Greenleaf Health

Heather Rosecrans, F.R.A.P.S

Executive Vice President, Medical Devices & Combination Products

BACKGROUND

- 30 plus years with the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) and over a decade as Executive Vice President for Medical Devices and Combination Products at Greenleaf Health

SPECIALTY

- Specialist in FDA's 510(k) program and classification of Medical Devices

EXPERIENCE

- Extensive previous experience in the development, FDA premarket review and marketing of medical devices
- Device regulation at multiple levels within CDRH, consulting for industry on medical device regulation in the US

Heather Rosecrans brings more than 40 years of public health and medical device experience to Greenleaf. She continues her commitment to public health by providing strategic consulting services and working with Greenleaf clients to deliver innovative devices to patients.

Before joining Greenleaf, Heather served as Director of the 510(k) Premarket Notification Staff at the FDA's CDRH. In this role, she was responsible for implementing administrative and regulatory policy for the 510(k) Program, the 513(g) Program, Classification and Reclassification, de novo petitions, and other premarket regulatory requirements.

Heather started her FDA career as a biologist in the Bureau of Medical Devices. In 1980, she joined the newly organized CDRH Premarket Application (PMA) Staff. For the next 7 years, she coordinated the administrative, scientific, and regulatory review of PMAs, as well as product development protocols, master files and associated submissions.

In 1987, Heather joined the 510(k) Section of CDRH's Program Operations Staff. In this role, she served as a Consumer Safety Officer and was a key contact for CDRH and within FDA on 510(k) matters. Heather held this position until 1992, when she became Director of the 510(k) Staff.

Heather's accomplishments include drafting guidance documents and regulations on the 510(k) Program, training FDA staff and other stakeholders as well as assisting in the implementation of the Medical Device User Fee Modernization Act, the Food and Drug Administration Modernization Act and the Safe Medical Devices Act.

Heather's extensive experience at CDRH—specifically her pivotal role in developing the 510(k) Program—enabled her to become one of the nation's leading 510(k) experts. Since its inception in 1976, more than 150,000 510(k)s for devices have been reviewed for a determination regarding substantial equivalence via the program. Heather has represented and spoken on behalf of CDRH in multiple forums, including national conferences, FDA advisory committee meetings, and international symposiums. Her published work includes numerous guidance and regulatory documents. She has also worked collaboratively with the Center for Medicare and Medicaid Services and other regulatory agencies.

Heather holds a B.S. in Biology from Pfeiffer College in Misenheimer, N.C.