

A CRM Software for Regulatory Compliance

Meeting the FDA's requirements for electronic records and electronic signatures used in the pharmaceutical industry

Marathon 21 CFR DB™

Our database and Customer Relationship Management Software has been designed for the biotech, medical, and pharmaceutical industries to comply with the Code of Federal Regulations Section 21 CFR Part 11 as required by the Food and Drug Administration.

Marathon 21 CFR DB™ validates data and works seamlessly with Marathon's intelligent data collection devices. The software provides sophisticated data encryption and storage, administrative and multi-level user security profiles, as well as tools for manipulating and retrieving data.

When used in conjunction with Marathon's time and temperature data loggers, the software provides a complete analytical solution for quality assurance standards.

SOLUTIONS

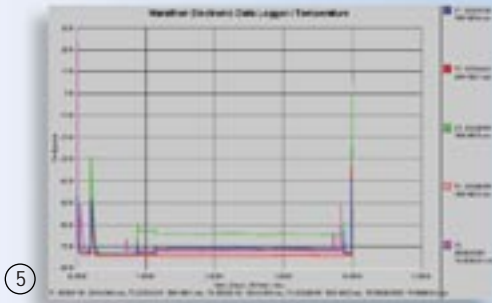
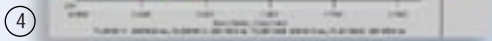
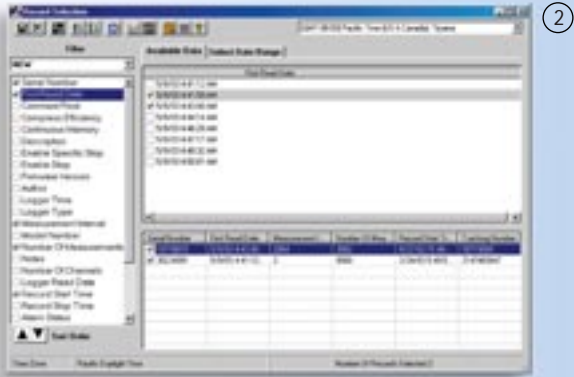
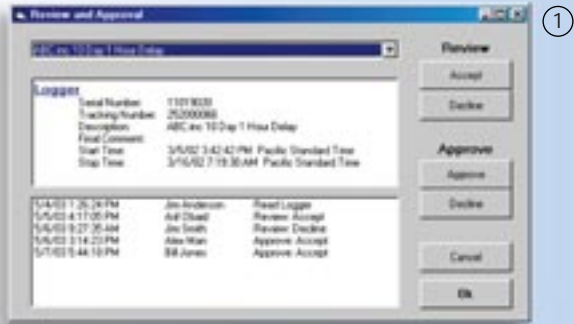
- Section 21 CFR part 11 compliant for the FDA
- Password protection (up to 10 alpha-numeric characters)
- Multiple levels of security privileges: system access can be customized for each User
- Microsoft Access Database: industry standard format allows exporting to other databases
 - Recommended Client / Server configuration with the database located on a secure server away from the workstations.

BENEFITS

- Sort by dates, product codes, tracking numbers, shipper or any user defined attribute to electronically manage your data.
- Electronic Signatures make paper records obsolete.
- Encrypted Data means no risk of record alteration.
- Electronic audit trails for regulatory compliance.

Our industry focused approach benefits your operations even if your best practices do not require regulatory compliance.





SYSTEMS REQUIREMENTS

Microsoft Windows Operating Systems 98, NT, 2000 and XP for client workstations. We recommend that the database software be installed on a Windows 2000 or 2003 server by your IS or IT department. All Marathon's electronic temperature data loggers are backward compatible with the *Marathon 21 CFR DB™* program.

CONTROLS FOR CLOSED AND OPEN SYSTEMS

Recorded files are encrypted to 128 bits or more in a RC4 variant. Recorded files are in binary, compressed and checksummed format proprietary to Marathon Products, Inc.

Complete and accurate electronic copies are available for reviewing the data, copying the raw data, exporting or by setting up "pdf printer" in order to print into a "pdf" format.

SECURE INDIVIDUAL ACCOUNTS AND PASSWORDS

Unique user names, login names, and alpha-numeric passwords up to 10 characters. Users can never be deleted.

AUDIT TRAILS

- Secure computer generated, time-stamped run-time audit trail of authorship, signatures, detailed configuration changes, imports and exports, administrator activities, etc.
- Audit trails are embedded in the history file guaranteeing retention alongside the records and available for review/copying.
- A separate Audit log monitoring individual logins, is kept outside the *Marathon 21 CFR DB™* program and can be deleted according to your Standard Operating Procedures.

SIGNATURE MANIFESTATIONS

Signed records contain printed name, date, time and meaning. Meaning includes Reviewed and Declined Review, Approved and Declined Approved, Record Created and Record Imported. Signed authorization (authorship) and optional operator entered note. Name, time-stamp and meaning are all embedded in the binary format history file.

DESCRIPTION OF SCREEN SHOTS

- 1) Reviews and Approval
- 2) Filter/Records Selections
- 3) Create Queries
- 4) Sample Graph with temperature profiles
- 5) Sample Graph with low temperature profiles