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 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 implemented closed-loop quality management processes are better able to capture downstream quality data and deliver it upstream for continuous improvement. This results in more robust quality management systems and improved product compliance. "
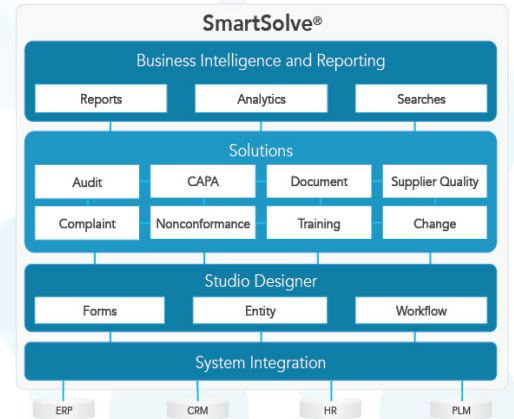>
> **Matthew Littlefield**
> President & Principal Analyst
> LNS Research, 2014

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.

SmartSolve®

Business Intelligence and Reporting

| Reports | Analytics | Searches |

Solutions

| Audit | CAPA | Document | Supplier Quality |
| Complaint | Nonconformance | Training | Change |

Studio Designer

| Forms | Entity | Workflow |

System Integration

ERP   CRM   HR   PLM

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

Supplier Quality
Manage supplier incoming inspections, audits, NCs, and CAPAs, and use data to evaluate and optimize your supply chain.

Training
Manage personnel skill sets and certification

Business 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.

On-Premise and Cloud

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. Your Pilgrim cloud applications are hosted in the most advanced infrastructure available, an SSAE 16 SOC 2 Type 2 certified data center.