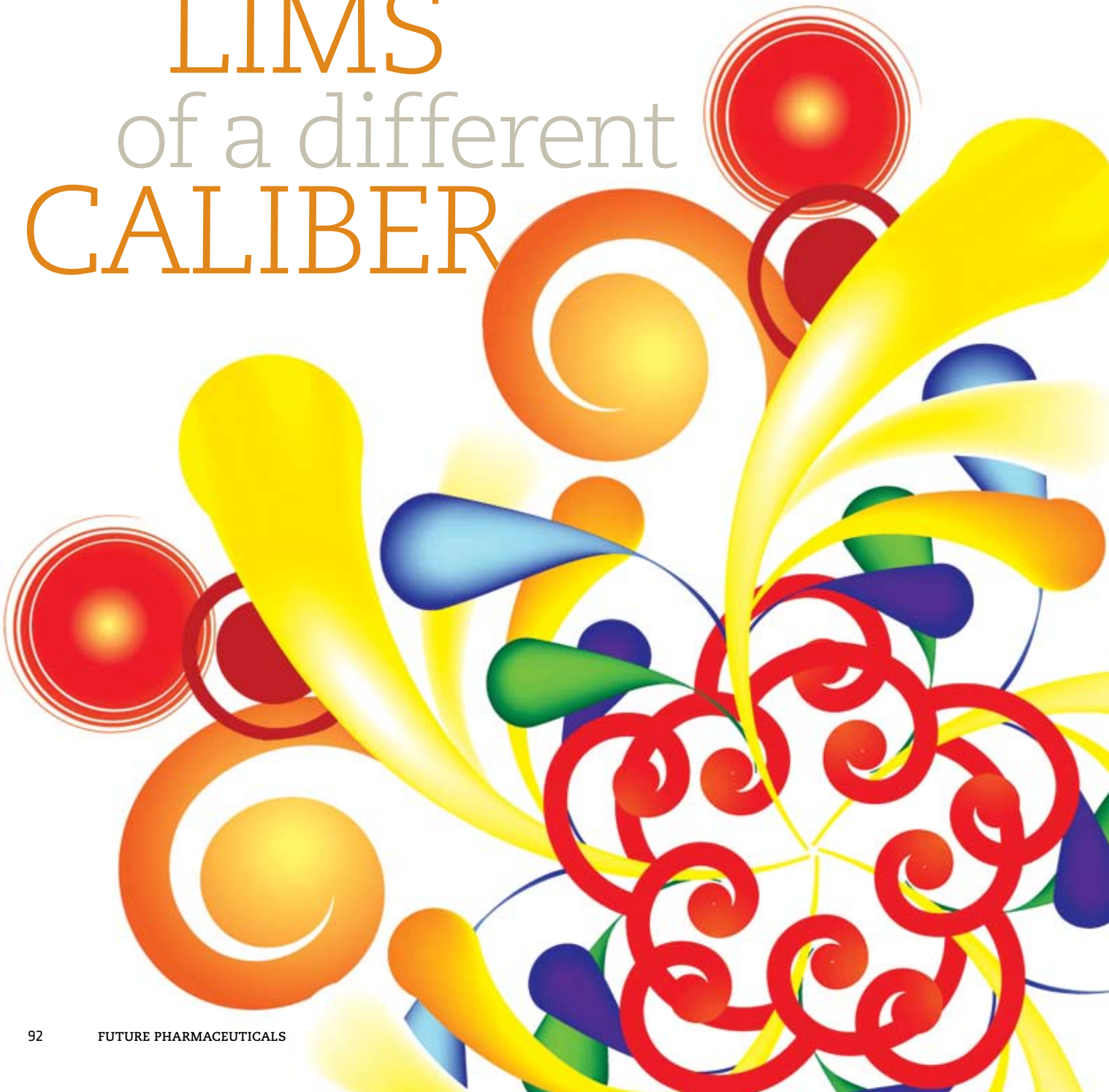




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LIMS of a different CALIBER



TIM KORBAR, Director of Sales at Caliber Infosolutions, talks to *Future Pharmaceuticals* about its introduction into the laboratory information management systems (LIMS) market

Future Pharmaceuticals Caliber Infosolutions is a recent addition to the U.S. LIMS market, and many readers and listeners may be unaware of your U.S. presence. Please give us an overview of Caliber Infosolutions.

