

# InfoSQA 10i



## Software Development and Validation Software

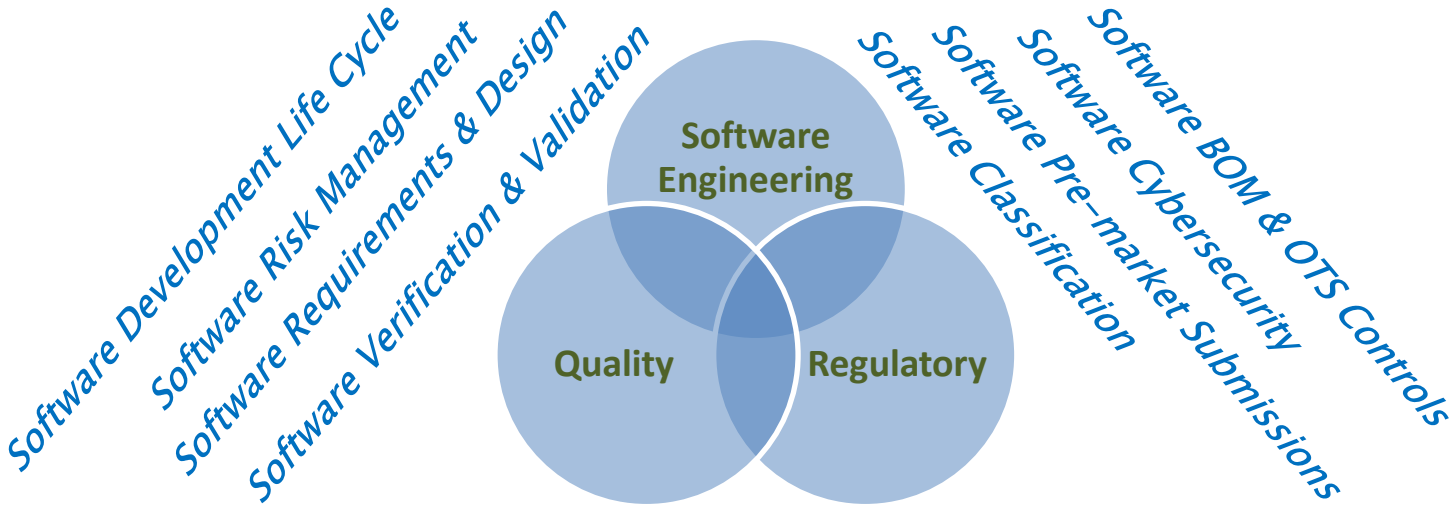
InfoSQA 10i is a comprehensive software solution for managing software development and validation in the medical device industry – for both Product and QMS software.



The screenshot displays the InfoSQA 10i web application interface. At the top, it shows the title 'InfoSQA 10i' and the version '10.0'. Below the title bar, there are navigation links for 'Home', 'My InfoSQA', 'Help', and 'Logout'. The main content area is divided into several sections:
 

- Software Development/Validation:** Includes a dropdown menu for 'QMS Software' with options like 'QMS Spreadsheet', 'Mfg and Test Equipment Software', and 'Product Software'. There are buttons for 'Open Existing' and 'Go', as well as 'Create New' and 'Search Existing'.
- Agile/Scrum:** Features a dropdown menu for 'Product Software' and a 'Go' button.
- My Activities:** Shows 'Records waiting for me' with a dropdown for 'Product Software' and a 'Go' button. It also includes 'My Records' with a dropdown for 'QMS Spreadsheet' and a 'Go' button, and a 'My Audit Trail' button.
- System Functions:** Contains buttons for 'Configuration', 'Audit Trail', and 'Security'.
- Reports, Metrics & Trends:** Includes a dropdown for 'Mfg and Test Equipment Softw' and a 'Go' button.
- Master Files:** Features a 'Manage Master Files' button.

