King & Spalding

Eric Henry

Consultant
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Eric Henry is a Senior Quality Systems and Compliance Advisor in the FDA and Life Sciences practice of King & Spalding. Eric has 30 years of experience in global quality and compliance roles (18 years in medical device and health systems leadership), with a specialization in software quality (including cybersecurity), medical device design controls, risk management, audit management, management controls, and QMS remediation.

Eric came to King & Spalding from Philips, where he was the Global Head of Quality Assurance / Quality Engineering for the Diagnostic Imaging Business Group and had responsibility for design controls, risk management, and a variety of other interim management system elements in seven business units spanning 14 sites globally. Prior to Philips, Eric led design quality assurance at Medtronic's Diabetes Business Unit, was responsible for software design controls and general design controls effectiveness for GE Healthcare for all GE businesses worldwide, and had software quality and software design leadership responsibility at Boston Scientific and Hologic.

Eric has hands-on problem-solving and organizational change management experience, as it relates to large process improvement initiatives, the defense of quality systems to third parties (e.g. FDA, notified bodies, CFDA), quality system remediation programs (including under FDA enforcement actions), and the execution of product development programs, where both quality and global compliance are mission critical.

Prior to entering the medical device industry, Eric led a software quality management and program management office consulting capability in the Washington, DC area and held software design and development leadership roles in a small startup, a mid-size healthcare software company, a large financial services regulator and stock market, and a large retail organization.

Credentials

EDUCATION
B.S., Wilmington University, summa cum laude

Events

SPEAKING ENGAGEMENT
December 7, 2020
Eric Henry to Speak on KenX Computer Systems Validation and Data Integrity Congress Virtual

Conference

November 17, 2020
Eric Henry to Speak at FDANews FDA Inspection Summit

November 10, 2020
13th Annual King & Spalding Medical Device Summit

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News

IN THE NEWS
November 11, 2020 • Source: Medtech Insight
Steve Niedelman and Eric Henry discuss the pandemic nudging the FDA to launch a voluntary pilot program that will allow agency investigators to conduct facility inspections virtually

October 17, 2019 • Source: Medtech Insight
Eric Henry explains why device-makers should consider the cumulative effect of software cyber security patches on products

November 26, 2018 • Source: The Washington Post
Eric Henry joins the Washington, D.C., office as senior quality systems and compliance consultant for the firm's FDA & Life Sciences team

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