Prime Technologies

Mobile Technology
A Generic Users Guide

A Prime Technologies, Inc. Guidance Document

Prepared by: Mike McClain and Frank Gellner

November 2005

Revision 1

ProCalV5
calibration management software

20 Hagerty Blvd., Suite 1

West Chester, PA 19382

P: 610-436-9703

F: 610-436-9097

ProCalV5@primetechpa.com

www.primetechpa.com

Mobile Technology
A Generic Users Guide

Table of Contents

Mobile Technology
A Generic Users Guide

1. Purpose

The purpose of this guidance document is to generically describe Mobile Technology and the benefits it offers to users, to suggest minimum Mobile Technology functionality requirements, and to provide a potential specification for the functionality. The information in this document would then be utilized by potential system designers in understanding Mobile Technology and in developing URS (User Requirements Specification) documentation for their implementation.

2. Mobile Technology Overview

This document contains a Prime Technologies' interpretation of Mobile Database Technology gained from experience developing, implementing and supporting Mobile Databases for GxP environments, ref: "Good Practice and Compliance for Electronic Records and Signatures", published jointly by ISPE and PDA.

2.1 Scenario

Many applications use a data store that often exists on some physically centralized server or group of servers, often referred to as the Production Environment. Data may be made available via LAN, WAN or even the Internet, but all of these items require some kind of communication link between users and the Production data.

2.2 Problem

Often, some form of work must be done in environments where a connection to such a server is not available, not reliable or simply not desired. This may be due to location, safety, security or other concerns. These work items may require read or write to this data store database, or some logical subset of data.

2.3 Potential Solution

A potential solution to this scenario includes the use of a secure, reliable Mobile Data Store on some form of Mobile Device, which contains a subset of the centralized data. The Device would have the user interfaces necessary to add, modify or delete applicable data within that subset of data. Once a communication link was available, a separate application function would handle the data transfer of the Mobile Data into the corresponding records within the centralized database. In an ideal world, the functionality of the Mobile Environment would be equivalent to that of a Production Environment. At a minimum, the Mobile Environment should have secure access to specific functions with appropriate modification tracking in an audit trail as well as electronic signature capture capabilities.

3. Definitions

3.1 Production Database

The Production (Prod) Database (DB) is the primary source of system definition and use including configuration, record creation, record retrieval, record approval, record modification, data input and reporting.

3.2 Production Application

The application software that accesses the Production DB directly, given necessary user inputs for required functionality.

3.3 Configuration

v. Populating the Production Application Database with specific option selections, security settings, values for standard features, adding any customer defined labels, fields or lists, installing custom reports or application add-ons.

n. The database elements involved in configuring a Database.

3.4 Mobile Database

A Mobile Database is an image of the Prod DB. When it is populated with appropriate Production configuration, data and security parameters, it can function independently (disconnected) from the Prod DB for a finite period in a compliant manner based upon the Prod DB compliancy. Ideally this Database has a structure similar to that of the Production Database, but this is not a requirement.

3.5 Mobile Application

A Mobile Application is any application software that is available on a Mobile Device that accesses only the Mobile DB for the required functions to be performed in a Mobile Environment. Ideally this application is operated in a manner similar to that of the Production Application, but this is not a requirement.

3.6 Export

The process of transferring data, using the Production Database as the source and the Mobile Database as the target.

3.7 Import

The process of transferring data, using the Mobile Database as the source and the Production Database as the target.

3.8 Data Transfer Application

The software used to perform Export and Import actions between the Production Database and the Mobile Database. This may include specific communication functions with the Mobile Device.

3.9 Mobile Operations

Generic term for all operations taking place in a Mobile Environment that are related to operations that would take place in a Production Environment.

3.10 Timestamp

A Timestamp is a data element that includes a date and time.

3.11 Mobile Device

A Mobile Device is any electronic Device capable of hosting a Mobile Application and a Mobile Database. This Device's data storage method should allow for persistent storage with or without a power supply. In the event of internal power supply depletion, data committed to the Mobile Database is also maintained. This Device must also have the capability of generating timestamp values based on some clock that is internal to the Device.

