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A Realworld Application Example

for a Safe and Capable Ph21 Tablet Testing Environment
at a Major Pharmaceutical Production Plant

Client's Requirements

1. provide a single point of long-term storage of all test results of solid dosage forms
2. test stations shall continue operating even if data transfer to Admin or Data Collector computer is (temporarily) out of order
3. provide acceptable response times on all systems
4. provide data safety/recovery in case of fatal hardware or software failures
5. provide separation of administrative and test operational tasks
6. provide uncomplicated printing of long-term batch summary reports
7. grant access 'from the outside' to the test result database for data mining purposes

The implementation details always depended on client's actual production and testing practice and therefore prior consultation and acceptance by the production and QC management is required before implementation can start.

Production and Test Infrastructure at Client Site

Client's production floor consisted of about 30 rotary tablet presses, from which most were round-the-clock in operation.

On the production floor there were two testing booths. One booth contained three universal tablet testers, the other booth contained two universal tablet testers. There was a sixth tablet tester in the coating department.

Another two testers were located in the R&D department. This systems ware not inter-connected with the remaining systems, however these were cross-linked to each other. Therefore a test performed on R&D system No. 1 was automatically transferred to R&D system No. 2. This ensured equal data base content on both systems and therefore provided redundancy in case if one system would fail.

All tablet test systems were equipped with a PC (Lenovo Think Center in various performance configurations), a flat-screen display, a sealed keyboard and a regular optical mouse.

On all testing systems revision R4.5-4 of the Ph21 production control software was installed with 'ODT' data transfer option enabled.

On all testing systems a local Microsoft Sql Express 2005(R) database server was installed, this allowed for continuation of testing on active batches even when ODT data exchange with the Admin system or Data Collector was out of order.

The samples were fed manually into the tester (operator takes a sample from the presse's outlet into a small paper bag, carries the sample to the nearest/free tablet tester, inserts sample into the vibration feeder, starts a new test). A paper report was automatically printed out at the end of test, the report was reviewed and filed.

At average there was about every half a minute to twenty seconds a tablet test completed.

IT Infrastructure

Besides of the PC-equipped test stations there were also:

1. An 'Admin' computer equipped with a Ph21 'admin' license¹. There was no test equipment connected to the admin system
2. A 'Data Collector' computer for bulk and long-term storage of test results
3. A large network-harddisk for the purpose of automatic daily database backups of the data collector
4. The database of the Data Collector is to be moved at a later time onto the companies' own Microsoft Sql Server system.

