



Product Brief

ReSol Systems has been developing software systems for the pharmaceutical industry. Our software is known as QCSFusion and it was designed to be user friendly and fully compliant with FDA regulations



Features

- Operates in stand-alone or network environments
- Industry's most comprehensive and user defined Review/Approval process
- Security - allows to control who, when and why users are accessing the system
- Document Repository for all documents types - internal and external
- GMP and 21 CFR part 11 compliant
- E-signatures
- Communication via e-mail (alerts / reminders)
- Multi-level structure so that documents can be organized effectively
- Secure documents allowing only authorized personnel to move, edit and archive



- Detailed audit trail include
 - System-stamped date and time
 - User who performed the activity
 - Information regarding action performed
 - Reason for changes



- Flexible roles / responsibilities that can be assigned based on customer need
- Review and Approval workflow

- Searchable
- Cross-references to link related documents
- Task list allows users to see assigned tasks



- Assign time requirements for certain workflows and issue alerts / reminders to assure timely completion
- Revision history
- Option to stamp documents for printing

- Capability to control variety of document types:
 - SOPs, policies, work instructions
 - Forms
 - Batch records
 - Certificates of Analysis (C of As)
 - Regulatory submissions
 - Regulatory correspondence
 - Deviations / Investigations - CAPA
 - Documentation related to change control
 - Validation documentation
 - Manuals, instructions
 - Employee training and qualification records
 - Project documentation
 - Investigation documents, photographs, etc.
 - Audit reports and follow-ups
- Change control process
- Editable templates (default and / or user created)



Suggested Minimum Hardware and Software Requirements



System	Requirements
Server Operating System	Windows 2003 Server SP2 or Higher (32 bit or 64 bit)
.NET Framework	NET Framework 4.5
Database	SQL Server 2008 R2 or Higher
Client computer Operating System and Productivity software	Windows XP SP3 or Higher MS Office 2007 or Higher