HPA INC
HEALTH POLICY ASSOCIATES INC

ARE YOU PREPARED FOR THE FDA? HPA HAS THE EXPERTISE YOU NEED

- Have you received a Notification of Inspection letter from the FDA?
- Do you have planned or pending critical submissions to the FDA?
- Do you have products with issues that require an FDA response?

Health Policy Associates, Inc. (HPA) is the internationally recognized leader in assisting medical device manufacturers with FDA inspections, interactions and responses.

Preventing and resolving compliance issues for new medical products requires specialized expertise in developing and implementing GMP (Good Manufacturing Practice) quality systems, understanding FDA and international regulations and compliance requirements, and managing interactions with the FDA during audit and inspection processes.

GMP/Quality System Auditing Services

For more than twenty years, HPA has been providing consulting expertise to the end-to-end process of bringing innovative new medical devices to market. HPA's comprehensive GMP/quality system auditing services include:

- **FDA QMSR (Quality Management System Regulation) mock audit:** To help prepare for an FDA inspection, HPA can conduct a GMP audit that mimics the FDA inspection process, providing an unbiased assessment of readiness for an actual FDA inspection.
- **FDA pre-inspection audit:** To evaluate the preparedness of manufacturing facilities for regulatory inspections, HPA conducts either a gap analysis or internal GMP audit to identify any problem areas in the quality system — e.g., complaint handling, design control, corrective action, manufacturing processes, special processes, etc. — prior to an FDA inspection. In addition, HPA can stand with you, providing assistance during the actual FDA inspection process.
- **Gap analysis:** FDA regulation 21 CFR Part 820 prescribes the requirements that medical device manufacturers must establish and follow in their GMP quality systems to ensure that their products consistently meet applicable requirements and specifications. HPA's gap analysis determines the current level of compliance with FDA regulations, quickly pinpointing any problem areas in the current quality system.
- **Full or partial internal GMP audit:** FDA regulations require medical device manufacturers to audit their GMP quality management systems and processes on a regular basis. HPA's internal auditing services provide an independent review of the full quality management system, as well as focused reviews of specific QSR processes.

ABOUT HPA

Health Policy Associates has spent more than 30 years providing high quality consulting services to the biologic 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 biologic 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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