HPA INC
HEALTH POLICY ASSOCIATES INC

HPA: EXPERT GUIDANCE FOR BRINGING CONNECTED HEALTH INNOVATIONS TO MARKET

The use of technologies such as smartphones, social networks and internet applications is enabling patients, consumers and medical professionals to monitor and manage health and wellness in new ways. But bringing innovative new connected health products to market can be a complex process.

- Is it unclear to you whether your technology should fall under general wellness or is a medical device?
- Is the data generated by your device accessible in the cloud?
- Does your technology provide a direct e-connection between patient and physician?
- Are you struggling with a compliant quality system for your connected health applications?
- Do you need assistance understanding the gray area between exempt devices and non-exempt devices?

Health Policy Associates (HPA) has the experience and expertise in connected health that can help your company navigate the tricky waters of this evolving space.

HPA's CONSULTING SERVICES FOR CONNECTED HEALTH TECHNOLOGIES

Regulatory Assessment and Strategy

- Determine whether your technology falls under general wellness or is a medical device, and identify the appropriate regulatory pathway for your specific technology.
- Provide input and guidance on regulatory implications of desired claims, uses and indications for the technology and the data generated by that technology.
- Perform strategic interactions with regulatory authorities, including the FDA, to confirm the planned approach and assumptions.

Quality System Design and Implementation

- Identify necessary quality system procedures necessary for regulatory compliance, and develop and deploy customized standard operating procedures (SOPs).
- Provide guidance through each phase of the quality process, including: design control, design verification and validation, document control and record management systems, and quality system training.
- Create state-of-the-art CAPA systems, and assist with implementation of effective CAPA programs.

US FDA and OUS Regulatory Submissions

- Provide support and analysis for pre-submission / pre-IDE meetings.
- Review regulatory package prior to submission, addressing agency questions and interacting with regulatory authorities to resolve issues.
- Prepare 510(k) pre-market notifications, Investigational Device Exemption applications (IDEs), supporting files and reports, and foreign applications as needed.
- Provide representation with the FDA and OUS regulatory agencies.

Clinical Trial Strategy, Design and Execution

- Determine clinical trial strategy and design required to support regulatory submissions.
- Perform project management, clinical monitoring, statistical analysis, study reports and audit preparation as needed to ensure successful product launch.

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

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