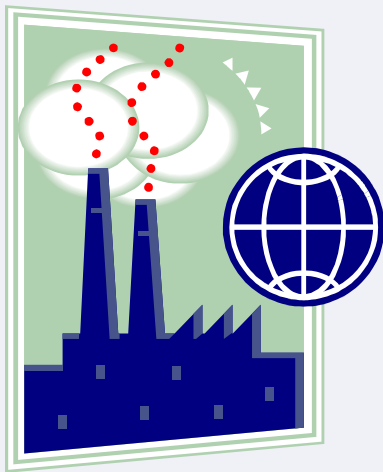


**Advanced Solutions
Consultants, Inc.**

ASC, Inc. is a consulting service provider in technical and business solutions to Quality, Compliance and Regulatory requirements for Medical Device, Diagnostics, Biologics and Pharmaceutical companies. This includes resolving issues on product/processes, quality systems, compliance, validations and six- sigma projects. Consultation is also provided on clinical audits and trials, training.



Advanced Solutions Consultants, Inc.

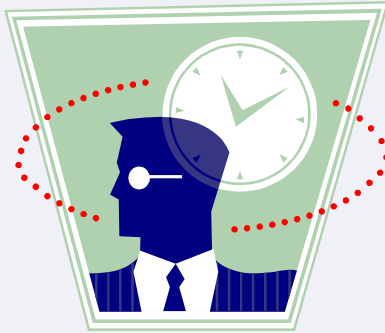
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**Advanced Solutions
Consultants, Inc.**

Mission:

ASC, Inc's mission is to provide complete solutions to Quality, Regulatory and Compliance challenges. ASC, Inc. is dedicated in supporting its clients in the Device, Diagnostics, Pharmaceutical and Biologics sector in maintaining high standards of Quality in their practices and in their products.



ASC, Inc.'s expertise includes regulatory, compliance, quality, new product development, FDA's Good Manufacturing Practices, CGMP's, GCP's and training support. There is strong technical support provided by individuals with extensive regulatory, FDA and ISO compliance knowledge with heavy industry experience in Medical Device, Diagnostics Pharmaceutical and Biotech industries.

Services Provided:

- Development and Implementation of Quality Systems/ QSR's/ ISO 9000:2000, ISO 13485, ISO 14000
- Regulatory advice to address warning letters, 483(s)/EIRs, consent decrees, recalls, imports, exports, and other compliance problems. Protocol writing, 510 (k) submissions, PMA's, Design Dossiers and Tech Files
- Research and Development– Documentation Systems, review of DHF's, Design Controls
- Quality implementation in Manufacturing
- Process Engineering, Quality Assurance and Quality control
- Support with FDA / ISO audits and training
- Supplier/ Contract manufacturer audits
- Training on QSR's, cGMP's, , GCP's, GLP's, ISO 9000:2000, ISO13485. ISO 14000, Design Control, Combination Products, IVD's, Internal Auditor and Quality engineering/ Six Sigma

ASC , Inc. brings extensive knowledge and experience in Product development, Six Sigma, Design Control, overall Quality Systems, Regulatory Submissions, Internal Audits, External Audits, effective responses to FDA 483's and warning letters etc. Specific focus area includes Class I,II and implantable Class III medical devices, Combination products and IVD requirements.

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