



## Quality Database vs. Q-Med Database

Sunday Business Systems offers two very similar products for different levels of compliance. The *SBS Quality Database* and the *SBS Q-Med Database* both offer solutions for Corrective and Preventive Actions (CAPA), Non-conformance management, audit management, etc. (refer to the Feature Comparison Table).

The [\*Quality Database\*](#) was designed for basic compliance where there are less rigorous requirements. The database is an excellent source of objective evidence that, for instance, corrective actions were completed and they were effective. The recorded data is sufficient to show the results and efficacy of the Corrective action program.

The [\*SBS Q-Med Database\*](#) was designed for rigorous compliance to FDA standards (21 CFR Part 820 and ISO 13485) with CFR21 Part 11 compliant electronic records and electronic signatures. Electronic signatures are required for approving several different stages of the Corrective Action. Containment approval, Corrective Action Plan approval, verification/validation approval, and final closure approval all require electronic signatures. This documents a more structured process for each of the steps. The Q-Med database also is more secure, with password expiration, account locking, and an inactivity monitor. Companies subject to FDA regulation may use the advanced features of the SBS Q-Med Database to show strict compliance to the Quality Management Standards.

The feature comparison is shown below:

Feature	Quality Database	Q-Med Database
<b>Nonconformance management</b>	✓	✓
Electronic signature for NC disposition approval		✓
More than 21 NC reports for analysis	✓	✓
Scan and link electronic files (pictures, supporting documents)	✓	✓
<b>Corrective Action Management</b>	✓	✓
Electronic signature for CAR containment		✓
Electronic signature for CAPA Plan		✓
Electronic signature for CAR closure		✓
Supplier Corrective Actions (SCAR)	✓	✓
More than 33 CAR reports for analysis	✓	✓
Scan and link electronic files (pictures, supporting documents)	✓	✓
<b>Preventive Action Management</b>	✓	✓
Electronic signature for PA Plan		✓
Electronic signature for PAR closure		✓
Electronic signature for verification and validation		✓
<b>Audit Scheduling</b>	✓	✓
Audit findings and conclusions	✓	✓



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Feature	Quality Database	Q-Med Database
Electronic signature documenting Audit closure		✓
Create a CAR from an audit finding	✓	✓
Scan and link supporting documents	✓	✓
<b>Risk Management</b>	✓	✓
FMEA (Failure Modes and Effects Analysis)	✓	✓
SWOT Analysis	✓	✓
<b>Project management</b>	✓	✓
Electronic signature for project closure		✓
Continual Improvement Project tracking	✓	✓
<b>Meeting Management</b>	✓	✓
record meeting minutes and action items	✓	✓
Electronic signature for meeting closure		✓
<b>Survey management</b>	✓	✓
Record and measure survey results	✓	✓
Rich, configurable reports	✓	✓
Export reports to excel, word, PDF	✓	✓
Email reports with a single click	✓	✓
Microsoft access (stand-alone) database	✓	
SQL based (Access front end / SQL back-end)	optional	✓
Change history Log / Audit trail		✓
Privilege based user login	✓	✓
Detailed user privileges (add/edit/delete / approve)		✓
Password encryption and expiration		✓
Inactivity monitor		✓



## Quality Database vs. Q-Med Database

The Quality DB meets the requirements of ISO 9001:2008 for a broad range of categories:

ISO 9001:2008 Standard	SBS Quality Database
4.2.4 Control of records	Electronic records
5.4.1 Quality Objectives	Measure quality objectives (scrap rate, scrap cost, CAR timeliness, etc)
5.6 Management review	Document management review meetings and resulting actions
8.2.1 Customer Satisfaction	Customer surveys Customer complaints
8.2.2 Internal audit	Internal Audit Management
8.2.3 Monitoring and measuring	Reports and analysis
8.3 Control of nonconforming product	Nonconformances
8.5.1 Continual Improvement	Measures Quality Objectives Documents Audit Results Efficient Data Analysis Corrective and Preventive Actions Management Review
8.5.2 Corrective Action	Nonconformances Corrective Actions
8.5.3 Preventive Action	Preventive Actions

The product's core strength is in corrective and preventive action management and documentation. It provides a clear and auditable method for documenting non-conformances, determining root causes, corrective actions, and preventive actions. Actions are also validated and verified using simple approvals.



## Quality Database vs. Q-Med Database

The Q-Med Database meets the requirements of ISO 13485 and CFR21 Part 11 for a broad range of categories:

ISO 13485 Standard	SBS Q-Med Database
4.2.4 Control of records	Records shall be established and maintained to provide evidence of conformity...
5.4.1 Quality Objectives	Measure quality objectives (scrap rate, scrap cost, CAR timeliness, PARs)
5.6 Management review	Document management review meetings and resulting actions (review input / Review Output)
8.2.1 Feedback	Customer surveys Customer complaints analysis and corrective action
8.2.2 Internal audit	Internal Audit Management
8.2.3 Monitoring and measuring	Reports and analysis
8.3 Control of nonconforming product	Nonconformance documentation, disposition, and analysis
8.4 Analysis of data	Analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate improvement of the effectiveness of the QMS
8.5.1 General (improvement)	Measures Quality Objectives Documents Audit Results Efficient Data Analysis Corrective and Preventive Actions Management Review
8.5.2 Corrective Action	Nonconformances Corrective Actions
8.5.3 Preventive Action	Preventive Actions

The product's core strength is in corrective and preventive action management and documentation. It provides a clear and auditable method for documenting non-conformances, determining root causes, corrective actions, and preventive actions. The CAR / PAR lifecycle phases are documented by electronic signature approvals. Actions are also validated and verified also using electronic signature approvals.

## About Sunday Business Systems

Founded in 2004, Sunday Business Systems provides cost effective software and training services to achieve compliance to quality standards (ISO9001, AS9100, TS16949, ISO 13485). SBS provides software solutions for document control, corrective and preventive action management, control of calibrated equipment, employee training management, and supplier management. Demo versions of our standard software products are available for free download from our website. In addition to our standard products, we use our extensive experience to develop custom solutions for small businesses. More information about SBS, including free software downloads, can be found at <http://www.SundayBizSys.com>.