Justification for Attending Premarket Approval (PMA) Medical Device Submissions Workshop

Dear [Manager Name],

I am requesting approval to attend AdvaMed's **Premarket Approval (PMA) Medical Device Submissions Workshop**, taking place **February 26–27, 2026**.

This two-day program delivers in-depth, expert-led training on navigating the complex PMA regulatory pathway, including submission structure, FDA expectations, clinical and regulatory documentation, review dynamics, and preparation for advisory panels and inspections.

The program features instruction from experienced regulatory and FDA leaders, including:

- **Jessica Ringel, Partner, King & Spalding** — covering foundational PMA requirements and preparation for advisory panels
- **Nam To, Policy Analyst, FDA** — presenting on strategy development and early interactions with FDA
- **Jhumur Banik, Team Lead/ Biomedical Engineer, FDA** — leading a session on quality system submission development and review
- **Jennifer Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific** — speaking on submission review and conditions of approval studies
- **Jacob Dyer, Senior Regulatory Officer, FDA** — guiding inspection-related content
- **Jeff Shapiro, Partner, FDA and Life Sciences, King & Spalding** — discussing post-approval maintenance of PMAs
- **Ken Skodacek, CDRH Deputy Ombudsman, FDA** — providing insights on dispute resolution and escalation pathways
- **Tony Blank, Senior Director of Regulatory Affairs, AtriCure** — facilitating applied learning sessions and breakout discussions

The workshop has **secured RAPS accreditation** and is approved for **up to 12 RAC recertification credits**, allowing me to maintain professional credentials while gaining targeted regulatory knowledge in a single concentrated program.

Cost: $[INSERT REGISTRATION FEE]

Attending this workshop would enhance our ability to build strong, compliant PMA submissions, anticipate and address common review challenges, and align regulatory strategies with current FDA expectations. The knowledge gained can be directly applied to ongoing and future regulatory initiatives.

Best regards,
[Your Name]