

Part 11 COMPLIANCE REPORT®

PHARSIGHT PKS SNARES EARLY DRUG DEVELOPMENT CUSTOMERS

Pharsight's new Knowledgebase Server (PKS) 2.0 and PKS Reporter products have won the Part 11 compliance business for two big early drug development contracts, product developer James Buzzard told *Part 11 Compliance Report* last week.

Early drug development is considered a relatively underserved Part 11 market, in part because the sense of urgency to comply is not as strong as it is further down the drug development line, experts tell *PCR*. There is a gap in IT spending between the early and later drug development stage because "failures are relatively inexpensive" in the early phase, said Buzzard, vice president of product management and services at Pharsight.

Those involved in clinical trials are generally more worried about and aware of Part 11 compliance issues because failure – via adulterated invalid data – can be costly. But Pharsight has had some luck convincing at least two firms to shore up their early stage compliance efforts.

Last month, Sanofi-Synthelabo Recherche said it would implement PKS and upgrade related modeling software in its drug development efforts. PKS is an enterprise data management and visualization system that helps enable pharmaceutical and biopharmaceutical companies to manage and control clinical and preclinical pharmacokinetic data and analyses in compliance with Part 11.

The PKS software is designed to complement Pharsight's modeling and simulation technology for computer-based drug-disease modeling and clinical trial simulation. Pharsight handles installation

and training, IQ and OQ, but not PQ, Buzzard said. The Pharsight suite can help labs cut backlogs in reporting time down from six months to several days, Buzzard added.

"Sanofi-Synthelabo Recherche has a long history of deploying technological innovation to dramatically improve the productivity of our drug development process," said Jean-Pierre Duret of Sanofi-Synthelabo Recherche. "The Pharsight Knowledgebase Server is a critical component of our information infrastructure, facilitating compliance and a more efficient means of managing clinical development data."

In August, Schering-Plough Research Institute bought PKS software. The company said it would implement PKS in its drug development efforts. "We expect the addition of the Pharsight Knowledgebase Server to our information infrastructure will enable us to use pharmacokinetic-pharmacodynamic data more effectively in our drug development program," said Anther Keung, Ph.D., senior principal scientist, pharmacokinetics, Schering-Plough Research Institute.

PKS was unveiled in July after conducting tests with several beta customers, Pharsight said. The new PKS version 2.0 functionality includes a stronger query tool to support data mining and cross-study meta-analysis, improved audit trail reporting and comprehensive support of document review and approval workflow with electronic signatures via PKS Reporter. The PKS suite will also include PKS Connectors to automate the integration and data loading processes between the PKS data warehouse and other legacy data sources and analysis tools.

For more information, contact the company at <http://www.pharsight.com>.