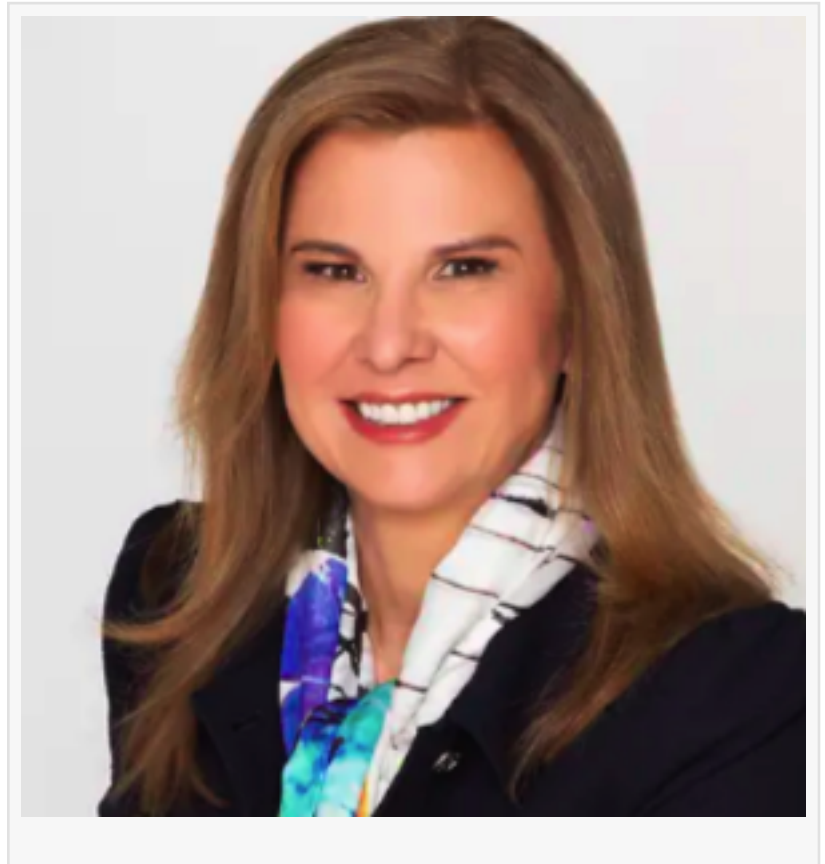


Influential Women Profiles: Dawn Bowen-Bolles, Regulatory Leader Driving FDA Compliance and Product Safety Excellence

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Seasoned Regulatory Specialist at Position Health, LLC Builds Robust Quality Systems and Guides Complex FDA Submissions Across International Markets

Position Health, Lake Forest, Illinois — Dawn Bowen-Bolles is a seasoned Regulatory Specialist at Position Health, LLC, where she has spent the past five years serving as the primary regulatory authority for a U.S.-based medical device company distributing products internationally. Despite entering the organization without prior medical device experience, she quickly stepped into a high-responsibility role, navigating an FDA audit within her first six months and establishing the company's foundational regulatory filing system and quality management system.



Drawing on a diverse professional background in legal work, consulting, education, food science, and research and development, Dawn applied decades of discipline and structured problem-solving to the highly regulated medical device environment. Her ability to adapt rapidly and build systems from the ground up has been central to strengthening compliance infrastructure across the organization.

In her current role, Dawn oversees all regulatory communications with distributors and government agencies, managing requirements that span manufacturing compliance, labeling standards, and both domestic and international product registrations. Her responsibilities extend across nearly every operational aspect of the business, ensuring that products meet strict

regulatory standards across multiple jurisdictions.

One of her most notable achievements came when she successfully guided a complex premarket submission through clearance with the U.S. Food and Drug Administration. During the process, new cybersecurity requirements were introduced mid-filing, significantly increasing the complexity and urgency of the submission. Working under tight deadlines and evolving regulations, Dawn delivered approval with minutes to spare—demonstrating her ability to remain composed under pressure and systematically break down highly complex regulatory challenges into actionable steps.

Dawn's career spans more than four decades and reflects a uniquely interdisciplinary professional journey. She has worked across food science, regulatory consulting, paralegal practice, teaching, and healthcare compliance, giving her a broad and practical understanding of how systems operate across industries. She holds two Bachelor of Science degrees from Michigan State University, a master's degree in the Art of Teaching from National Louis University, and a Paralegal Certificate from Loyola University Chicago, where she graduated with a 4.0 GPA.

Dawn attributes her long-standing success to her diverse background and her strong foundation in project management. Throughout her career, she has approached every responsibility as a structured project—whether managing FDA filings, overseeing multi-million-dollar capital planning initiatives, or teaching in academic settings. This mindset allows her to break complex challenges into actionable steps, maintain discipline, and communicate effectively even in high-pressure environments.

When faced with overwhelming situations, Dawn emphasizes the importance of pausing briefly, resetting focus, and returning to short-term priorities while keeping long-term outcomes in view. She notes that discipline and clarity of focus are essential to navigating regulatory environments, particularly when deadlines are tight and requirements continue to evolve. She also believes that professional experiences—both positive and challenging—serve as ongoing learning opportunities rather than defining personal identity.

Dawn encourages young women entering the regulatory and healthcare industries to approach each role as a learning opportunity rather than a fixed career definition. She emphasizes the importance of building strong organizational and project management skills early, staying open to new areas of knowledge, and actively engaging in networking and volunteer opportunities to broaden experience and confidence.

Dawn also identifies increasing regulatory complexity as one of the most significant challenges in her field today. This includes evolving FDA requirements such as cybersecurity considerations in premarket submissions, as well as the growing influence of artificial intelligence on compliance systems and documentation standards. At the same time, she sees meaningful opportunity in the expansion of remote work, which allows organizations to access broader talent pools and

enables professionals—particularly women—to build stronger networks beyond geographic limitations.

Across her career, Dawn has remained grounded in core values of discipline, persistence, and a structured, project-driven work ethic. She is also deeply committed to service, volunteerism, family, and lifelong learning—principles that continue to shape both her professional and personal life.

Working remotely from the Lake Forest company headquarters, Dawn maintains a structured daily routine that mirrors a traditional office environment, intentionally preserving boundaries between work and personal time. She continues to serve as a steady, trusted presence in the highly complex field of regulatory affairs, contributing to the safe and compliant delivery of medical technologies in global markets.

Learn More about Dawn Bowen-Bolles:

Through her Influential Women profile: <https://influentialwomen.com/connect/dawn-bowen-bolles>

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