Charles Ischi AG
TESTING TECHNOLOGY

Press Release

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# Charles Ischi Ph21 software compliance with FDA 21 CFR part 11 guidelines

As data Integrity becomes increasingly important, tablet developers need tested and proven solutions that make regulatory compliance an integral part of the basic testing and analysis process.

Charles Ischi Testing Technology's Ph21 laboratory automation software has been newly confirmed as fulfilling all main requirements and latest revisions of the US Food & Drug Administration's (FDA's) 21CFR part11 regulations on electronic records and electronic signatures (ERES).

The advanced automated features incorporated into the Ph21 package mean that data integrity and ERES compliance is built into every part of the data acquisition and analysis involved in quality assurance testing in tablet and solid oral dose development.

**What is Ph21?**

The Ph21 pharmaceutical quality assurance system gives users central control and evaluation of data from across a wide range of tablet or disintegration testers and weighing machines. Once stored on a central database, the program allows product-specific data to be applied to all tests on the connected devices.

It uses its own encrypted data import/export or the well-established Open Platform Communications (OPC) standard to enable synchronization and structuring of data being exchanged between a Ph21 Supervisory Control And Data Acquisition (SCADA) control system and a PPC (Production Planning & Control) process development system.

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The system supports the connection of several external pharmaceutical testing devices, including Kraemer Elektronik's well-known UTS tablet testing systems, tablet hardness testers and disintegration testers, scales, as well as weighing systems for in-process control.

The Ph21 system can be also installed and operated as a client-server application.

Numerous interfaces are available for communication and data exchange with external software applications, allowing flexible data export to in-house Data Management System (LIMS, OPC,MES).

The platform has found widespread industry acceptance with more than 1,000 Ph21 licenses active worldwide.

**FDA 21 CFR part 11 requirements**

The entire Ph21 software package is 100% compliant with the FDA's 21 CFR Part 11 requirements that define the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records.

This built in compliance allows users to choose a wider scope of evaluation options for completed tests. Automatic backups in the background guarantee failsafe in-process control (IPC).

Examples of Ph21's integral data controls include:

- Automatic data completeness check whenever an event is stored with incomplete entries blocked.
- All relevant activities automatically logged in Ph21's Audit Trail with date/time, name and responsible person ID, as well as unique identity of device involved.
- All activities and changes protected by password Log In and assigned authorities.

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- Change control system within Ph21 Audit Trail backed up by Master Data change control log.
- Data Confirmation feature allowing authorized second person to review data and confirm record, making them protected from future alterations.
- Comprehensive 'Archive' feature that automates archiving and further protects data integrity from subsequent alteration.

The entire software platform and system architecture are thus 100% compliant with FDA 21 CFR Part 11 regulatory guidelines that define the criteria under which electronic records and electronic signatures (ERES).are considered trustworthy, reliable, and equivalent to paper records for pharmaceutical and healthcare purposes.

In the core system design, special care has been taken to ensure proper operation of the system, with each new version only being released after passing the internal testing / verification and validation procedure.

The Ph21 platform also complies with European Regulations for software applications in GMP-critical environments within the pharmaceutical industry.

https://www.ischi.com/software/ph21-software/

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