MAXINE FRITZ Q&A HOW TO IMPROVE PHARMA COMPLIANCE AND EFFICIENCY WITH NSF

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US-based public health organization NSF International has been on a mission to improve global human health since 1944.

Maxine Fritz oversees the pharma-biotech practice at NSF International and is responsible for carrying that mission forward when it comes to the consulting, compliance and training services the company offers to the pharma industry.

With more than 25 years industry experience, her role is a technical, as well as a managerial one, advising clients in the pharmaceutical, biologics, biotech and medical device industries on how to improve quality and ensure compliance.

She is a former FDA investigator who specialized in biological and pharmaceutical product inspections.

Here she answers Pharmaceutical Technology's questions about NSF and the big issues affecting the pharmaceutical industry.

Dominic Ponsford: What is it that sets NSF apart from other experts that pharmaceutical companies might choose to go to?

Maxine Fritz: *"We have competition in our space and some of these companies are quite good. Many of these companies use the same resources. What sets us apart is we have a very collaborative cohesive team that works well together, that understands our clients' needs. We have good communication skills and we try to listen very carefully to what our clients' needs are and impart to them our advice in a collaborative partnership-type manner.*

"Not all consultancy companies do that. They come in with a hammer and they say you will do it this way or hit the highway and it becomes a very unfriendly approach. We have a lot of very good relationships with our clients. Many of our clients I have known for 20 plus years.

"A lot of it goes down to our people. Yes, we have great processes to help our clients achieve their goals, but we also have really good people. For us, and for me personally, it's the people that make the difference."

DP: Why should our readers get in touch with NSF as opposed to other similar companies in the market? What are the potential benefits?

MF: *"What they have to gain is expertise and a number of different types of consultants. We are here to help them solve their problems and find solutions for things that they've not been able to find. We provide guidance and consultation and we are very strategic thinkers."*

DP: What are the big issues that people are coming to you with in the industry at the moment?

MF: *"Data integrity is at the forefront. We are working with a number of clients on data integrity issues.*

"This is interesting to me because it is not new. Data integrity has been around for over 20 years and yet it is something that both companies and regulatory bodies did not pay enough attention to.

"The regulatory bodies now realize that data integrity is an issue and companies are coming to us for those reasons. We have, in my opinion, world-class experts in data integrity so companies do come to us for that.

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"Other than that, it is simple remediation, helping companies remediate their problems, continuously improve their management systems and their quality systems."

DP: What are the other big issues facing the pharmaceutical industry this year?

MF: *"Generics and over-the-counter drugs areas that have largely been ignored and the agencies are now looking at very closely because they are finding that some drugs, even though they are over-the counter-drugs, are not necessarily made in conditions which would be expected by the agency. It's an area that's largely been ignored. When they get ignored, they get casual about certain things.*

"Aseptic processing is always challenging for a lot of companies. As new products evolve there will be an increase in aseptic processing because many of these products cannot be terminally sterilized."

DP: What are some of the key ways pharmaceutical companies can minimize their risks while also maximizing efficiency?

MF: *"By having quality built in rather than having compliance built in. Compliance tends to bring complexity to systems, but if you build a quality mindset to begin with, the chances are, you're going to be in compliance.*

"A lot of companies don't build all the requisite quality pieces in and then they end up trying to backfill it with compliance. When they take that approach, compliance tends to add complexity, it doesn't lend towards efficiency, which then leads to increased cost."

DP: How do you tackle the challenge of being in a leadership role at large and diverse organization?

MF: *"It's not always easy because we are part of a corporation with many diverse product lines. My tendency is to be very transparent. I'll tell you in a constructive manner where the problems are and work towards a common goal."*

DP: What is it that drives you and your colleagues forward?

MF: *"The thing that gets us out of bed in the morning is our clients. We truly enjoy working with our clients and customers. We believe in being teaming with them. When they have good days, we share their good days and when they have pain, we feel their pain as we work side by side with them. We all have the same common goal.*

"We all try to live to the NSF core values which are the protection of public health."

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.

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

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