COVANCE CENTRAL LABORATORY COMPLETES ISO 15189:2012 ACCREDITATION

Minimizing your cost and risk through quality management

Pharmaceutical sponsors increasingly seek strong partnerships and verified demonstration of quality data in their global drug development journey, an effort that also leads to overall cost savings. The College of American Pathologists (CAP) standard provides a solid foundation for quality but sponsors have started to request more holistic, global quality standards through ISO 15189:2012.

As a continued commitment to meet sponsors’ needs and extend ongoing quality, Covance recently completed ISO 15189:2012 accreditation at the Indianapolis laboratory, the largest central laboratory in the United States. The US site joins locations in Switzerland, Singapore, China and Japan that have achieved this milestone. “ISO certification highlights our extensive quality standards that meet or exceed client expectations,” said Paul Kirchgraber, Vice President and Global General Manager, Covance Central Laboratory Services.

If you’re ready for global quality standards, consider these three benefits of working with an ISO-accredited central lab:

▶ International data confidence
As a standard that has gained international respect with newly revised, comprehensive quality provisions, ISO 15189:2012 helps improve clinical trial outcomes by minimizing potential risk through quality management and governance. “Given the more holistic standards of ISO, clients in Europe and Asia have already started giving preference to ISO-accredited labs,” said Diane Corbett, Vice President, Global Quality Assurance, Covance Central Laboratory Services.

Clinical trial laboratories that structure their quality management systems around this international standard give sponsors greater confidence that their data package will withstand the scrutiny of global regulatory agencies.

▶ Continuous quality improvement
With a focus on risk management and continuous quality improvement, ISO 15189:2012 provides two complementary approaches. Processes are examined to identify and mitigate potential risks, while simultaneously ensuring enhancements in methods and approaches.

“The continuous improvement aspect of the ISO standard also ensures that each iteration presents opportunities to reveal new efficiencies in protocols and enables the delivery of more robust data with less cost and shorter turnaround times,” said Nancy Taylor, Quality Management System Lead, Covance Central Laboratory Services.
Direct oversight of referral labs

External testing and referral labs are specifically mentioned in the 2012 revision of ISO 15189. “Under this standard,” said Marian Mutch, Director, Global Quality Assurance, Covance Central Laboratory Services, “central laboratories are accountable for monitoring and managing any referral labs to ensure that applicable quality standards are met.”

Our Expanded Laboratory Management Solutions (ELMS) team of more than 30 dedicated lab professionals will oversee each referral lab’s performance and quality to seamlessly integrate your globally combinable data. “This will assure our clients that lab testing performed outside the four walls of Covance will be proactively monitored, reducing the risk of non-compliant data delaying completion of a trial,” said Paul Kirchgraber.

Whether you’re working directly with the Covance central laboratory system, the extensive LabCorp network or any third-party referral laboratory, you can count on the timely delivery of accurate data.

As higher levels of quality have become the new expectation for central laboratory services, it’s essential to work with a partner who can improve efficiencies, reduce the risk of costly delays and provide timely, reliable data. Through our network of five ISO 15189-accredited global central laboratories and our ongoing ELMS support for external testing, you can rely on our proven experience in quality management.

Let’s work together to deliver the actionable results you need to keep your clinical trial on track and advance your treatment to the market, faster.

Learn more about our globally consistent clinical trial solutions at www.covance.com/cls