeing where you are at with your quality systems is a much better model than trying to build a compliance model that doesn't always fit very well.”



## ABOUT MAXINE FRITZ

Maxine Fritz has over 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.

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