

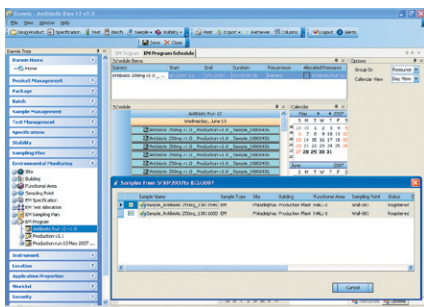
Count on Thermo Scientific Darwin LIMS to support the complex testing, workflow and regulatory requirements of your pharmaceutical manufacturing R&D and QA/QC operations.

Thermo Scientific Darwin LIMS™

Information Management for Pharmaceutical Manufacturing R&D and QA/QC



Environmental Monitoring, a core feature of Darwin, provides essential functionality including test allocations for monitoring sampling points and frequency of collection.



Challenge

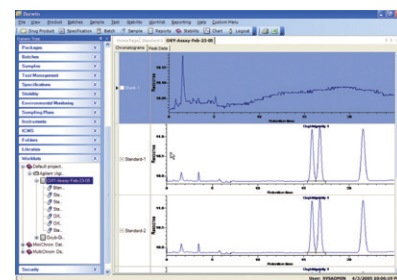
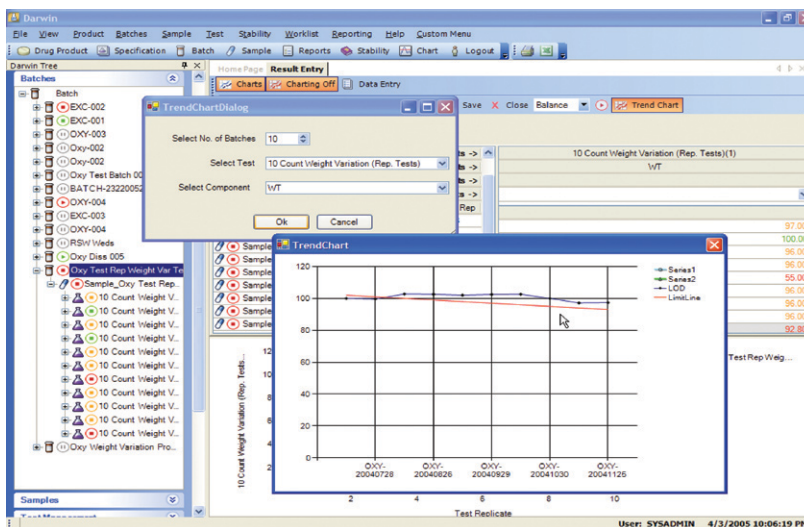
Bringing a drug from discovery to market can take as much as 15 years, and the management of its data can be one of a pharmaceutical company's biggest assets. However, the unique challenges this industry faces - such as regulatory compliance, dynamic sample testing and complex batch-centric (non-continuous) manufacturing processes, have been a significant burden. Drug companies have had to undergo lengthy, costly customization projects for the generic laboratory management systems (LIMS) that are so vital to the management and security of their data.

Facing continuous pressure to control costs, increase efficiency and build their pipeline, the pharmaceutical industry is looking to technology vendors for real solutions. Purpose-built software that delivers

extensive pharmaceutical functionality out-of-the-box can help significantly reduce the time it takes to implement and validate a LIMS, increase user acceptance and simplify future system upgrades.

Count on Thermo Scientific

With purpose-built functionality that is supported by our helpdesk, covered in the Darwin user manual and incorporated into the upgrade process, the Thermo Scientific Darwin solution is significantly different from generic LIMS that require extensive customization to meet pharmaceutical requirements. Out-of-the-box functionality can lower the cost of implementation and validation for pharmaceutical customers and minimize project risk. Reduced customization means reduced validation, shortened deployment and easier ongoing support.



Purpose-Built Functionality

Darwin was built – from the ground up – with standard functionality to serve the unique needs of pharmaceutical manufacturing R&D and manufacturing QA/QC labs. Customer-defined compliance configurations, auditing, electronic signatures and justifications can be tailored to meet every department's needs. Data can be assigned to the appropriate compliance level to allow researchers greater flexibility during exploratory work, while still enforcing adherence to company SOPs and regulatory guidelines for cGMP quality control data. Darwin features a comprehensive test library that includes complex pharmaceutical testing methods for dissolution, dosage unit uniformity, product assays and stability that simplifies the process of designing, implementing and managing stability studies. Darwin also includes environmental monitoring as standard, which is essential for product quality and compliance. ICH-compliant templates are included to let users start building stability protocols and studies as quickly as possible. It's everything pharmaceutical users need - and nothing they don't.

Darwin interfaces not only with database systems such as SAP, but also allows interactions with other data-treatment applications. Integration tools provide a graphical environment to build bi-directional instrument interfaces, database interfaces and application level interfaces. Darwin comes pre-configured to integrate with other Thermo Scientific systems, including the Atlas Chromatography Data System.

Darwin was designed with user acceptance in mind. The graphical user interface is modeled after the popular Microsoft® Office suite

of applications and is therefore intuitive and familiar to users. In addition to its ease-of-use, the interface is extremely flexible. Using industry-standard tools such as Microsoft Visual Studio®, individual user preferences can be created and preserved, from modifying screens to developing version - and privilege-controlled reports.

Thermo Fisher Scientific is the worldwide leader in laboratory software and related services, providing enterprise-wide, multi-laboratory solutions that have become the corporate standard at leading organizations. Our Thermo Scientific LIMS and CDS manage mission-critical laboratory data in 19 of the top 20 world's leading pharmaceutical companies. To support our global customers, we provide implementation, validation, training, maintenance and support from the industry's largest worldwide informatics services network.

Darwin is part of a comprehensive portfolio of Thermo Scientific software solutions for the pharmaceutical industry, which includes Watson LIMS™, the industry standard in bioanalytical laboratories; Galileo LIMS™, for in vitro ADME studies in early stage discovery and development; Nautilus LIMS™, for discovery and R&D; Atlas CDS™, an enterprise chromatography data system that integrates tightly with Darwin; Enterprise Pharmacology (EP) Series™ and Kinetica™ analytical database tools for pharmacokinetics and pharmacodynamics; and GRAMS spectroscopy analysis software.

Visit us on the web at www.thermo.com/informatics
or call +1 866 463 6522 (US) or +44 161 942 3000 (Intl).

"On looks alone, Darwin wins the coolest GUI award. Sleek interface, simple commands, placing power at the fingertips, it seems that Darwin is a complete rethink of the LIMS interface."

Jeff Vannest
J&R Consulting Inc.
LIMS Consultants