PHARMACEUTICAL | SURGICAL DEVICES | DRUG DELIVERY | MEDICAL EQUIPMENT
OCULAR | IMPLANTS | DENTAL | DIAGNOSTIC DEVICES | ENT | VETERINARY | VASCULAR

STRESS ENGINEERING SERVICES INC.

SES Medical Technologies

ISO 13485:2016 & ISO 9001:2015 Certified | ISO 17025:2005 Accredited for Several Test Methods
ISTA Certified Testing Laboratory Member

December 2018

DHF Remediation

Stress Engineering Services, Inc. (SES) has the depth and breadth of experience in medical device development to serve your needs for design history file remediation, allowing your team to focus on developing innovative products to meet the needs of your customers.

Tell Us How We Can Help
DHFs can become surprisingly complex documents because it may have been created by several projects, incorporating many changes or it may have been acquired from other companies and contain significant legacy elements. Sometimes the passage of time means a DHF no longer complies with the applicable standards, regulations, and FDA guidance so it presents a business risk.

We offer DHF Remediation services to create and update the DHF of the device throughout its lifecycle. This includes a gap analysis of your design history file to identify disparities between your medical device DHF and the applicable standards, regulations, and FDA guidance. Based on those findings, SES works with you to develop a DHF remediation plan. Depending on your need, we can lead or assist the implementation of the remediation plan to create or update the elements of the DHF to comply.

FMEAs

Failure Mode and Effects Analysis (FMEA) is a structured bottom-up risk evaluation technique widely used in the medical industry as part of a comprehensive risk management effort. The most common types of FMEAs for medical applications include:

- Design (DFMEA)
- Process (PFMEA)
- Application (AFMEA)

Each of these FMEA types can be applied to varying levels. For example, the DFMEA is commonly used at the system, subsystem, or component level.

SES has decades of experience with FMEAs in a variety of industries. We can support your FMEA needs by facilitating your team, supplying subject matter experts to your team, or executing the FMEA with our internal resources.

FMEA Brainstorm Session

ASME V&V 40 Standard Release

The ASME V&V 40 Standard to assess the credibility of computational models used to assess the performance and safety of medical devices has been released. This standard lays out the verification & validation activities necessary to develop *Regulatory Grade Computational Models* that can be used to generate scientific evidence for regulatory submissions.

SES has many years of experience applying physics-based computational models of varying rigor to develop a deep understanding of the mechanics of a medical device and assess its safety and performance.

Read more about Computational Modeling of Medical Devices in our August Newsletter.

SPE Medical Plastics Minitec
Biodegradable/Resorbable Polymers: Recent Themes and Challenges in the

Medical Device Industry
Technical Presentation by Rob Klein, Associate II with SES
February 4, 2019 | immediately precedes MD&M West
Sheraton Park Hotel at the Anaheim Resort

MD&M West 2019
February 5-7, 2019 | Anaheim Convention Center | Anaheim, CA
SES Medical - Booth #2097
Polymer Laboratory at Stress Engineering - Booth #2095

Missed our latest newsletter?

Click here to read about Cleaning Chemical Compatibility.

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

- **New Product Development**
- **Polymer Science & Engineering (Full Polymer & Metallurgical Labs)**
- **Systems Engineering**
- **Risk Assessment**
- **Human Factors**
- **Sustaining Engineering**
- **Failure Analysis**
- **Package Development**
- **Verification Testing**
- **Equipment Validation & Development**

Our services help clients achieve not only technical success in avoidance or remediation of failures, but also commercial success in removing costs, risk and time from their process and product designs.

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

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