TIM KORBAR Caliber Infosolutions, Inc. is a U.S.-based technology company that was formed by three major investors: Innovation Works, Pittsburgh Life Science Greenhouse (PLSG) and Caliber Technologies Pvt. Ltd. Caliber Infosolutions established its U.S. operations in early 2008, catering to the U.S. and European markets. Our LIMS technology is licensed through our sister company, Caliber Technologies of India. Caliber Technologies was founded in 2001 and has played a significant role in the spread of information management systems for the laboratories throughout India and Asia. Over the past three years, Caliber has received many awards and acclamations, including selections to the Deloitte Technologies Fast 50 companies in India, as well as Deloitte's Fast 500 companies in Asia Pacific, posting 252 percent growth over the past three years. Because of their heralded web-based products, Caliber Technologies has placed more than 95 percent of the LIMS system in India, and they are now participating in the introduction of this award-winning technology in the U.S. CaliberLIMS is based on Microsoft web technology, and was one of the first systems to interface with enterprise-wide systems like SAP and Oracle ERP Systems. Caliber is very fortunate to have access to a great software development talent pool in India that provides high value development and support resources.

FP Is "technology" Caliber's strategy for success in this already crowded U.S. LIMS market?

TK It certainly is one of the strategies. Looking at it from a macro view, we feel that technology is certainly a key piece, but it alone will not guarantee success. Leadership plays as much a part of success as technology. Recent consolidation in the LIMS marketplace saw a well-established

LIMS supplier that was dominant five years ago become another product succumbing to market and financial pressures that are mainly due to leadership indecisions and legacy support requirements. Many of the LIMS systems in use today have the same legacy support burden that plays havoc with version control and product enhancements, especially as it relates to validation. Caliber, on the other hand, is entering the U.S. LIMS market with the experiences and success of a senior management team that brought Caliber Technologies forward to dominate the Indian LIMS market.

Another important consideration is to understand the customer's regulatory requirements. For example, a key requirement in the pharmaceutical and biotechnology software industry is the strict validation requisite that includes 21 CFR Part 11, GxP and GAMP. In many cases, this turns out to be the costliest, most resource-intensive and time-consuming part of the implementation process. Therefore, it stands to reason that reducing this overhead would greatly benefit our customers. By employing modular design concepts and using object-oriented technology, CaliberLIMS offers a single product with multiple functionalities. A simplistic explanation of this concept is: Once a module (or object) is validated, it remains validated unless changed. Therefore, adding functionality by adding modules instead of code or code changes only requires that the connection be validated instead of the entire process. Additionally, Caliber's architecture reduces the resource impact when upgrading and during version change.

FP How can LIMS help tier two and tier three companies leverage the advantages that these types of systems provide?

TK One important factor in the success of a LIMS system is scalability. Many newer and/or smaller companies (often referred to as tier three and most tier two organizations), who have the same reporting and compliance obligations as the larger tier one companies, have financial restriction and cannot immediately justify nor afford

a LIMS system to manage them. This does not make them less compliant, but less efficient, with an increased risk of non-compliance. In order to maintain compliance, these companies employ the more traditional paper-based system that requires additional resources, usually personnel, in order to meet these demands. CaliberLIMS provides much of the laboratory's informational needs within the umbrella of its core product. One example of a module that is implemented in an integrated as well as a standalone comprehensive application is Caliber's Stability Studies Management module. Many tier three pharmaceutical companies need to manage their stability protocols but can't afford a LIMS. The stability studies management module is a very affordable stability management system that provides comprehensive management of stability samples and protocols as either an integrated application within CaliberLIMS or as an independently operated application. As an independently operated application, the stability studies management system can be seamlessly integrated into a future CaliberLIMS implementation.

FP What trends do you see emerging in the pharmaceutical laboratory or business environment?

