HPA INC
HEALTH POLICY ASSOCIATES INC

HPA PRODUCT ASSURANCE SOLUTIONS

Turnkey Solutions for Complex Problems in the Manufacture of Medical Devices and Biologics

HPA's Product Assurance team is a group of seasoned veterans, each with 20-30+ years in the medtech/biotech industry, with deep expertise in various aspects of product assurance, from operations to QA, RA, and compliance. HPA delivers solutions tailored to your specific product assurance needs, providing the precise expertise you need to successfully bring your medical device and biologic innovations to market.

Product Development

- Product development assistance, including project planning and project management.
- Supply chain support: identify contract manufacturing services, audit suppliers.
- Creation of packaging, shelf-life, and transit test protocols/reports.
- Technical support for aseptic processing operations: facilities/equipment requirements and design, utility and equipment qualification, process development and validation, controls and monitoring.
- Assistance establishing programs for contamination control/monitoring and sterility assurance that are compliant with regulatory expectations.
- Engineering consultation and assistance.

Project Management

- Interim management: quality, regulatory, operations, engineering.
- Assistance with problem solving for all phases of medical device/biologic design and manufacturing.
- Facilitation of process risk assessments; technical support for implementing risk mitigations.
- Training/mentoring on aseptic processing, terminal sterilization, and microbiological testing and control.
- Conduct of/assistance with structured failure investigations and root cause analyses for microbiological contamination and loss of sterility.

Regulatory

- Support for selection of Notified Body for ISO 13485 certification.
- Strategies for regulatory medical device PMA & 510(k) submissions/responses.
- Preparation of PMA and 510(k) submissions.
- Strategies for and preparation of Pre-IDE and IDE submissions and Q-subs.
- Regulatory requirement assessments for new devices.
- Creation of Technical Files/Design Dossiers.
- Conduct of comprehensive mock regulatory inspections, identification of and support for corrective actions, and verification of effectiveness.

Compliance

- Preparation of and support for International Registrations and renewals, for example:
  - Canada, Health Canada license
  - European Union, CE mark (Technical Files/Design Dossiers)
  - Australia, TGA registration
  - China, CFDA registration
- Construction of responses and remediation of findings to Quality System Audits from FDA/Notified Bodies (Form 483, warning letters, import alerts).

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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