Eric Schmisseur

Director of Quality—Device

PERSONAL PROFILE

According to Eric Schmisseur, the drive for quality in a pharmaceutical company or medical device manufacturer is focused first and foremost on regulatory and product compliance—including the rigorous internal planning, testing, verification and government approvals required for safety and efficacy.

The ultimate goal of quality leaders, says Eric, is "to make order out of chaos." Potential chaos can result from any of four basic problems, he explains. First, the company may lack internal agreement on simple, clear, thoughtful "story" [process] and strategy for regulatory compliance. Second, it may fail to commit that story/strategy to paper.

Third, there can be too many people and departments with overlapping or poorly-defined functions. Fourth, unreasonable time and resources might be wasted on chasing some arbitrary standard of "perfection," when simple excellence will suffice.

"I live by a motto that I got from Voltaire, which loosely translates as 'Don't let the perfect be the enemy of the good,'" Eric says.

He acquired this pragmatic philosophy early in his career. After taking his BS in mathematical statistics at Southern Illinois University, Eric entered the aerospace industry, working at Allied-Bendix and McDonnell Douglas. The stakes were too high to indulge in the pursuit of unattainable perfection, says Eric, because when an armed military bomber is in flight, every product failure is "potentially catastrophic."

> **"Quality is not a piece of the jigsaw puzzle along with design, manufacturing, production and documentation. Quality is the glue that holds all the pieces together."**
>
> — Eric Schmisseur —

After the Cold War ended, Eric transitioned to medical devices and pharmaceuticals, leading quality teams for companies including Sanofi, Amgen, Watson Laboratories, Perrigo Co., Bard Access Systems and Windgap Medical over a 25+ year career.

There Eric managed staffs of up to 56 people. He developed and ran internal and external auditing processes; developed and implemented supplier source inspection programs; managed quality assurance, document control and document quality engineering; developed test inspection methods, process validations and much more.

He also led Amgen's Corporate Quality System audits and internal quality audits of Amgen API and aseptic filling facilities to both FDA and EMEA regulations. He launched Sanofi's first-ever Class II software medical device. He has headed up quality efforts for combination products, and has reviewed and approved process validation protocols and reports for molding, fill finish, sterilization, and assembly at the company's CMO.

"What I enjoy most about working in quality in pharmaceuticals and medical devices is the opportunity to step up and get things done," Eric declares. "And, as an ApiJect team member, I am enthusiastic about being part of an organization that can deliver positive change in the world.

"The BFS Prefilled Injector is going to make a huge difference, and combatting COVID-19 is just the beginning," Eric says. "I am especially excited about what we can do to bring vaccines and therapeutics to people in less-advantaged countries all over the globe. I believe we have the opportunity to help change healthcare for the better on a worldwide basis."

ERIC SCHMISSEUR

"Quality is everyone's responsibility."

The quest for quality touches every point of a pharmaceutical product's journey, from initial R&D through production and eventual use in the field, according to Eric Schmisseur.

The goal of the quality group in a pharmaceutical or medical device company is ensuring regulatory compliance. Yet their role reaches beyond filing FDA-required paperwork or hosting government inspection tours, according to ApiJect's Director of Quality—Device Eric Schmisseur.

INTERVIEWER: Eric, you have stated that the core responsibility of the quality team in a pharmaceutical company or medical device manufacturer is ensuring regulatory compliance.

ERIC: Yes, as long as you add, "in the most efficient and practical way."

There seems to be a widespread myth that "quality" means simply filing the right documentation, or running technical tests after production but before shipment. Another myth is that you "add quality" into the mix, in much the same way that you might add a carburetor to a new car coming off the assembly line.

Quality is definitely not a discrete element that gets injected into the manufacturing process at a single, discrete point in the production journey of a product. The quality team is responsible for creating and implementing a series of systems that, together, add up to what we call "Quality by Design."

What is Quality by Design?

Quality by Design means that the quality of the product is planned at the earliest moment in the development of a product. The quality team is engaged at every step, beginning with the reviewing the design, development and then the commercialization of our product and our platform.

The field of quality, says Eric, offers "the opportunity to step up and get things done."

For an innovative systems manufacturer like ApiJect, the quality function will include reviewing drawings and resulting specifications. It also includes Quality Control, which covers testing in the lab. It embraces Quality Assurance, which includes reviewing systems, documentation and engineering. We also do the final inspection of the product, which is also Quality Control. So we really fit into the entire product cycle.

Quality also has role in risk assessment and acceptance?

