

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

Executive Vice President, Medical Devices & Combination Products



BACKGROUND • 30 plus years with FDA

SPECIALTY • Specialist in FDA's 510(k) program

EXPERIENCE • Extensive previous experience in the development, approval, and marketing of medical devices

Heather Rosecrans brings more than 30 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 Food and Drug Administration's (FDA) Center for Devices and Radiological Health (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 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 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 staff and assisting in the implementation of the Medical Device User Fee Modernization Act and the Food and Drug Administration Modernization 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 120,000 products have been cleared 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