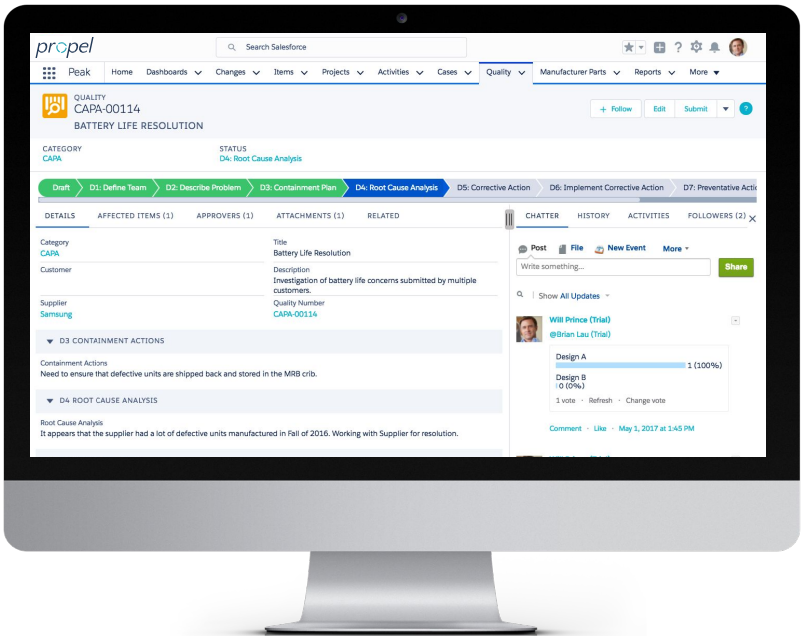
MEDICAL VALIDATION PACK
FOR PROPEL CLOUD PLM SOFTWARE



REDUCE YOUR VALIDATION TIME AND COSTS

The Propel Medical Validation Pack (MVP) offers pre-configured, out-of-the-box best practices to help life sciences companies build in product and process quality using Propel's cloud PLM system.

While many PLM systems solely focus on engineering and quality, Propel also enables life sciences companies to more easily and securely engage with strategic customers, technology partners, suppliers and channel partners on product development, sales enablement, regulatory compliance and customer adoption.

Software Validation

Infrastructure Qualification
Functional Validation
Inter-Release Validation

Customer Validation

Validation Methodology
UAT/PQ Creation
Validation Documents

Validation Continuity

Release Assessment
Validated Environments
Customer Success Team

SOLUTION HIGHLIGHTS

- Validation Master Plan (VMP)
- IQ, OQ and PQ protocols, scripts and results
- User (URS) and Functional Requirements Specifications (FRS)
- Approval and trace matrices
- Data migration protocols
- Validation Summary Report (VSR)

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Software Validation for Propel Cloud PLM

Propel aligns our qualification, testing and validation approaches with best practices in the life sciences industry. Our validation has three major components:

- **Infrastructure Qualification**: Propel maintains qualification of all hosting infrastructure. Propel's software is built on the Salesforce platform, which are hosted in secure facilities that comply with ISO 27001 and SOC1 Type II standards. These facilities maintain 100% data redundancy in geographically separate locations. Your data is encrypted and backed up daily, and disaster recovery environments are periodically tested.
- **Functional Testing**: Propel develops and executes validation scripts after every release. Propel also does a comprehensive revalidation of all system functionality every two years.
- **Inter-Release Validation**: For every major release, Propel assesses the validation impact for every patch. Propel re-executes validation scripts for medium and high risk items, and validation signoffs are required before releasing any patch.

Working with Customers to Become Validated

During implementations, Propel works with you to establish a focused validation methodology. Propel helps with planning, managing, testing and preparing for validation, as well as performing customer audits if requested.

Propel's Professional Services team works with you to configure our software according to your requirements. Propel creates a User Requirements Specification (URS) and Performance Qualification (PQ) to confirm system configuration and ensure Propel's software meets your business requirements.

Document Name	Purpose of Document
PropelQS – 1000 Validation Plan	Master Framework for Validation Plan
PropelQS – 1010 SDLC Deliverables	Master Framework for SDLC Deliverables
PropelQS – 1020 Approval Matrix	Master Framework for Approval Matrix
PropelQS – 1030 Trace Matrix	Master Framework for Trace Matrix
PropelQS – 1040 URS	Master Framework for User Requirements
PropelQS – 1050 FRS	Master Framework for Functional Requirements
PropelQS – 1060 Data Migration Plan	Master Framework for Data Migration
PropelQS – 1061 Data Migration Qualification	Master Framework for Data Migration Qualification
PropelQS – 1062 Data Migration Proof	Master Framework for Data Migration Report
PropelQS – 1063 Data Migration Report	Master Framework for Data Migration Report
PropelQS – 1070 IQ	Master Framework for Installation Qualification (IQ)
PropelQS – 1071 IQ Proof	Master Framework for IQ Proof (Screen Shots)
PropelQS – 1072 IQ Report	Master Framework for IQ Report
PropelQS – 1080 OQ	Master Framework for Operation Qualification (OQ)
PropelQS - 1080 OQ AML	
PropelQS - 1080 OQ Items	
PropelQS - 1080 OQ Changes	
PropelQS - 1080 OQ Quality	
PropelQS - 1080 OQ Import Export	
PropelQS – 1081 OQ Proof	Master Framework for OQ Proof (Screen Shots)
PropelQS - 1082 OQ Report	Master Framework for OQ Report
PropelQS – 1083 OQ Test Summary Report	Master Framework for OQ Summary
PropelQS – 1090 PQ	Master Framework for Performance Qualification (PQ)
PropelQS – 1091 PQ Proof	Master Framework for PQ Proof (Screen Shots)
PropelQs – 1092 PQ Test Summary Report	Master Framework for PQ Report

Propel's Medical Validation Pack provides customers a comprehensive set of scripts, tests and protocols for validation

Continuing to Stay Validated

Propel has three major releases each year and conducts regression testing after each major release. Before each release, Propel creates a Release Impact Assessment, which details all upcoming features, potential risks and enablement details.

Propel also provides pre-release environments where you can test your current configuration against the upcoming release. Any new Propel feature or upgrade that has no impact on validation can usually be accepted under change control with little or no testing. New features that may have a potential GxP impact must be turned on or configured by your Propel administrator.

To help streamline validation, Propel's Customer Success Team works with every customer to help plan for validation activities and implementation of new features.