# All Under One Roof

Stress Engineering Services is structured as a "force multiplier" for your organization. Our seasoned professionals can be brought in and added to your team, or work on a portion of your development, to reduce your technical risk and/or accelerate your schedule. We support most technical aspects of regulatory affairs, new product development, and production support, all under one roof.

Our typical engagement is via a statement of work which governs what we will do for you, when it will be done, and what it will cost. You will have one point of contact, the project manager, who will bring together the various SES resources needed to most efficiently address your specific needs.

## For Medical Regulatory Support

## Call SES Today at 513-336-6701

ON THE WEB AT **INNOVATION.STRESS.COM**

CINCINNATI / HOUSTON / NEW ORLEANS / CALGARY

STRESS ENGINEERING SERVICES INC.



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STRESS ENGINEERING SERVICES INC.

ISO 9001:2008 & ISO 13485:2003 Certified

# SES Medical

## Regulatory Support

# Technical Support for Regulatory Professionals

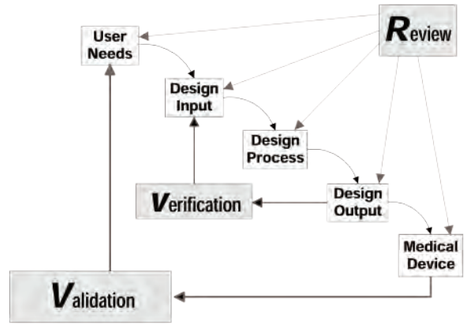
Stress Engineering Services (SES) has had a dedicated focus on medical products since the mid 1990s. Our original focus was and is engineering analysis and testing. In recent years we have tailored our offerings to include regulatory support activities.

### Support for Human Factors Engineering

In 2016 the FDA finalized the guidance document updating their recommendations for "Applying Human Factors and Usability Engineering to Medical Devices." This document provides guidance in new product development to help ensure that new products are safe and effective. To help our customers understand the impact of this on their product development process, Stress Engineering Services has hired an expert in this field. SES can assist you in updating your new product development process, developing a human factors section for your development process, and audit readiness.

### Support for Waterfall Design Process

Stress Engineering Services has a long history in the oil and aerospace industries, both of which are heavily regulated. SES has adapted our systems and regulatory experience from these industries to include support for almost every aspect touched in the Waterfall Design Process.

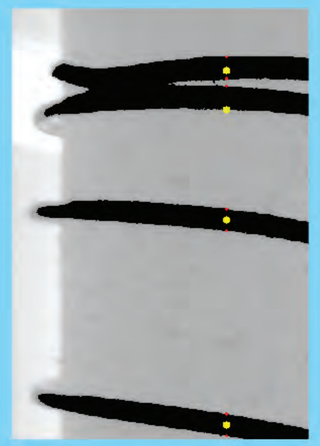



*Application of Design Controls to Waterfall Design Process (Source: www.FDA.gov)*

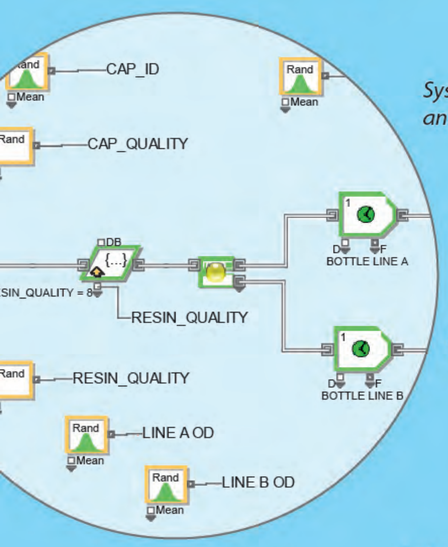
### Some Standard SES Capabilities Include:

- Support for implementation of Human Factors and Usability to your New Product Development Process
- Fault Tree Analysis support (planning, execution, or review)
- Failure Mode and Effects Analysis support
- Independent Third Party Review
- Traceability Review for User Needs through Verification Planning
- Technical Support to aid in or justify engineering decisions, including responses to warning letters
- Technical Support for CAPA activities
- Compliance with EN ISO 14971:2012 for CE Marking

# How Can **SES** Support Your Product Development?

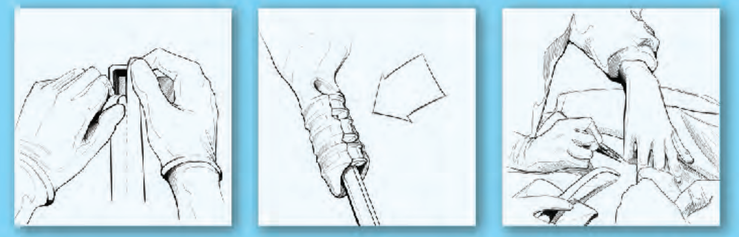


*Part Inspection*




*Systems Engineering and Risk Analysis*

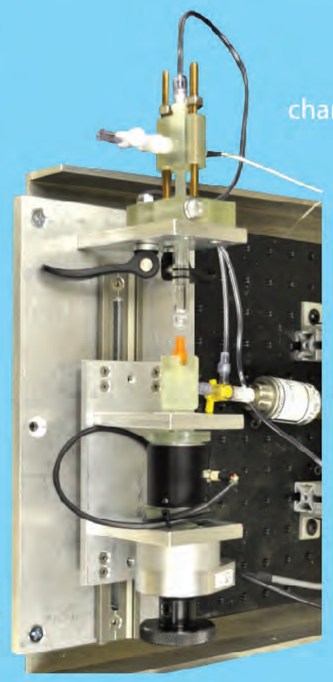
*Custom Testing*



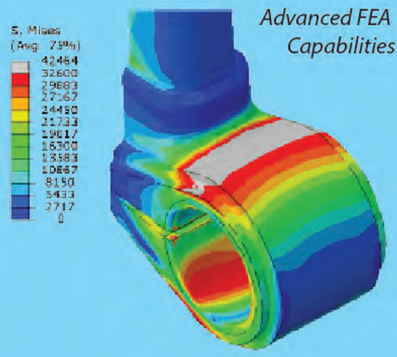
*Understanding Human Factors Design Requirements*

*Collaborative Ideation Session*

*Real-Time Aging Chambers*



*Custom Testing Setup*




*Advanced FEA Capabilities*

**USER NEEDS**

user research

interface design

usability evaluation

requirements development

**DESIGN INPUTS**

baseline testing

material characterization

fault tree

failure modes and effects

engineering analysis

ideation

**DESIGN PROCESS**

bread board testing

finite element analysis

tolerance analysis

design for manufacturability

design for assembly

prototype procurement and assembly

prototype testing

**DESIGN OUTPUT**

verification planning

formative evaluation

**VERIFICATION**

requirements traceability

validation planning

manufacturing support

**VALIDATION**

summative evaluation

custom testing

process monitoring

MEDICAL DESIGN / HUMAN FACTORS / INDUSTRIAL DESIGN / MEDICAL TESTING / RELIABILITY / MANUFACTURING / MATERIALS

STRESS ENGINEERING SERVICES INC.