



# Enterprise Quality Management

Enterprises operating in today's dynamic and highly competitive Life Sciences industry face complex challenges assuring quality and achieving regulatory compliance. Growing regulatory scrutiny, dispersed global operations, and increasing media and legal exposure are elevating quality management to the executive offices of Life Sciences businesses.

Pilgrim Quality Solutions, an IQVIA company, is the only global software vendor focused specifically on the demands of the Life Sciences industry. Since 1993, Pilgrim's enterprise quality management software (EQMS) has helped hundreds of world-class organizations ensure patient safety, improve product quality, and achieve regulatory compliance across their global value chain.

## Strategic Insights through an Enterprise-wide View of Quality

Quality Management is no longer just a manufacturing concern. Industry standards and regulations govern all phases of the product lifecycle, including clinical trials, production, distribution, and customer service. Organizations realize the strategic value of quality information when product and supplier quality intelligence is shared throughout the enterprise. Pilgrim's closed-loop enterprise solution allows departments to learn from each other, prevents issues from recurring, and enables organizations to significantly enhance the quality of their operations, products, and services.

### Benefits

- ✓ Tightens Controls
- ✓ Improves Product Quality
- ✓ Enhances Patient Safety
- ✓ Achieves Regulatory Compliance
- ✓ Mitigates Liability and Risk



### Pilgrim Quality Solutions

- ✓ 20+ years of Quality Management
- ✓ Dedicated to Serving Life Sciences
- ✓ Quality and Regulatory Support Team
- ✓ The Most Complete EQMS Suite
- ✓ Compliance-Ready

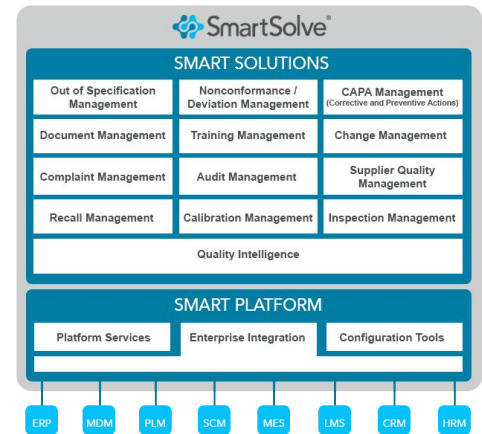
“Companies that have deployed enterprise quality management systems formalize core risk, nonconformance and continuous improvement processes across functions. This results in improved product compliance and a higher rate of successful new product introductions.”

**Dan Jacob**  
Analyst, LNS Research  
2016

# SmartSolve®

## Your QMS Platform for Compliance

Delivered on a compliance-ready platform, Pilgrim's SmartSolve® provides closed-loop process integration unmatched in the market. It is based upon ISO 9001 standards and supports the most stringent regulatory requirements. With electronic signatures, audit trails, validation packs, and electronic reporting, SmartSolve gives you control and confidence so you can focus on progress, not problems. Opportunities, not obstacles. Whether you are ready to automate a single process or optimize your entire quality management system, SmartSolve prepares you to succeed.



## Processes Managed



### Audits

Plan for and conduct internal and external audits.



### CAPAs

Build risk-based corrective and preventive action workflows to quickly resolve and prevent issues.



### Change Control

Record change requests and securely track approvals, progress, and trends.



### Complaint Handling

Capture customer issues, implement resolutions, and simplify adverse event reporting.



### Documents

Create, share, and control critical documents.



### Nonconformances & Deviations

Drive to the root cause of problems to quickly focus on prevention and correction.



### Out Of Specifications

Ensure consistent out-of-specification (OOS) lab result investigations.



### Recalls

Manage product recalls while protecting your customers, brand, and regulatory compliance.



### Supplier Quality

Reduce supply chain risk with incoming inspections, audits, NCs, and CAPAs.



### Training

Manage personnel skill sets and certification.

## Quality Intelligence and Reporting

Robust business intelligence coupled with pre-built standard reports provide instant visibility to quality trends and quick access to proof needed during regulatory audits.

“ We really value Pilgrim's all-in-one suite approach. ”

**Raymond Vandick**  
QA Training Manager  
Organogenesis, Inc.

## Cloud and On-Premise

Whether you want to host SmartSolve applications within your enterprise or prefer to leave that to us, you gain access to our industry-tested, validation-ready quality management solutions. Pilgrim Cloud applications are hosted in the most advanced and secure infrastructure available, an SSAE 16 SOC 2 Type 2 certified data center.