Yes, and that includes both patient risk and product risk.

What is quality's relationship to the customer experience in the marketplace?

To begin with, a good quality team acts as the company's internal "eyes of the customer" on every process to help make sure products are truly safe and effective. If there are customer complaints, or if there is a recall, the quality team will also be responsible for investigating the reports and managing our response.

If the quality team is responsible for documentation and filing paperwork with regulators, how else do you interact with regulators?

We handle all regulatory inspections, of course. But I should explain that quality is not simply or solely the responsibility of the quality team.

You have said that "Quality is everyone's responsibility." Can you expand on that?

Our total approach to compliance with regulations is usually owned by both the quality specialists and the management. Quality is everyone's responsibility because every person who signs a document is affirming regulatory compliance, and to some degree is responsible for that.

A person who signs something that they know is false, will personally be held accountable, but the quality team members assigned to the oversight of that specific process or component will also be held accountable as well.

However, if there's a problem, there still has to be someone who is ultimately responsible, and that would be myself and the other quality individuals who take the lead in determining how the company's total system is put together and implemented.

Your motto is "Don't let the perfect be the enemy of the good." How does that translate into practical, day-to-day management when it comes to ensuring quality?

The mission of the quality team is to make certain that people are compliant with regulatory requirements, but that does not mean defining a narrow path and then saying, "This is the only way to go. Everyone must be compliant in the specific way that we have decreed." The quality function needs to be flexible.

How does quality impact a company's competitive position in the marketplace?

Because we live in such a highly regulated world, it's to our benefit as a company to recognize that the quality system should be treated as a business process, and should be managed and resourced like any other business process.

If you can be more efficient and effective by making it your goal to be good enough to clearly be in compliance and meet the market's needs in a safe, effective and reliable way, then you can reduce costs. In this way, your quality system itself becomes a measurable business advantage over your competitors.

You began your career in the aviation industry. The developer of radar for the RAF in World War II was famous for his approach to quality control. He said, "I recommend going for the third-best alternative, because the second-best is always too late, and the first-best never arrives."

There is nearly always more than one way to meet a regulatory goal. And, the attempt to achieve "perfection" can carry an unacceptably high cost in terms of resources, efficiency and time—especially in a global emergency like a war or a pandemic, when speed is paramount. But there is also plenty of applicability for this idea of "not letting the perfect be the enemy of the good" in more ordinary conditions, as well. An effective quality team lives by cost/benefit analysis, with the understanding that we never add risk to the patients.

Speaking of European approaches to quality, how does the U.S. regulatory framework differ from Europe's?

Nobody in the world takes the U.S. approach to combination products. For example, in Europe, essentially your device has to be fully approved as a medical device before you put the drug into it, while the U.S. looks at it as a one integrated product, which I think is more progressive.

Another example is that the FDA treats a medical device and the supporting software or the accompanying app as a medical device, and there are specific regulations for that.

For example, there are apps out there now that tell you how to take your insulin or give you reminders and specific information on biologicals. These apps assist patients to manage their prescription adherence and be more knowledgeable about their medications.

In fact, I think the biggest change in the pharmaceuticals industry over the past dozen years or so—and this includes packaging to some extent—is the greatly increased focus on combination products.

How has that change come about?

For decades, the perception of a prefilled syringe or an auto injector was that they were simply "functional packaging." Around 12 or 15 years ago, that changed. Now the prefilled syringe or auto-injector and the drug they contain are viewed as a combination product.

Many people still want to separate pharma from devices, but the FDA is very much aware of how integrated devices and pharmaceuticals have become. Regulators are thinking hard about questions such as: "When you put drugs and devices together, what happens? What does that mean? How are we going to control the outcome to ensure safety and efficacy?"

The FDA has done a really good job of addressing these questions, and is probably the world leader in that aspect of medical device and pharmaceutical regulation.

The quality field is largely a technical discipline, but like many leaders at ApiJect, you place a high value on "the human factor."

Nowadays, executives in many industries seem to believe that it's all about building their own careers—as if anyone could separate their individual success from that of their team, which you obviously can't.

I strongly believe if you spend a little time with people, and get to understand their concerns and what works for each person's career, obviously it works out better for them—but it also works better for you and your company in the long term, even if their career doesn't continue with the company you're in.

Quite frankly, if people hear that you are the guys who take care of people's careers, then the best people will approach you and want to work for you. It is a true win-win scenario.

We could call it "the quality approach to team building and management." Thank you, Eric.