TK The trend toward a LIMS system that will offer seamless connectivity to other best-of-breed systems common to research and manufacturing operations in a regulated environment including ERP (Enterprise Resource Planning), MRP (Manufacturing resource Planning), CDS (Chromatography Data Systems), SDMS (Scientific Data Managements Systems), ELN (Electronic Laboratory Notebooks) and secure web services is becoming an ever-increasing request. Whether it's due to industry consolidations (mergers and acquisitions) or the need to consolidate disparate systems within an organization, the ability to seamlessly connect to other major systems is critical to our customers' operational success. Many of the organizations looking to add LIMS functionality either have other specialized systems in place or will be adding them in the future. This is a given with tier one companies who have made and



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continue to make significant investments in purchasing or maintaining these best-of-breed systems but may be an unnecessary initial expense for tier two and especially tier three organizations. The issue lies predominately with planning for future growth of the tier two and tier three companies. As their success and their business grow, the requirement to add this functionality also grows and the need increases for this functionality. With a modular product like CaliberLIMS, adding this capability at a single site or as an enterprise implementation can be managed with significantly reduced implementation and validation costs.

Another side to consolidation is the reduction of the number of commercial and home-grown software packages or point-specific programs that have accumulated through normal business activities. For instance, those used to track and manage reagents and other chemicals, manage LC/GC columns and monitor instruments and their suitability for use. Because these point-specific systems require additional specialized support resources, the support and management of multiple software products can inundate IT support staffs in any size organization. This is why more and more companies are looking for ways to reduce IT overhead by moving toward a more homogeneous environment. LIMS systems can incorporate almost any

functionality into their system by coding it into their core product, but by doing so opens up a revision and validation nightmare, and is usually cost-and-resource prohibitive. The easiest and most financially acceptable alternative is to incorporate their functionality into a single software solution like CaliberLIMS. CaliberLIMS provides most of these tools in its core CaliberLIMS system. As mentioned earlier, our modular design helps reduce support resources while decreasing the risk of non-compliance, and accomplishes this by integrating the desired functionality under the CaliberLIMS umbrella.

FP From a business and operational perspective, going paperless has been a driver for the pharmaceutical industry over the past five to seven years. **What is Caliber doing to help enable this paperless environment?**

TK The paperless laboratory environment has been a possibility for several years. There are many reasons why it is not the laboratory norm, and it basically comes down to money, time, resources and risk. Even so, most laboratories are moving in the paperless direction by incrementally adding tools that support the paperless process. Many regulatory agencies are encouraging the use of electronic submissions

and paperless environments.

LIMS is one of the key systems in a paperless laboratory environment, and CaliberLIMS provides a wide range of capability through its many modules that are designed to address all of the functional requirements a laboratory may need, as well as providing certified connections to other laboratory and manufacturing electronic systems the organization may already have. For example, by using bar code entry to identify instruments, products, reagents, standards and much more help to simplify data entry and reduce transcription errors is part of the CaliberLIMS Inventory Management set of modules. The eNotebook module uses templates or worksheets that mimic the analyst's paper method or protocol to provide a seamless transition to a paperless environment. The set of Application Integration modules includes the ability to collect data directly from instruments through validated connections, limiting data input errors and automatically flagging samples that are out of specifications.

Finally, as more and more companies in the highly regulated pharmaceutical and biotech industries move toward a lower compliance risk and more efficient operations, there will be an increase in electronic paperless laboratory environments in both single laboratories and in multi-site enterprise configurations. **FP**



TIM KORBAR, Director of Sales, Caliber Infosolutions, provides Laboratory Information Management software (LIMS), implementation and support services for small-scale organizations through enterprise-wide companies in regulated and non-regulated environments. He has worked in laboratory informatics for the last 17 years, starting with Waters Chromatography Informatics group as an original member. At CambridgeSoft Corporation, he was a member of the initial development team for electronic laboratory notebooks (ELN) for pharmaceutical research chemists, and at VelQuest Corporation, Mr. Korbar worked with Quality Control, compliance-based ELN. At Beckman and Applied Biosystems, he was a member of their LIMS group.

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