PALADIN MEDICAL®

Your Champion for Product Success

Elaine Duncan, President

Elaine Duncan, MS.ME., RAC, is the founder and president of Paladin Medical, Inc. Elaine is a certified regulatory affairs professional with a master's degree in engineering (mechanical/biomedical). Elaine holds an appointment as an Adjunct Professor of Biomedical Engineering in the F. Joseph Halcomb III, M.D. Department of Biomedical Engineering at the University of Kentucky.

Brief Resume

Elaine Duncan is a recognized leader in regulatory/clinical strategies for new medical technology development. Prior to forming Paladin Medical in 1987, Elaine held key executive positions in start-up medical companies, including vice-president of new ventures, vice-president of research and development and vice-president/director of regulatory affairs/ quality assurance. Her Fortune 500 company experience in acquisition and technology assessment gives Elaine a unique understanding of the due-diligence required for mergers and acquisitions within the medical industry. Ms. Duncan works with clients to define the best regulatory approach for new products, helping companies to develop IDE trials and nonsignificant risk studies for premarket submissions.

Clients with concerns for biomaterials selection and biocompatibility analysis, including combination products and tissue engineering, will find Elaine's experience extremely helpful. Elaine also has in-depth experience in pre-clinical testing and GLP regulations. She has had broad experience in diverse areas, including artificial hearts, vascular grafts, spinal implants and various disposable sterile products. Please see Profiles of Success for additional information.

In 1992, Elaine Duncan received the Medical Alley Outstanding Contribution to the Health Care Industry Award. Her service as the editor of Biomaterials Forum for over 12 years was recognized in 1999, with the C. William Hall Award from the Society For Biomaterials. In addition, Elaine has served on the board of directors and in other leadership positions of the Society For Biomaterials. She is a member of numerous biomedical organizations, including AAMI, ASTM and ORS as well as a frequent contributor to industry publications. In April 2000, Elaine was honored with induction into the University of Kentucky College of Engineering Hall of Distinction, and in 2007, as a member of the Quadrangle Society. Elaine also serves as a member of the Dean's Advisory Committee of the College of Engineering at the University of Kentucky.

We serve a global clientele who produce their products for the worldwide medical device community. We assist U.S. device manufacturers in understanding requirements for the European Union and Canada and preparing their documentation for assessment by a Notified Body to obtain the CE Mark and/or assessment by a Canadian Registrar for licensing in Canada. Risk management and device validation are universal expectations. I have a real-world, pragmatic understanding of how to translate device requirements into product qualification in order to assure products meet user needs.

Please feel free to request a full C.V and continuing education report via email,

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