



The Training Database vs. T-Med Database

Sunday Business Systems offers two very similar products for employee training management for different levels of compliance. The *SBS Training Database* and the *SBS T-Med Database* both offer solutions for defining roles and responsibilities, training requirements, and recording training history, etc. (refer to the Feature Comparison Table).

The [Training Database](#) was designed for basic compliance where there are slightly less rigorous requirements. The database is an excellent source of objective evidence that training programs have been defined and are being executed in an efficient manner. It is also an invaluable tool to ensure measures of training effectiveness are maintained.

The [SBS T-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 training events and document revision changes.

The T-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 T-Med Database to show strict compliance to the Quality Management Standards.



The Training Database vs. T-Med Database

The product feature comparison is shown below:

Feature	Training Database	T-Med Database
Employee Positions		
Define prerequisites / qualifications	✓	✓
Define employee roles and responsibilities	✓	✓
Define required Training for each position	✓	✓
Employees may hold multiple positions	✓	✓
Training records		
Create a training schedule (of future events)	✓	✓
Record training events	✓	✓
Scan and link electronic documents such as signed rosters	✓	✓
Scan and link test results and other measures of effectiveness	✓	✓
Reports and analysis		
Management dashboard showing overall compliance		✓
Training history reports	✓	✓
Training gap reports (what is needed)	✓	✓
Training requirements reports	✓	✓
Export reports to excel, word, PDF	✓	✓
Email reports with a single click	✓	✓
Microsoft access (stand-alone) database	✓	
General		
Create training classes (courses)	✓	✓
Define certification and recertification frequencies	✓	✓
Group classes into training skills	✓	✓
Maintain headcount reports	✓	✓
Privilege based user login	✓	✓
SQL based (Access front end / SQL back-end)	optional	✓
Change history Log / Audit trail		✓
Detailed user privileges (add/edit/delete / approve)		✓
Password encryption and expiration		✓
Inactivity monitor		✓



The Training Database vs. T-Med Database

The Both T-Med and the Training Database meet the ISO 9001:2015 Human Resource Requirements:

ISO 9001:2015 Standard	SBS Training Database / T-Med Database
7.2 Competence	
determine the necessary competence of person(s) doing work under its control that affects its quality performance, and	Define prerequisites, training requirements, roles, and responsibilities.
ensure that these persons are competent on the basis of appropriate education, training, or experience;	monitor gap and requirement reports to ensure employees are properly trained and or certified
where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and	Maintain evidence of training effectiveness
retain appropriate documented information as evidence of competence.	Enter employee training records into the database with appropriate electronic/scanned documents as supporting evidence

The T-Med Database meets the requirements of ISO 13485 and CFR21 Part 11:

ISO 13485 Standard	SBS Training Database / T-Med Database
6.2.1 General Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.	Define prerequisites, training requirements, roles, and responsibilities and compare training history to requirements.
6.2.2 Competence, awareness, and training The organization shall a) determine the necessary competence for personnel performing work affecting product quality,	Define prerequisites, training requirements, roles, and responsibilities.
b) provide training or take other actions to satisfy these needs,	monitor gap and requirement reports to ensure employees are properly trained and or certified
c) evaluate the effectiveness of the actions taken,	Maintain evidence of training effectiveness
e) maintain appropriate records of education, training, skills, and experience	Enter employee training records into the database with appropriate electronic/scanned documents as supporting evidence



The Training Database vs. T-Med Database

The SBS Training Database and the T-Med Database meet the requirements of API Q1:

API Q1 Standard	SBS Training Database / T-Med Database
4.3.2.2 Personnel Competence Personnel shall be competent based on the appropriate education, training, skills, and experience needed to meet product and customer requirements.	Define prerequisites, training requirements, roles, and responsibilities and compare training history to requirements.
4.3.2.2 Personnel Competence Evidence of the determination of competence of personnel shall be recorded and maintained.	Enter employee training records into the database with appropriate electronic/scanned documents as supporting evidence.
4.3.2.3 Training and Awareness The organization shall: a) provide for quality management system training and job training;	Define prerequisites, training requirements, roles, and responsibilities.
b) ensure that customer-specified training and/or customer-provided training, when required, is included in the training program;	Define Training Requirements
c) ensure that the frequency and content of training is identified;	Determine certification and recertification frequencies
e) maintain appropriate records of education, training, skills, and experience	Enter employee training records into the database with appropriate electronic/scanned documents as supporting evidence. Maintain evidence of training effectiveness

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>.