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To Whom It May Concern:

MEDRAD, Inc. is a worldwide market leading manufacturer and distributor of medical devices that enable or enhance diagnostic and therapeutic medical procedures for computed tomography, magnetic resonance, and cardiovascular applications and is a global company. The company's Global Center is located in Warrendale, Pennsylvania, 18 miles north of Pittsburgh. MEDRAD products are sold to hospitals and medical imaging centers in over 85 countries.

I am pleased to recommend Regulatory and Quality Solutions LLC. Maria Fagan worked for MEDRAD for over 12 years and played an important role in the growth of the company over that time period. Maria participated in the development of MEDRAD's quality system, writing of Design Control and Manufacturing Quality procedures, and consequently played an important role in MEDRAD's journey to receive the Malcolm Baldrige National Quality Award. Maria is a recipient of the MEDRAD President's Award for Leadership. She's known for her outstanding abilities to develop people and treat her reports as if they were family members. In Maria's most recent projects, she developed a regulatory system and implemented regulatory plans for the successful worldwide launch of our Cardiovascular SBU's new Cardiovascular Injector System, MEDRAD AVANTA, and developed the regulatory strategy for MEDRAD's Class III in-development catheter product. Additionally, Maria has experience with post-market surveillance and stays abreast of the current regulatory environment.

Lisa Casavant worked for MEDRAD for over 4 years and held the roles of Sr. Compliance Engineer and Sr. Regulatory Affairs Specialist in the Computed Tomography (CT) SBU. She participated in the development of complex regulatory strategies, interfaced and met with FDA on new products, completed 510(k) submissions, and contributed to the successful worldwide launch of these products. Lisa provided regulatory guidance to new product development teams, and was appreciated for thinking out-of-the box and for her assistance in reaching business-balanced decisions. Lisa's skills stretched beyond Regulatory Affairs and into post-market product risk assessments and situation analyses. She participated in providing guidance to all SBUs and manufacturing on assessing risk and responding to field issues.

It is my pleasure to recommend Regulatory and Quality Solutions LLC. I believe that Maria's and Lisa's regulatory and quality system leadership, skill and knowledge can contribute to the success of any company.

Sincerely,

  
John P. Friel



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