propel

Validation Accelerator Pack

Ensure your Quality Management System (QMS) is properly validated

For medical device companies, software validation is a necessary -- and often time-consuming -- part of risk mitigation. Propel can help. From providing a complete set of thorough documentation to being your full service validation provider, Propel helps you take the least burdensome approach to validation, with support that's sized to fit your needs and budget.

Propel Validation Accelerator Pack:

- Fully executed OQ, updated for each of Propel's three annual releases.
- Medical device customers **pull** Propel software releases when ready; *updates are never pushed*
- Straightforward IQ - Propel is cloud software!
- Pre-written PQ protocols for Propel's out-of-the-box QMS processes
- Samples of other required documentation, including Validation Plan, URS, FRS, Trace Matrix, Validation Final Report.
- Templates for Risk Assessment, GxP Assessment, 21 CFR Part 11 Compliance Assessment
- All documents and IQ/OQ/PQ protocols are updated for each major release

Optional Services

- Full service validation: Modify PQ protocols to match your company's configuration, execute PQ protocols, provide full set of accompanying documentation (URS, FRS, Trace Matrix, etc.)
- If validation will be performed by your own staff, we provide optional hourly advisement services to guide your team.

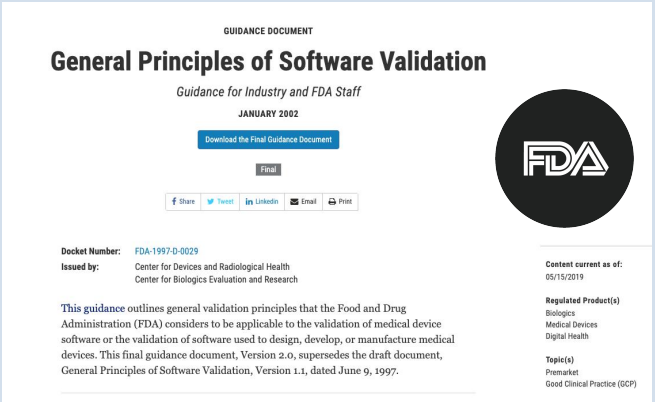
For all customers, Propel offers "starter" procedures that can be turned into company-specific SOPs and Work Instructions.

These include:

- ECO/DCO
- Training Records
- Complaint
- CAPA
- NCMR
- SCAR
- Audit
- Equipment Calibration
- Supplier Qualification
- First Article Inspection

Propel QMS helps customers become compliant with:

- 21 CFR Part 820
- 21 CFR Part 11
- ISO 13485
- EU MDR


GUIDANCE DOCUMENT

General Principles of Software Validation

Guidance for Industry and FDA Staff

JANUARY 2002

Download the Final Guidance Document

Final

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FDA

Docket Number: FDA-1997-D-0029

Issued by: Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

This guidance outlines general validation principles that the Food and Drug Administration (FDA) considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices. This final guidance document, Version 2.0, supersedes the draft document, General Principles of Software Validation, Version 1.1, dated June 9, 1997.

Content current as of: 05/15/2019

Regulated Product(s)
Biologics
Medical Devices
Digital Health

Topic(s)
Premarket
Good Clinical Practice (GCP)

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