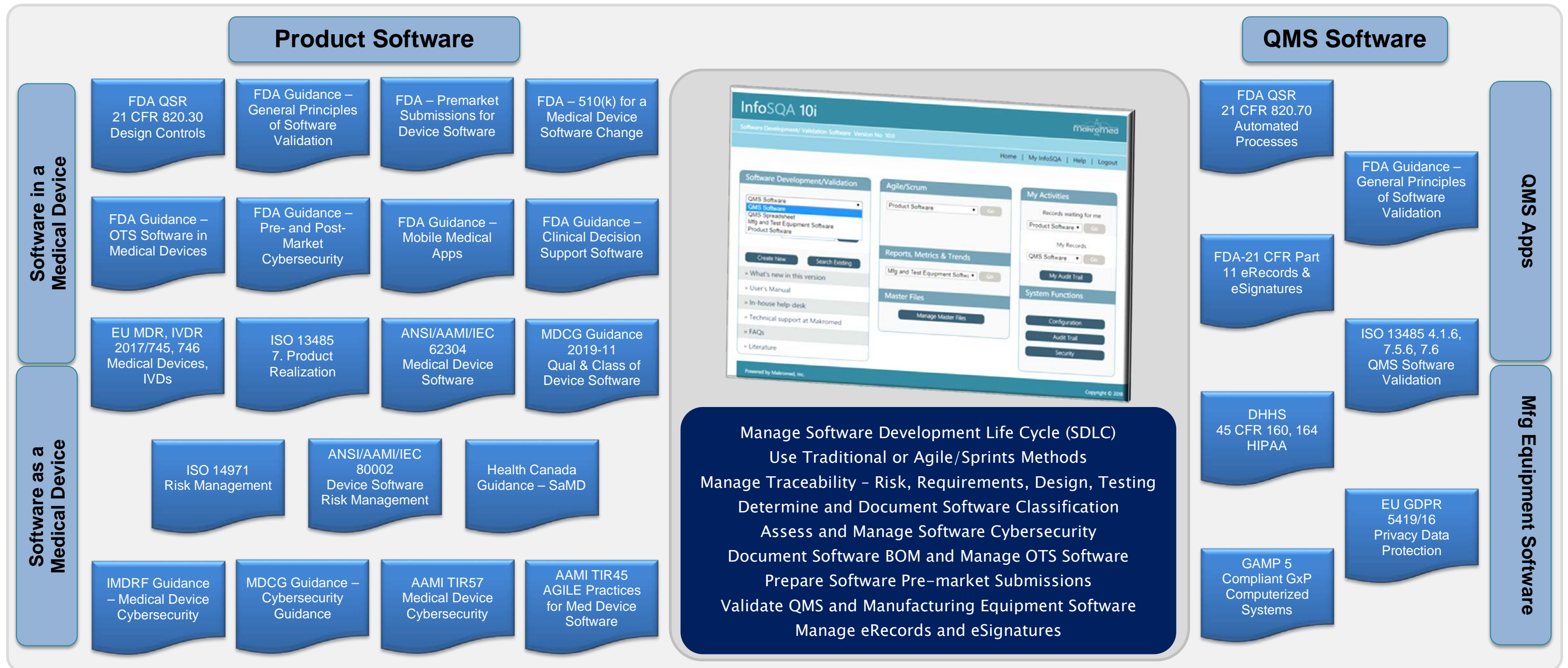
 At the bottom of the interface, it states 'Powered by Makromed, Inc.' and 'Copyright © 2018'.



## Software Development and Validation Software

### InfoSQA10i

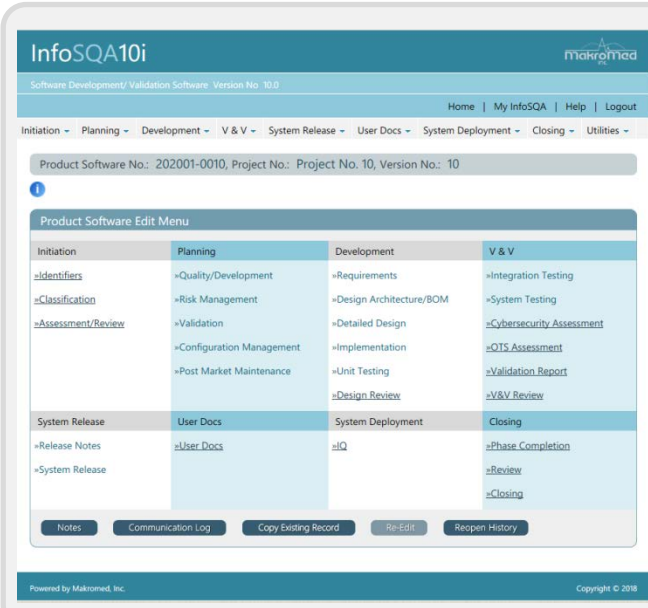
- One central place where Software Engineering, Quality and Regulatory teams can collaborate.
- To address the requirements of multiple international regulations and standards.
- For both Product and QMS software.



# InfoSQA 10i



## Software Development and Validation Software



**For Product Software, manage the entire SDLC:**

- Classification:** Risk Level, Regulatory Class
- Plans:** Quality, Risk, Validation, Configuration, Post-market
- Development:** Requirements, Design, Implementation, Reviews
- V&V:** Testing, Cybersecurity Assessment, OTS Controls, Reviews
- System Release/Deployment and User Documents**

**For QMS Software, manage:**

- Classification:** Risk Level, Part 11 Compliance
- Plans:** Quality, Validation
- User Requirements**
- Validation:** Testing, Part 11 Assessment, Reviews
- Deployment:** IQ, OQ, PQ

**Classification**

Product Software :

Incorporates Machine Learning Technology (ML)?

Incorporates Artificial Intelligence Technology (AI)

Medical Device to be connected to private network?

**Cybersecurity Assessment**

Click here to populate Cybersecurity Assessment Questions/Items

Section	Cybersecurity Risk	Assessment Questions
A. Identify and Protect Device Assets and Functionality	Prevent Unauthorized Use. (a) Limit Access to Trusted Users and Devices Only	Limit access to devices through the user ID and password, smartcard, biometric, etc.
A. Identify and Protect Device Assets and Functionality	Prevent Unauthorized Use. (a) Limit Access to Trusted Users and Devices Only	Use automatic timed methods to log out users from the system where appropriate for the device.

**Level of Concern Assessment**

Question No	Question
001	Does the Software Device qualify as Blood Establishment Computer Software? Blood Establishment Computer Software is defined as software products intended for the manufacture of blood and blood components or for the maintenance of blood establishment personnel use in making decisions regarding the suitability for the release of blood or blood components for transfusion or further manufacture.
002	Is the Software Device intended to be used in combination with a drug, biological product, or device an accessory to a medical device that has a Major Level of Concern?

OTS Assessment

OTS Level of Concern:

Required Deliverable
OTS Software Hazard Analysis
Basic Documentation
OTS Software Hazard Mitigation
Justification of Residual Risk



88 Stiles Road Salem, NH 03079 USA  
 tel: 603 890-3311  
 fax: 603-890-3322  
 email: info@makromed.com  
 web: www.makromed.com