Operating Procedures

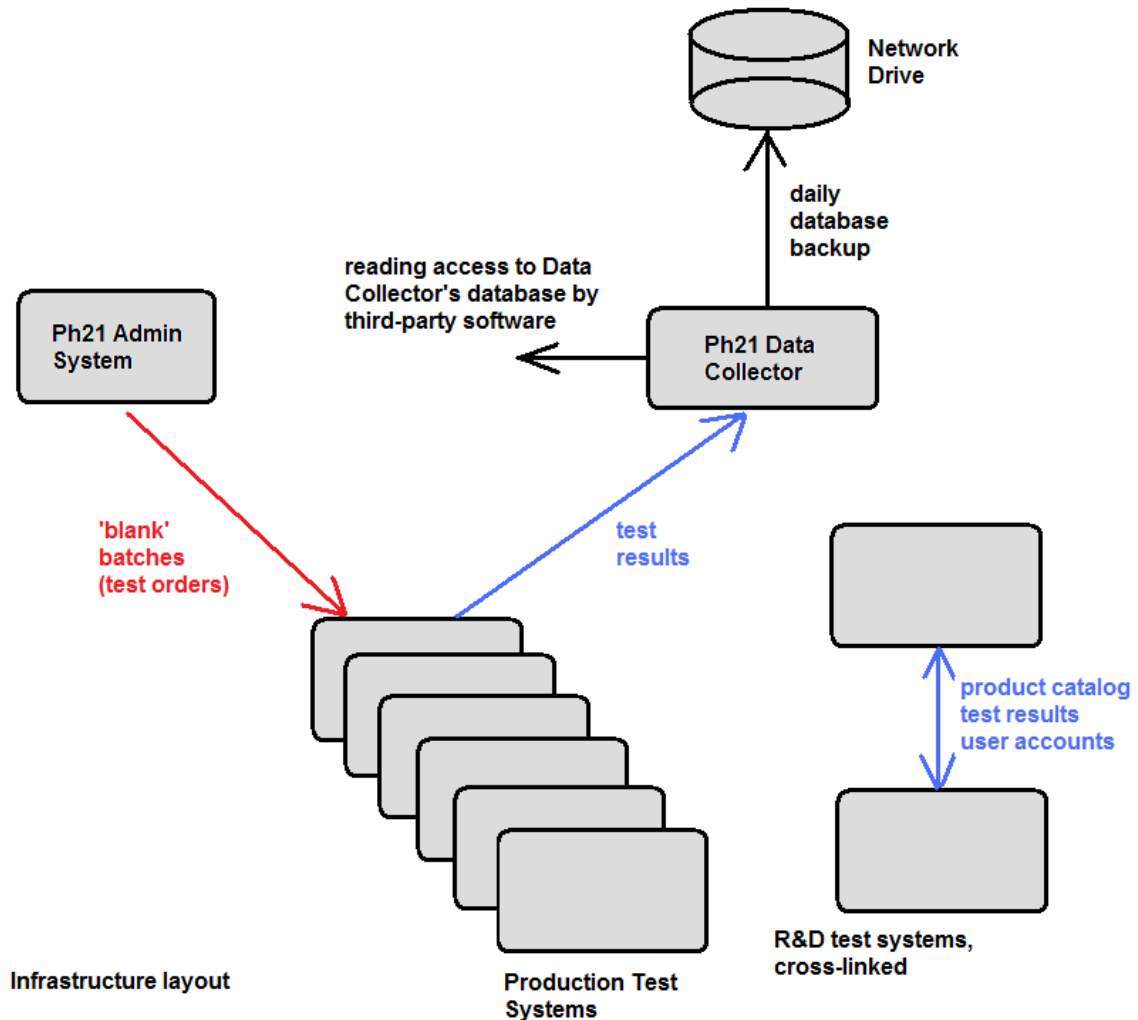
1. The 'Admin' system served only for the following purposes:
 - a. batch preparation/creation
 - b. maintenance of the product and standards catalog
 - c. creation of new operator accounts

Batch preparation (creation of a new 'blank' batch/test record) was ONLY allowed to be performed by an supervisor (or otherwise sufficiently authorized person). This restriction was applied by respective configuration the Ph21 access control

2. Batch preparation/creation on the Production Test Systems was also possible but was inhibited by respective configuration the Ph21 access control on all testing systems.
3. The 'Data Collector' system served only for the following purposes:
 - a. collecting test results
 - b. daily database backup
 - c. complete batch report printing facility
 - d. long-term (monthly, annually) batch summary report printing facility
 - e. online access to outdated test results
 - f. gateway to third-party data mining software
4. Test results were automatically sent from the production test systems via ODT to the Data Collector every time a tablet test was completed.

¹ admin licenses are stripped-down Ph21 licenses which do not allow tablet testing, but do allow all the other functions (batch creation, report printing, archiving etc.)

5. If a production year was finished, and annual reports were printed a blank database was attached onto the Data Collector system to take the data of the coming year.
6. The Data Collector was available 7/24. The Data Collector was not switched off or the Ph21 Software was not be closed for an extended period of time². Installation of an UPS was intended to prevent power failures.



Automatic Backup and Recovery

Ph21 Services provided an integrated backup utility which copied the Data Collector's database files in predefined time intervals (daily copy was chosen) onto an external network harddrive. During the backup procedure the Ph21 software was stopped for a short period of time and was automatically continued when the backup was completed.

During the backup the inter-connected production test systems were unaffected and were continuing testing and sending test results. The test results then were buffered temporarily in the Data Collector's local 'import' folder.

² the Ph21 ODT data communication is tolerant to short-term interruptions of the data network or to data receivers being off-line for some time. In this case undeliverable data records are buffered at the sender's side.

The inter-connected production test systems didn't require data backup because all batch records were already backed up on the Data Collector. Therefore outdated batches could be deleted from the Production Test Systems at any time.

The Admin system did not store test results. However changes to the product catalog had to be secured. This was done by using Ph21's integrated autoarchive function.

Other Aspects

A time synchronisation of all inter-connected Ph21 systems was provided. Identical dates/times are essential for proper operation of the ODT network.

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Director of Ph21 Services Ltd.
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