FDA REGULATED INDUSTRIES SUPPORT

HukariAscendent meets the needs of FDA regulated clients in the areas of US FDA Regulatory Compliance services and Quality System (QS) support. Whether your business is in pharmaceuticals, medical devices, food, or even tobacco, we have the skills to help you be successful and cost effective in today's business environment. Our capabilities include:

- Basic Engineering support (mechanical, electrical, HVAC) with built-in sensitivity to regulatory requirements and contamination management
- QS program development and implementation
- Supply Chain documentation
- Supplier qualification and risk management
- Software quality assurance,
- Corrective And Preventive Action (CAPA) assistance including Observation Form 483 and Warning Letter analysis and response assistance
- Hazard Analysis development and maintenance
- Mentoring so the responsible organization can learn by doing and become self-sustaining

HukariAscendent employs engineers and scientists with several decades of experience in quality system development, implementation, and improvement-based audits for a variety of high technology manufacturing and operating organizations. **Hukari**Ascendent can meet your needs by providing knowledgeable personnel with significant engineering and system validation experience. Our personnel have worked in a variety of industry settings, providing our clients with exceptional value through innovative, cost-effective solutions. **Hukari**Ascendent provides FDA standards-based, quality assurance program support to all phases of facility lifecycle. New construction, start-up, operation, existing facilities, modifications, and facility closures each have unique quality assurance aspects oversight, commissioning, qualification and computer system validation requirements.

HukariAscendent specifically offers:
Supply Chain 'Tune-ups' – updating and validating Approved Supplier's Lists, generating supplier data summaries, assisting in identifying critical suppliers, and organizing that information into a report demonstrating oversight
Voluntary Audit Program Pre-assessment – performing a preliminary assessment to determine readiness for a Third Party ISO 13485 Audit for the Office of Compliances Voluntary Audit Program.

One of the most resource-deficient areas across the FDA-regulated activities is Quality Assurance, especially in program start-up and validation. HukariAscendent's network includes personnel with quality assurance program development and execution expertise as well as significant mentoring, validation and oversight experience. HukariAscendent has recently provided:

- Quality program development support for a client with multi-billion dollar commitments
- Direct support for a global full-services engineering and construction company during client audits leading to a Construction and Operating Combined License Application (COLA) submission to the U. S. Nuclear Regulatory Commission
- Direct quality assurance support for facility design and commissioning effort including

program development, oversight, and specification review
- Direct quality assurance support for an international client to develop quality assurance program infrastructure and provide quality assurance program oversight
- NQA-1-1994-based supplier audits
- Strategic leadership for an innovative restructuring of a major government contractor's procurement quality and purchasing process that saved upwards of 30% of the procurement costs for quality-significant commercial items
- Annual Quality Assurance Audit for a large global leader in consulting, design, design-build, operations, and program management

HukariAscendent personnel have extensive, industry-recognized expertise in current U. S. quality regulations, standards, and validation such as:

- NQA-1-1994, NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications
- 10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- 10 CFR 72.140, Quality Assurance Requirements

HukariAscendent personnel have the experience and ability to translate the above experience in highly regulated technologies into the FDA regulated activities in the areas of quality systems, Corrective And Preventive Action systems, and validation such as:

- 21 CFR 820, Quality System Regulation
- International Organization for Standards (ISO) 9001:1994 "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing,"
- Quality System regulation (61 FR 52602)
- ISO 13485 Quality Systems--Medical Devices--Supplementary Requirements to ISO 9001.
- ISO 14971 Risk Management—Medical Devices
- Medical Device Quality Systems Manual, A Small Entity Compliance Guide First Edition
- Quality Management Systems - Process Validation Guidance
- Corrective and Preventive Actions (CAPA) Inspections

HukariAscendent also offers a variety of audits to meet your specific needs, including:

- Gap Assessment Audits – Typically performed before quality system implementation (QSR, ISO 13485) to identify current level of compliance and areas for possible improvement.
- Pre-certification Audits – An internal audit, performed prior to the official registrar medical device certification audit to identify any outstanding areas of concern.
- Internal Audits – Depending on your needs, we provide two levels of internal audits. During a full on-site audit of your quality system we will review and examine your existing procedures and provide recommendations for improvements. A "desktop" audit focuses only on specific procedures of concern and typically occurs off site, through a review of relevant documents.
- Subcontractor / Supplier Audit – Many medical device companies outsource some or all of the manufacturing of their product. We can perform on-site audits of your vendors and suppliers to give you assurance that your product is being manufactured in accordance with all applicable standards and regulations.