



Life Science Best Practices: Moving Beyond Compliance

UNDERSTANDING “WHY” VS. “HOW”

IN THIS PAPER:

A Case Study of B. Braun Medical Inc.'s strategy to go beyond compliance requirements, through an initiative to “educate,” vs. merely “train” their employees.





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B. BRAUN MEDICAL INC.

B. Braun Medical Inc. (B.Braun), a leader in infusion therapy and pain management, develops, manufactures and markets innovative medical products and services to the healthcare industry. The company is committed to eliminating preventable treatment errors and enhancing patient, clinician and environmental safety. Guided by its “Sharing Expertise®” philosophy, B.Braun continuously exchanges knowledge with customers, partners and clinicians to address the critical issues of improving care and lowering costs. The B. Braun Group of Companies in the U.S. includes B.Braun, B.Braun Interventional Systems, Aesculap® and CAPS®. B.Braun’s U.S. headquarters is located in Bethlehem, Pennsylvania. The B.Braun Group of Companies employs more than 50,000 employees in over 60 countries throughout the world.

As a member of the highly-regulated medical device industry, B.Braun has maintained a focused commitment on compliance with all regulatory requirements, including those of the U.S. Food and Drug Administration (FDA) and the International Standards Organization (ISO). Despite its consistent compliance with applicable regulations, the company is determined to go beyond those requirements.

Kimberly Paris, Corporate Vice President of Quality, explained, “*We wanted to move beyond compliance in a way that would benefit our employees, our company and ultimately, our patients. This involved creating a strategy and program that emphasized the ‘why’ of learning instead of simply the ‘how’ of compliance.*”

B. Wise!: Beyond Compliance

B.Braun’s strategy to go beyond compliance requirements stood on a basic premise that was shared by the entire operations leadership, including the Chief Executive Officer. “Our existing program focused on instructing people ‘how’ to do their jobs,” said Paris. “We agreed that if our employees better understood why these regulations were important, they might be able to make better decisions along the way, minimizing the need for reactive responses instead of proactive ones. With the entire operations leadership aligned with that idea, we realized that we had to do something different than what we were doing.”

B.Braun created a new program, named B. Wise!, to reflect its goal of education instead of traditional training. The ambitious initiative began with a clear understanding of the existing training infrastructure along with clarity of the job functions and needs of targeted employees. “We then had to decide how to implement a system based on that understanding. With a dispersed workforce and challenges related to in-person training, we knew that we were looking at online learning. One option was to develop the content in-house. We had Subject Matter Experts (SMEs) but we lacked expertise in adult learning. So, we began to look outside at companies that had extensive regulatory and Good Manufacturing Practices content with expertise in adult learning, which led us to UL,” explained Paris. It was also important to Paris that the content be updated on a regular basis which certifies that current industry regulations are reflected within the courses. “This ensures that our employees are being trained on current standards and that our in-house SMEs were not spending their time updating courses, but are focused on developing effective training programs,” added Paris.

UL’s first step was to conduct a thorough assessment of the company’s operational network: R&D, regulatory affairs, quality, supply chain, engineering, technical services and manufacturing. That matrix defined the knowledge needs of personnel in each area. “UL identified the knowledge needs of each job function and the content available to address those needs; we knew our organizational structure and the accountability and needs of our employees. With that shared knowledge, we could clearly identify the best courses for our organization across the different operations,” said Paris.



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Rolling Out B. Wise!

Armed with a formal matrix and related content, the company began planning the rollout of its innovative B. Wise! program. Compliance and training professionals across the business spectrum recognize the importance of an efficient program rollout. Explained Paris, “We began by identifying the mistakes we knew could occur in a rollout – mistakes we were determined to avoid.” Among the practical hurdles B.Braun identified were how many employees needed computer access in order to take the online training and how many computers were needed and available to implement the program. Where were they located and how accessible were they to each site? How much content was reasonable for each individual to complete in what period of time? How do you prevent “training fatigue” or the perception that the new content was just one more layer of training? How do you generate buy-in from employees in different job functions, at different sites and with different knowledge requirements?

