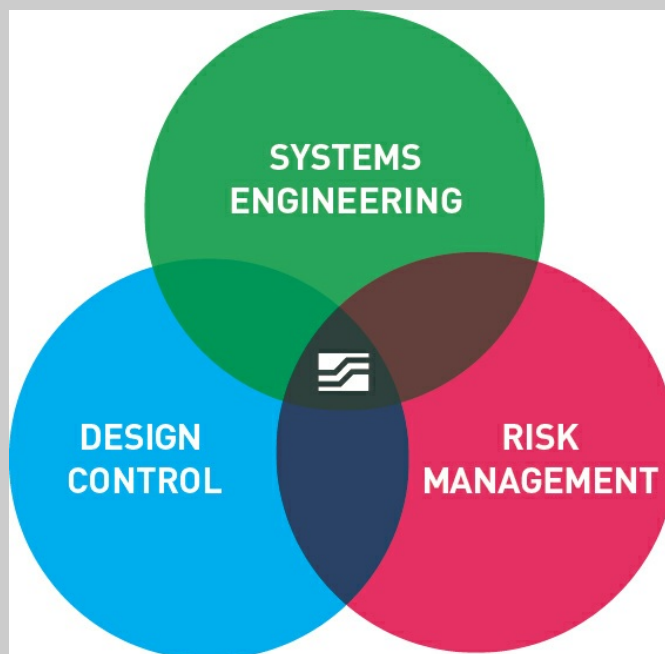


Integrated Work Process Approach

The development of complex products and systems requires a strategic approach. At Stress Engineering Services, Inc. (SES), we use an integrated approach which blends the activities and outcomes of multiple work processes.

Our staff has experience with Systems Engineering, Risk Management and Design Control best practices. More importantly, we have experience integrating these work processes together which allows us to provide the best custom solution for your unique project.



SYSTEMS ENGINEERING

Systems Engineering is an interdisciplinary approach aimed at the successful design, realization, technical management, operation and retirement of a system. Common systems engineering activities include identification of system objectives, requirements definition, design evaluation, configuration control, technical assessment, technical planning and decision analysis.

RISK MANAGEMENT

Risk Management is a comprehensive approach to identify, assess, prioritize and control risk. Common risk management deliverables include: hazard analysis, fault tree analysis, risk mitigation, failure mode and effects analysis, reliability assessment and financial risk assessment. The SES approach embraces a broad view of risks: product risks, business risks, human risks and environmental risks.

DESIGN CONTROL

Design Control is a formal methodology to guide the design and manufacture of a product. Common design control procedures and processes include design inputs, design outputs, reviews, change controls, validation, verification, design transfer and design history files. For the medical industry, the FDA has published a design control guidance document related to FDA 21 CFR820.30 and Sub-Clause 4.4 of ISO 9001.



SES is proud to announce that we passed our 2017 quality management system audit. We are now ISO 13485:2016 (medical device) and ISO 9001:2015 (general industry) certified for the design, development and provision of related engineering services. These certifications verify that we have effective product design, development and documentation processes in place which empower and enable us to provide safe and effective results.

The Polymer Laboratory at SES received ISO 17025:2005 accreditation for several test methods.

**[ISO 13485:2016](#) & [ISO 9001:2015](#) Certified
[ISO 17025:2005](#) Accredited for Several Test Methods**

Upcoming Events



May 7-11, 2018 | Orlando, FL
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Technical Resources

[Integrated Work Process Approach](#)

[January Medical Newsletter](#)

Stress Engineering Services Inc. (SES) provides expert engineering consulting services for:

- **New Product Development**
- **Polymer Science & Engineering**
- **Systems Engineering**
- **Risk Assessment**
- **Human Factors**
- **Sustaining Engineering & Failure Analysis**
- **Package Development**
- **Verification & Validation**

The SES approach leverages engineering mechanics, polymer science/ materials engineering and human factors expertise to deliver custom solutions to meet each client's unique need. SES's services help clients achieve not only technical success in avoidance or remediation of failures, but also commercial success in removing costs from their process and product designs.

To learn more about Stress Engineering Services Inc., visit our [website](#) or contact us at 513-336-6701.

ISO 13485:2016 & ISO 9001:2015 Certified
ISO 17025:2005 Accredited for Several Test Methods