Large Pharmaceutical Manufacturer

MARKETING DRUGS SAFELY

CASE STUDY

Booz Allen Hamilton is helping a major pharmaceutical company make drugs safer for the public.

About Booz Allen

Booz Allen Hamilton has been at the forefront of management consulting for businesses and governments for more than 90 years. Integrating the full range of consulting capabilities, Booz Allen is the one firm that helps clients solve their toughest problems, working by their side to help them achieve their missions. Booz Allen is committed to delivering results that endure.

For more information, contact

Christian Burger
Senior Vice President
+49-89-54525-546
burger_christian@bah.com

www.boozallen.com

Client's Challenge

Prescription drug use is on the rise in America and Europe, and new drugs are continuously coming to market. But for every promising cure, there can also be harmful—sometimes fatal—reactions and multibillion dollar judgments against drug makers. To protect the public, governments around the world are tightening drug safety laws and regulations. Although many companies might view the new oversight and regulations as obstacles, one global pharmaceutical giant set out not only to comply with emerging safety rules but also to turn them into a strategic advantage.

The company realized that all drug makers would have to improve drug safety management, and its own organization fell short. Drug safety teams lacked a holistic approach to managing risk across product lifecycles. The organization was overly complex and burdened by a silo mentality. It focused on compliance rather than eliminating risk. To rethink its approach, the company engaged Booz Allen Hamilton to analyze the regulatory climate and then partner with its leaders in defining new operating models that give more weight to drug safety.

What Booz Allen Hamilton Did

Booz Allen helped the client consolidate a complex, decentralized drug safety operation and create new governance structures that grant safety teams more authority.

To do this, Booz Allen worked with the company first to understand the impact of changing regulatory and legal requirements, and then translated those insights to reposition the drug safety risk management (DSRM) function within the organization.

Booz Allen spoke to regulators, product liability insurers, and other world-class pharmaceutical manufacturers about the changing regulatory environment. Clearly, the DSRM function would need to step out beyond its traditional compliance role—it would need the authority to provide medical and strategic input throughout the drug development and marketing process.

We helped the client solidify DSRM's authority, structure, and decision rights. For example, DSRM would weigh in on pay and performance evaluation criteria for marketers, creating incentives that would lead to deeper dialogue with physicians about introducing drugs responsibly. The changes reposition the DSRM function from an obligatory overhead cost to a value-driver, working proactively and strategically to protect the overall organization.

Results

The recommendations Booz Allen made are helping this organization not only position itself to achieve success in spite of tough new regulations, but also take an unprecedented step to meet the realities of the pharmaceutical industry head on and continue to introduce life-saving medicines while keeping patients safe.

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