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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

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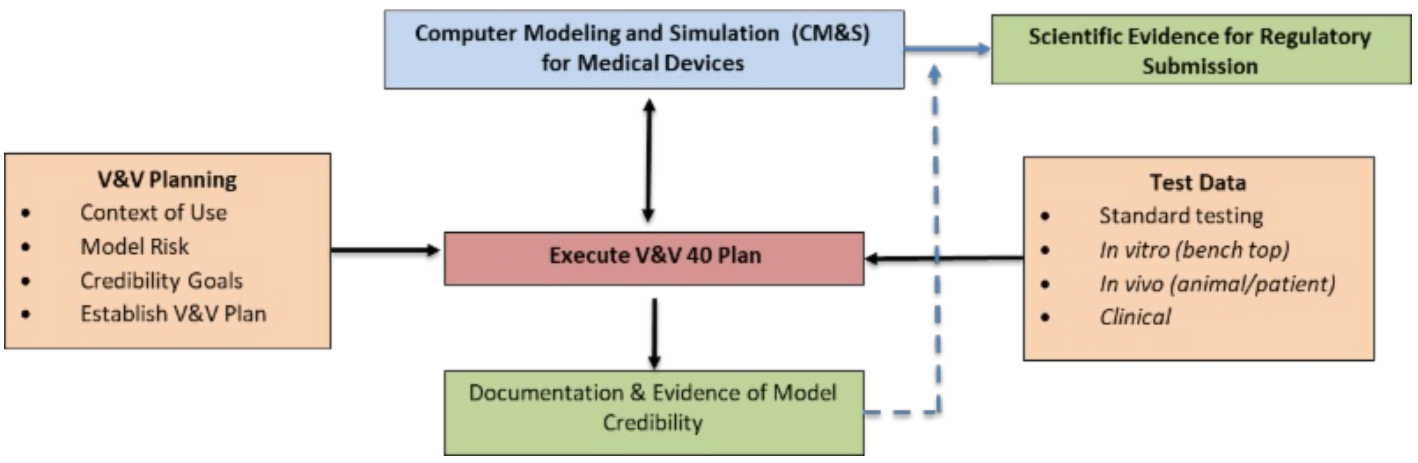
Computational Modeling of Medical Devices - ASME V&V 40 Guide

The FDA has identified an important role for computational modeling and simulation (CM&S), i.e. in silico methods, in its recent strategic priorities. The FDA envisions a greater reliance on scientific evidence obtained from physics-based computational models in future regulatory submissions. The potential roles include CM&S embedded in a medical device (e.g. physiological logic in a control system), CM&S as valid scientific data (e.g. device performance, safety factors, etc.), and CM&S as the medical device (e.g. clinical diagnosis and treatment planning). To fully leverage CM&S of medical devices, a methodology to establish *credibility* is necessary. Credibility is the trust obtained through the collection of evidence in the predictive capability of a computational model for a specific context of use.



CM&S can be used throughout the device lifecycle, supporting non-clinical and clinical activities. Several use scenarios and cases that are challenging to replicate experimentally or clinically can be evaluated. CM&S also offers the opportunity to assess aspects of *in vivo* device performance without subjecting patients to potential harm or unnecessary risk. However, as the reliance on computational models increases, there is a need to ensure that the models represent a *credible* approximation of reality. Incorrect assessment of the device performance and/or safety can have significant consequences. The ASME V&V 40 guide (to be published in 2018) provides procedures to standardize the *verification*, *validation* and *uncertainty quantification* (VVUQ) necessary to demonstrate the credibility of computational models for medical devices. The guide provides a framework for risk-informed credibility assessment of the model and helps determine 'how much' VVUQ is needed to support using a model for a context of use.

The credibility strategy laid out by the guide includes definition of the context of use, assessing the model risk, establishing thresholds for the credibility factors, developing a V&V plan, execution and credibility assessment. Credible models can be utilized to capture the influence of the range of design variables and product use factors, respond faster to future policy changes, assess manufacturing quality, and potentially reduce risk to patients by reducing the number of end points from clinical trials.

Stress Engineering Services, Inc. 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. We also have extensive test labs with the ability to generate reliable comparator data for validation. By leveraging the expertise and experience of our engineers and capabilities of our test labs, we can assist you in developing adequate V&V plans, establishing the model credibility, and utilizing the CM&S data in regulatory submissions.

Upcoming Events

2018 Combination Products Summit Sponsor
Join SES at Xavier University | September 12-14, 2018
Click here to register today!

Visit SES in Booth 215 | October 8-9, 2018 | Orlando, FL
Contact Erin at erin.sefton@stress.com to set-up a meeting during the show.

Missed our latest newsletter?

Click here to read about Design for Usability and our expertise in Human Factors Engineering.

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

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