This Device typically should not require a communication link to any other Device to operate, unless the Device is implemented as a system of Devices operating without a communication link to the Production Data. Once these minimum features are met, the ideal Mobile Device should have user interface capabilities on a par with the Production Application. Examples of Mobile Devices include laptops, tablet PC's, and PDA's.

3.12 Transient Data

Section 4.5 – Transient Data from the "Good Practice and Compliance for Electronic Records and Signatures", published jointly by ISPE and PDA, states:

> Systems that only handle transient data are excluded from 21 CFR Part 11. These are systems that acquire data, temporarily store it in files, but as part of normal workflow pass that data on to a printer or another system before the process task is complete. An example would be a laboratory instrument, e.g., an HPLC that acquires the data then passes it on to a chromatography management system. In this example, data stored in files on the first system is done so, for the purpose of temporarily gathering information that is passed along, and those files are not subsequently accessed for use, including in the case of "emergencies". Such attempted re-use would be prevented by procedure and/or security provisions. In such a case, the first system should NOT be considered as having records to which 21 CFR Part 11 applies. However, the GMP data is managed by the receiving system.

PTI interpretation: Transient data, or temporary data, is electronic data that cannot be edited once it has been saved to some electronic format. Therefore, it does not require an audit trail, and does not consist of an actual electronic record, as defined by 21 CFR Part 11, until passed on to a receiving system and merged with some other data via some software process.

4. Transfer from Production to Mobile Environment

4.1 Export

Exporting of the data includes copying of data from the Prod DB to the Mobile DB using some valid Data Transfer application. This process must ensure data type and referential integrity of the Mobile DB.

4.1.1 Creation/Population of Mobile Data

A Mobile DB must be capable of being cleared of data and completely populated with new data at some point, to include all data that is necessary for mobile operations to take place. This may include, but is not limited to:

- All or some subset of the configuration data elements,
- Business data elements such as compliant electronic records.

Technical or Procedural controls or warnings should be in place to prevent the clearing of data that has not yet been imported back into the Prod DB.

4.1.2 Update of Mobile Data

If available, a Mobile DB may be capable of accepting updates and/or additions to its current set of data. Technical or Procedural controls should be in place to potentially prevent the replacement of modified or newly entered data that has not yet been imported back into the Prod DB. Data should still be able to be replaced if this action is valid. All conflicts should be reconciled automatically or by some user input.

4.2 Critical Elements

The critical elements of the data that is transferred from the Prod DB to the Mobile DB include:

- Security Settings,
- Audit trail preferences/settings,
- Compliance-related settings,

The functionality behind these elements should be maintained by the Mobile Application in accordance with current Production Application configuration.

4.3 Mobile Synchronization

After having its data populated, some aspects of the Mobile Environment must be synchronized to the Production Environment before being disconnected. Technology or Procedural controls must be in place to make any adjustments determined necessary to synchronization.

Synchronization should address:

- File Access (if applicable)
- System Clock

4.4 Production Flags

If applicable, some Production Data may need certain flags to be set, potentially including the timestamp of the record's last export. This may be useful for:

- Record locking – Users of the Production Application may not be able to modify a record while it is exported to the Mobile DB.
- Handling of Conflicts – Upon import (discussed below), records with the same identification but with different export dates may need to be accepted or rejected based upon user preference, technological requirements or procedural controls. This may also take record modification dates and audit trail details into account.

4.5 Reconciliation of Export Conflicts

When records are encountered during export that have been changed in the Mobile Environment but have not yet been imported, there must be a reconciliation process to inform the user of the possible conflict. The user may be allowed to replace the record with a new version from the Production Data, or ignore that specific record transfer and keep the current Mobile Data as it was found.

4.6 Post-Export Production Environment

After the export process has completed, the Production Application would ideally have configurable tools which prevent modification of Prod DB records that have been copied to the Mobile DB environment. At a minimum, some function of the system should inform users of the current Exported state of each record so procedures can be put in place to deal with potential reconciliation issues. If business processes require that records continue to be modified, the reconciliation process of Mobile DB records back to Production must account for this possibility.

