

Genealogy Method Development Software

- Graphically represent the isolation and extraction of metabolites and residues for biological matrices
- Determine the relationship of each sample with the original material analysed (recovery and concentration).
- Monitor the progress of the study and be able to determine the origin of each sample
- Select from multiple calculation algorithms

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- Implement normalised children and multiple parent calculations
- Automatically trigger calculations and easy reporting of results
- Fully configurable security levels to control user access
- Full audit trail recorded for every user of the system
- FDA and GLP Compliance including 21 CFR part 11

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- Oracle® Client/Server architecture
- Direct interface to Instrumentation
- Windows® 95/98/NT/2000, XP compliant

Genealogy Method Development Software

The isolation of metabolites and residues from biological matrices can be a long and complex process. Keeping track of the extraction systems used, and the calculations necessary to determine the concentration of each component in the extraction system, presents a number of problems. The Trace™ system has been designed to address these problems.



- Monitor the progress for a study and be able to determine the origin of each sample
- Determine the relationship of each sample with the original material analysed (recovery and concentration)
- Calculations are continuously updated offering easy access to results
- Complete control from Study Definition through to Final Report

Instrument Interfaces

To achieve the goals of productivity and GLP confidence, Trace™ avoids transcription errors by capturing raw data, either directly from the instrument, or via sample result data files from analytic

instrumentation systems. There is no transcription necessary.

Report

Enables you to obtain immediate calculations on any part of the extraction scheme, with raw data sheets throughout the scheme, and the ability to export the extraction schemes in diagrammatic

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form to a Word document. Saves considerable time in the preparation of the final report.

Benefits

Significant time savings in the area of QA auditing final reports, as the system contains a full audit trail of all changes. In addition to the obvious saving of resources there are also other intangible benefits to be gained such as the use of standardised algorithms and the establishment of a consistent, though flexible, approach to studies. Trace™ gives fast QA turnaround.

Regulatory and FDA 21 CFR Part 11 Compliance

Trace™ is designed to support fully, GLP and associated regulatory requirements for both laboratory operations and laboratory software design. This includes full audit trails and functionality to meet with the FDA 21 CFR Part 11 ruling for electronic signatures and electronic records.

Platform

Trace™ is designed as a multi-user networked package allowing users to work on different trees within the same study, or even the same tree at different stages of the sample extraction.

Quality Assurance



and this is reflected in our systems. Our continued efforts in this area have resulted in ISO 9001 accreditation for: Design, development and supply of laboratory information management systems, scientific applications software with ongoing maintenance support,

Quality of service and product is of paramount importance to LabLogic

Certificate No:1535/97

ISOQAR ANSI+RAB QUALITY

QMS

including the supply of instrumentation systems for pharmaceutical, agrochemical and contract research organisations.



Client

minimum 200Mhz Pentium minimum SVGA 800x600, 256 colours mouse or other pointing device printer (or access to a network printer)

Operating system Microsoft[®] Windows 95 with 16Mb (32Mb preferred)

Microsoft[®] NT4 workstation with 32Mb (64Mb preferred)

Microsoft[®] Windows 98 with 32Mb Microsoft[®] Windows Millennium with 32Mb

Microsoft[®] Windows 2000 Prof. with 64Mb (128Mb preferred) Microsoft[®] Windows XP with 128Mb

SQL*Net 2.x and Required Support Files with Oracle[®] 7 SQL*Net 8.x and Required Support Files with Oracle[®] 8.x

rioMb for a local client installation ~10Mb free required after installation

It is possible to store the Trace™ executable program and online help either locally or on a network fileserver. Issues to consider in order to make this decision include the fact that storing the executable on a central server will ease updating the software and also the client installation process. Conversely, storing the executable locally will reduce network traffic and improve the performance of the software.

Server

Due to the nature of Oracle and the client/server architecture of Trace™ , the server platform is largely immaterial. Trace™ requires an Oracle server. Full stop.However, Trace™ supports only the following Oracle[®] server versions. • Oracle[®] Server 7.3 or higher with SQL*Net 2.x.

Oracle® Server 8.x with SQL*Net 8.x

Pentium running NT Oracle Server 7.x, 8.x DEC Alpha running OpenVMS and Oracle Server 7.x Several varieties of Unix servers with Oracle Server 7.x

Default initial sizing of the database at install-time is 60Mb.To estimate future database sizing assume between 2Kb and 10Kb per sample.



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