Reiterating what many compliance professionals say, Paris admitted, “It’s not an easy thing. Rolling out a new program across multiple departments, an initial workforce of 2,000 people, different locations ... it can be quite daunting. We knew there were some things that were crucial to success and we have learned many best practices along the way. We have also discovered some things we will do better as we continue the rollout across our entire organization and, potentially, at other companies in the B.Braun Group.”

BEST PRACTICES:

Compliance Training Rollout



Define the message. “This wasn’t one more training program and we wanted to make sure our employees understood that,” said Paris. “Coining our program B. Wise! was the first step in promoting the message of education instead of training – of “why” instead of simply “how.” We needed to define how this was different, how it would benefit our employees, and how it was a real investment by the company in our employees’ development and futures.”



Communicate continually. The company developed an “advertising” program to support the rollout, using multiple types of marketing materials and techniques to communicate the message. “We used a variety of materials and techniques to get the message out that this program was coming and why it mattered. We needed our employees to see that they would benefit and that this program was a company commitment to them, to their development and to their effectiveness.” Among the reinforcing materials were screensavers, notepads, internal promotions and even candies.



Create and maintain top-level buy-in for the program. “There had to be buy-in at all levels of the organization, including at the top. Before, during and after the initial rollout, we continued to communicate with individuals at the highest levels as well as leaders at each plant, quality leaders and HR managers at each site.”



Take it slow. Instead of attempting to roll out the entire program of courses at one time, the company took a measured approach. “We didn’t want to drop 30 courses in our employees’ laps and say, “Go to it.” Instead, the company set up a program to deploy two courses per month with the expectation for employees to take one course per month. This provided employees with the option of taking an additional course if desired. “Our goal is for employees to retain the knowledge they were gaining, not to race through a pile of courses in one day.” Equally important was ensuring that the courses were available whenever the employee chose to take them. “The UL online courses could be accessed from any location that offered internet access, so employees were free to take the courses when they wanted to, as long as they completed them within the one month period.”



Continue to generate support. Maintaining enthusiasm for the program is an ongoing effort. “One of the techniques we used to increase the interest among employees in the new program was holding contests. For example, the first employee to complete the required courses successfully would receive an iPad. Then, we expanded it to departments and sites: The first department to complete the first round of courses would get a free lunch,” said Paris. Beyond the inevitable competition among employees for “first place prizes,” an added benefit was a reinforcement of the message that the company was making an investment in its employees.



Value feedback – positive and negative. “Some of the feedback we received was positive. Employees from some sites really understood what we were doing and were enthusiastic about it. At other sites, there was less positive feedback, but we learned from that as well. One of the surprises was that not all managers were communicating the message to their employees as we had hoped and that lack of communication had a direct impact on the way the department approached the program and embraced the message we were conveying.”

The Next Steps

B.Braun is preparing to rollout additional courses to other segments of the company. “The ongoing expansion of B. Wise! points to our continuing emphasis on education vs. training. Our goal is for our employees to have a better comprehension of the subject material and a better understanding of why it is so vital to their jobs and our company,” explained Paris. “As the rollout continues, we are especially mindful of avoiding training fatigue by using multiple communication techniques and learning methods.”

Assessing the effectiveness of the program is a challenge shared by many organizations. “It’s difficult to measure the success of B. Wise! It’s easy to measure activity, but more difficult to quantify the direct results. Obviously, we can measure how many people complete the courses but that doesn’t automatically demonstrate greater competency or understanding of the bigger picture. The goal is for B. Wise! to translate into better decision-making by our employees, resulting in our ability to be more proactive as an organization and less reactive. We believe that the program will lead to improved performance and we’re confident that we’ll see that demonstrated through positive results in our business, product quality and compliance.”

Other affiliates of the B. Braun Group are watching B. Braun Medical’s experience with considerable interest. As the first in the group to develop, launch and manage B. Wise!, B. Braun Medical Inc. is setting the groundwork for what may be a much broader application of the new approach. “In the end,” said Paris, “We’re confident that our emphasis on “why” instead of simply “how” will have direct benefits for our employees, our company and the continued confidence of our patients. We believe the work we’re doing now could have value far beyond B.Braun.”



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Kimberly Paris,
Corporate Vice President of Quality
B. Braun Medical Inc.

About UL EduNeering

UL EduNeering is a business line within UL Ventures. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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