5. Mobile Operations

5.1 Change Control

If record changes are permitted while in Mobile they must be controlled. Approved records that are changed while in Mobile:

- Must track changes in a full function Audit Trail that is compatible and can be integrated with the Prod DB Audit Trail upon reuniting,
- Approval Status must be adjusted to suit the new condition of the changed record.
- Modification and/or approval timestamp fields must be updated with each modification event.
- Approved records that are changed in Prod while a version is in Mobile must,
  - Note changes in Prod Audit Trail,
  - Adjust Approval Status to suit changed record,

5.2 Critical Requirements

- Data collected while in the Mobile Environment must be associated with the User logged on when it was added.
- If Data is changed or added while in the Mobile Environment, these events must be captured in a full function Audit Trail.
- User security settings must be enforced in the Mobile Environment.
- User security settings must not be modifiable in the Mobile Environment.
- If the user happens to change their password, this password is only maintained on that instance of the Mobile DB, and not transferred to Production.
- Approval policies used in the Mobile Application must be compatible and integrated with those in Production when imported, but not necessarily the same as Prod's.

5.3 Possible Mobile Applications

5.3.1 Reporting

5.3.2 Master record data entry

5.3.3 History record data entry

5.3.4 Field Device Communication for the purpose of:

- Calibration
- Configuration
- Verification

These may include the processing of Transient Data with such Devices into electronic records in the Mobile DB.

6. Transfer from Mobile to Production Environment

6.1 Import

Importing of the data includes copying of data from the Mobile DB to the Prod DB using some valid Data Transfer Application. This process must ensure data type and referential integrity of the Prod DB.

6.1.1 Data Merge

As a general rule:

- New data added in the Mobile Environment should be added to the Production Environment if that data is compatible with all necessary related records that should already exist in Production.
- Modified Mobile Data should replace any Production Data that has not been modified since it was exported.

- All audit trail entries entered on the Mobile should have their details imported as they were captured, but flagged as having been performed in a Mobile Environment.

6.2 Reconciliation of Import Conflicts

Conflicts may occur when timestamp fields related to the most recent modification event in the Prod DB have been updated since the last timestamp of modifications made for the copy of this record in the Mobile DB. When changed records are encountered during import there must be a reconciliation process to:

- Inform the user of a possible conflict.
- Lead a process of reconciliation.
- Merge records according to reconcile decisions.
- Merge Audit Trails.
- Abandon un-merged records in a predictable fashion.

7. References

7.1 "Good Practice and Compliance for Electronic Records and Signatures, Part 2, Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures", published jointly by ISPE and PDA, 2001

8. About Prime Technologies, Inc.

Prime Technologies is committed to the development of quality compliant software. ProCalV5 systems are installed in many of the top pharmaceutical and ISO certified organizations. Our software development and testing procedures have been fully audited and approved by numerous fortune 100 companies.

ProCalV5 represents the latest in our ongoing quest to provide the ultimate in sophisticated calibration management solutions. All ProCalV5 products are validated by our quality staff before release and successfully validated by our customers under intense internal Quality and Regulatory scrutiny. A full complement of additional staffing is available to assist you with all aspects of your project implementation needs.

9. About The Authors

Mike McClain is a Programmer Analyst at Prime Technologies, Inc. Mike has over 4 years of experience in developing Computerized Calibration Management Software solutions for FDA and industrial business applications, and has helped produce numerous business process-related enhancements to the ProCalV5 line of software products. Mike has extensive experience in customer and project support environments fusing the needs and expectations of users with the realities of compliance in a software based solution.

Frank Gellner is the Quality Assurance Manager at Instrumentation Technical Services and Prime Technologies, Inc. With over thirty years of leadership experience in instrumentation technology, control system design and project execution with DuPont, Frank has a vast and diverse perspective on instrumentation and calibration management. His current role with Prime Technologies, producers of ProCalV5 Calibration Management System (CMS), is deeply involved with many of the world's top 10 Pharmaceutical Companies in the planning, compliance and successful project management of their Enterprise-Level CMS Implementation Projects. Frank has played a leadership role in many international projects involving global and enterprise level Control System and CMS Solutions. Frank is also the author of other papers on validation implementations and a full set of calibration procedures now available on the Instrumentation Technical Services web-site http://www.calservice.net/.

Mobile Technology
A Generic Users Guide