HPA INC
HEALTH POLICY ASSOCIATES INC

HPA QUALITY ASSURANCE

Quality assurance becomes increasingly challenging as medical device, drug and biologic products move through the manufacturing process. With a QA team unmatched in the industry, Health Policy Associates (HPA) has been setting the gold standard in healthcare quality assurance for more than 23 years. HPA provides QA/compliance support to leading clients in the medical device and pharmaceutical markets and has the knowledge, experience and systems to meet both your rigorous standards, and those of federal and outside regulatory agencies.

HPA's Quality Assurance Team - 150+ Years of Experience

HPA's QA/compliance experience is second to none, resulting in a laser focus on the training and processes so critical to safe, strategic healthcare manufacturing. Our QA team's more than 150 collective years of healthcare industry QA experience includes:

- Extensive backgrounds in medical device research and development
- Pharmaceutical and healthcare experience in highly regulated environments
- Industry-leading quality management and systems integration expertise
- Management of operations for leading manufacturers of instruments, implants, serialized capital goods, mobility products and diagnostic equipment
- An elite understanding of well-documented procedures
- Significant experience interacting with regulatory bodies and meeting regulatory requirements, including:
  - FDA's AIP (Application Integrity Policy) Program
  - Consent Decrees
  - Data Integrity Assessments

HPA's Trusted Quality Assurance Services

HPA's objective is to ensure best practices, compliance and safe operations. Our foundational systems are based on best practices in the industry and a unique understanding of regulatory requirements. HPA's experienced QA team works closely with you to:

- Meet all federal and state regulatory requirements for the manufacture and distribution of your medical device/drug/biologic products
- Draft and implement standard operating procedures to align with what is actually being done
- Execute to your existing standards or create a quality management system from scratch to comply with the unique requirements of your business
- Conduct quality system reviews to:
  - Address customer complaints
  - Evaluate the health and functionality of the quality system
  - Assess management engagement in continuous improvement efforts
  - Address common topics such as: compliance with requirements, training and competency, status of any implemented corrective actions (CAPA), and process improvements

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.

Health Policy Associates, Inc.
690 Canton Street, Suite 302
Westwood, MA 02090
+1 (781) 329 2993

Office Locations:
Westwood, MA
Cambridge, MA
Silicon Valley, CA
San Antonio, TX

info@healthpolicyassociates.com
www.healthpolicyassociates.com

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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