Regulatory Expert of the Year

USA

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Alan Schwartz, President and Founder of mdi Consultants, Inc., has decades of experience in FDA regulatory affairs, quality assurance, and international compliance. He brings a rare blend of hands-on expertise and strategic insight to his role as an expert witness. In this interview, he shares how his foundational years at the FDA shaped his approach, the pitfalls companies still face, and what distinguishes a truly effective regulatory affairs expert in today's complex landscape.

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Q You began your career as an FDA investigator in the early '70s—how has that foundation shaped your approach as an expert witness today?

Working for the U.S. Government at the FDA teaches you how to navigate various situations. One key skill you develop is the ability to listen before responding. You also learn to measure your words carefully to avoid putting yourself in a compromising position.

I once had the opportunity to go out on an FDA assignment with the press (CBS TV) to collect samples of freshly caught fish suspected of containing PCBs. When we couldn't find any freshly caught fish, the reporter had to interview me instead about the issue of contaminated fish. My response had to be appropriate—not based on personal opinion, but on facts. I had to learn to stick strictly to what was known.

That was valuable training: listen carefully to the question before answering, and always stick to the facts.

Q With hundreds of quality systems implemented and thousands trained in FDA regulations, what do you see as the most common compliance missteps companies still make?

Probably the biggest problem companies face is that—even though management is committed to making good products—they sometimes overlook what's needed to ensure compliance with manufacturing regulations.

A lack of true management commitment to quality is the most common issue we find that leads to serious problems.

The second major issue is arrogance in dealing with the FDA. When a company—especially a large one—believes it already knows the answers and refuses to bend, it creates significant concerns for the agency.

Companies need to understand when to "fight," when to compromise, and when to concede. Cooperation with the FDA is usually easier, less expensive, and less punitive in the long run.

Q How do you ensure your expert reports translate complex regulatory frameworks like QSR and cGMP into clear, actionable testimony for legal teams and the court?

The quality regulations (21 CFR 820, QSR/cGMP) are actually straightforward to understand and implement. The challenge lies not in the regulations themselves but in understanding how the FDA will enforce its policies. The regulations don't change often—the last major update to the QSR was in 1997.

Because I've been involved with these regulations since they were first implemented in 1978, I can explain them clearly and concisely. I've trained new staff on these systems, many of whom were encountering regulatory requirements for the first time. I also helped companies address FDA issues, often through corrective actions that included staff training.

So, explaining the regulations clearly is critical to both corrective action and long-term compliance.

Q You've led companies through FDA audits and ISO certification around the world—how does that global perspective influence your expert witness work?

Working with companies across the globe gives you deep insight into how industries function. Good companies, regardless of location, operate the same way: management ensures a robust quality system is in place and followed.

What varies is the influence of national culture on a company's quality structure. Understanding this helps me assess different situations and tailor my written opinions, deposition responses, and testimony accordingly.

Q You've authored over 50 articles on Quality Assurance and Regulatory Affairs—how has publishing and thought leadership shaped your credibility and voice as an expert?

What makes a good expert witness? It's a fair question. Longevity in a specific field, combined with the ability to make complex topics understandable to an arbitrator, judge, or jury, is key.

Also important is the ability to assess a problem and offer guidance in a way that strengthens the legal case.

Equally critical is knowing how to listen to questions and take the time to deliver a clear, well-structured response. That often means slowing things down and taking a deep breath before answering.

Q What qualities do you believe distinguish a truly effective expert witness in regulatory affairs from someone who's simply knowledgeable?

The most important quality is understanding the difference between regulations and the policies the Agency uses to enforce them. The FDA is known to change enforcement policies quickly as part of its adaptive process. When the FDA sees a pattern that raises concerns across the industry, it may revise its policy to address that issue.

As an expert witness, being aware of both FDA policies and regulations is essential to supporting your client. Anyone can be familiar with the written regulations—but unless you actively deal with the FDA and understand how their policies shift, your expertise will be limited.