

Save over \$200k and 18 months in FDA preparation

(diy) Regulatory Kit

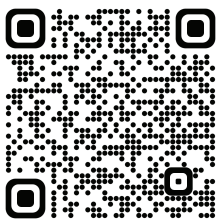
Required. Affordable. Easy to Use.

Streamline your FDA or EU submission with our SaMD/SiMD regulatory kit.

This do-it-yourself kit includes a full set of design templates **required by the FDA** for your submission or technical file.

Our kit also includes associated processes and training that provides you with **guidance and best practices** to help you complete your design history file (DHF).

- ✓ **LOW COST ACCESS**
- ✓ **AUTOMATED DESIGN CONTROLS**
- ✓ **CONTINUOUSLY UPDATED**
- ✓ **ON-DEMAND TRAINING**
- ✓ **MONTHLY SUPPORT**



Purchase Kits
today!



Successful FDA
submissions start 18
months in advance.

Do it yourself with
in-depth training and
expert support!



Included in our premium (diy) Regulatory Kit

Full SaMD/SimD Design Templates

- 24 ready to use templates
- Complies with FDA guidances and international standards
- Designed by medical software experts

Software Online Agile Regulatory (SOAR®) Training

12-month subscription

- 15, 90-minute on-demand courses
- 20+ hours of training, led by industry experts

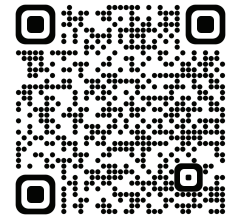
Greenlight Guru eQMS 12-month license

- Electronic Quality Management System (eQMS) with ISO 13485 QMS compliant standard operating procedures
- Developed by software technical and quality experts at Greenlight Guru, an award winning platform

Monthly live Q&A sessions

- Hourly Q&A sessions with industry experts in software
- Consulting available upon request
- Full pre-submission audit available upon request

Purchase Kits
today!



SOAR® Fundamentals training for today's
medical device software engineer.

