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Grace Powers, MS, MBA, RAC (US, EU, Global, Device)

Grace Powers is an independent regulatory affairs consultant. She founded Powers Regulatory Consulting in 2015 to help clients with regulatory strategies and submissions. Her clients have included universities, investors, start-ups, and mid-size medical device companies.

She has twenty years of industry experience in medical devices including research and development. She has previously worked for Brookhaven Medical, Bard Medical, CardioMEMS, and Novoste, all in the Atlanta area.

She has leadership experience with managing regulatory affairs responsibilities related to all pre- and post-marketing regulatory activities and submissions. Her RA submission experience includes FDA submissions such as 510(k)s, Pre-Submissions, 513(g)s, de novos, IDE, PMAs (including Supplements, Real Time Reviews, 30 day noctices), and EU Technical Documents (CE marking including MDR).

She has also managed an International RA team which including Canadian licensing, TGA, Japan, China, Russia, Latin America and other country submissions. Grace holds an BE in Biomedical Engineering from Vanderbilt University, an MS in Biomedical Engineering from UCLA, and an MBA from Georgia Tech. She is RAC US, RAC Europe, and RAC global and RAC Device certified.

MEDICAL DEVICES

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