

## HELPING CARDIOVASCULAR COMPANIES ADVANCE NOVEL THERAPEUTIC TECHNOLOGIES

In HPA's 23-year history, our team has worked with a wide variety of novel cardiac implants/devices and diagnostic tools. Whether your needs involve assistance with regulatory strategy/submission or clinical trial strategy, design and execution, HPA has the experience and expertise to get your technology from prototype to commercialization.

With a proven track record of advancing technology in a streamlined, ultra-efficient fashion that leads to quicker, more economical approvals, HPA can serve as a valuable asset to your cardiovascular company.



### HPA's Cardiovascular Medical Device and Diagnostic Technology Expertise

**HPA has extensive experience working with companies to deliver a wide range of cardiovascular medical device and diagnostic technologies, including but not limited to:**

- Coronary and peripheral stents
- Drug-eluting and drug-coated balloons
- Vascular closure and access devices
- PICC & drainage catheters
- Vascular grafts and patches
- Technologies treating heart failure
- IVC Filters
- Catheter-based ablation technologies
- Diagnostic and mapping catheters
- Thrombectomy devices
- AAA stent grafts
- Cardiovascular monitoring devices
- Intravascular imaging devices



## ABOUT HPA

Health Policy Associates has spent more than 20 years providing high quality consulting services to the medical device and biotech community, helping companies bring their innovations to market. As specialists in regulatory compliance and clinical consulting, HPA helps medical and biotech manufacturers optimize their product development processes while avoiding potential pitfalls.

From clinical trial strategy and design to precision data analysis, HPA's team of industry experts has guided leading manufacturers around the globe to regulatory success again and again, with unrivaled accuracy and efficiency. HPA enhances the efficiency with which a company executes its product development timeline by: developing strategies and plans that meet regulatory and market needs, evaluating and supplementing company resources, managing clinical and/or regulatory functions, developing and implementing quality system and compliance strategies, and assisting with venture capital financing strategies and valuation milestones.

Because of our experience focusing exclusively on the medical device and biotech industries and dealing with some of the most unique and complex products under development, our clients are assured that HPA consultants can resolve their problems and address their specific needs.

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## HPA Services

HPA's goal is to provide practical and highly efficient consulting solutions to companies involved in developing new medical device technologies, pharmaceuticals or biologics. HPA's high-quality consulting services include:

- **Clinical Trial Strategy and Execution:** Protocol development/ Case Report Form design, clinical site identification, management and monitoring, database and EDC creation, data analysis, report writing, regulatory submission preparation.
- **Data Management and Analysis:** Database design and hosting, real-time data access and query resolution, customized data analysis and reporting.
- **Worldwide Regulatory Consulting:** Regulatory strategy development, project plans, FDA submission management including presentations, submissions, reports and filings, development of worldwide regulatory strategies.
- **IRO/Data Integrity Auditing:** AIP services including FDA audits and integrity reports, IRO services including OIG work plans, reviews, reporting and submissions.
- **Quality Systems/Compliance Consulting:** Quality system design, compliance strategy development, internal and supplier GMP auditing, FDA inspection assistance, risk management, medical device reporting, application of corrective/preventive action procedures, product recall support.
- **Venture Capital Investing:** VC identification, project plan and timeline development, valuation milestone development