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Next-Gen Lab Services

PPD SMEs share insight on the flexible space and services next-generation laboratories require.

Scientific expertise paired with industry-leading technologies are needed to support today's pharmaceutical landscape. Contract labs provide advanced testing services such as bioanalytical, biomarkers, central lab, GMP, and vaccine sciences.

To support next-generation pharma/biopharmaceutical products, including growing demand for analytical support of cell and gene therapies (CGT), a next-generation lab requires a focus on data mobility and services for CGT products, real-time lab services and new technologies.

Ryan Ellefson, Associate Director, Lab Informatics, Mary Scanlan, Ph.D., Director, and Catherine Liloia, Director, Cell Lab, PPD Laboratories GMP Lab, discuss what a next-generation lab entails, evolving lab testing and services, areas where there is increased demand, and specific challenges where sponsors seek solutions. –KB

Contract Pharma: *What does a next-generation lab entail with respect to services and technology?*

Ryan Ellefson: Next-generation laboratories require a greater focus on data mobility, making data on demand a vital service. With the advent of artificial intelligence (AI) and machine learning (ML), having a contract laboratory that can not only utilize data connections within its walls, but also present and connect that data to client systems will maximize these benefits. This is not just for connectivity with the results but with all key scientific data—instrument files, sample details, experiment data and results. Having this service and technology will allow contract laboratories to seamlessly integrate with pharma companies and will accelerate predictive analytics.

Mary Scanlan: Flexible space and services also will be critical for a next-generation lab. Cell and gene therapies are dominating the drug development landscape. New labs will need flexible

laboratories that can adapt to the handling, safety and contamination controls required for these therapies.

Testing needs vary greatly among gene therapies, cell therapies and RNA therapies. With complex manufacturing processes and large test panels, labs will need an extensive array of technology across cell-based assays, molecular biology, chromatography, and plate-based and specialty services to provide the wide variety of testing required. Automation is ideal to reduce repetitive tasks for scientists, while platform approaches to early phase products can add efficiencies.

Cathy Liloia: Various analytical readouts are now linked to cell-based methods, resulting in a greater need for coordination across functional areas or broadened cross-training. Laboratory space must be designed to efficiently perform work while maintaining process flows that consider biosafety and contamination prevention. Method performance and data analysis expectations continue to evolve as laboratories and agencies gain experience in expanding product areas, which means strong statistical support is key.

CP: *What are some advances with lab testing/services? (scientific, data solutions, technology etc.)*

RE: Lab testing is continually evolving with new technology to improve the quality of data collection as well as providing more in-depth analysis on drug products to ensure the safety of patients. This increases the data volume and analysis needs, which shifts the focus on establishing standardized data models to improve on not only the data mobility, but also to enhance the speed of processing and insights. Robotic process automation (RPA) and AI in data analytics provide the tools that will deliver on the efficiency and processing required.

MS: With the growth of CGT products, testing needs are shifting to include more molecular biology and cell-based assay testing, including tests that use sequencing, ddPCR, AUC, flow cytometry, etc. Development and optimization expertise in those techniques will be essential for success. Assays using new technologies should be trended for performance to identify areas for improvement and hone in on key parameters. Technologies such as HoloLens from Microsoft enable collaboration with experts throughout the country and even globally. Key laboratory processes that often depend on consistent technique can be viewed and optimized remotely through this technology.

CL: Suitable Part 11 compliance solutions are also being identified for analyses that are critical to ensure product safety and efficacy, but were previously uncommon in GMP testing. This applies particularly to sequencing, AUC, and flow cytometry software developed for research and diagnostic use and therefore may require supplementary GMP controls to ensure appropriate user rights and audit trail.

CP: *In what areas are you seeing increased demand?*

RE: The large molecule areas have tremendous growth in demand. This demand is driving new technology into the laboratories from an instrumentation and data management standpoint. File sizes from instruments have slowly grown and are now hitting in the multiple gigabyte range for every run. This means storage, processing power and data mobility need to expand quickly to meet this shift in science. Data lakes, data models and cloud storage all offer a means to better ramp up and meet the shift of this data need.

“Demand for analytical support of CGT products in particular is increasing rapidly. In addition to high demand for method development services, many customers are seeking a platform method approach to apply to their gene therapy pipeline.”

MS: Demand for analytical support of CGT products in particular is increasing rapidly. In addition to high demand for method development services, many customers are seeking a platform method approach to apply to their gene therapy pipeline. This strategy can significantly reduce the time and cost of method development for early phase products. While not applicable to all methods, this approach is suitable for many methods, and provides fit-for-purpose methods appropriate for R&D and process characterization testing.

CL: Training in many of these technologies is extensive in both laboratory testing and data review. Therefore, a mature forecasting process must be in place to have sufficient staff ready while maintaining low error rates. More agility is needed by supporting laboratories as process changes further overlap with method development and industry alignment of routine testing panels continues with regulatory agency feedback. This might involve further method optimization or the introduction of a new method to the release panel previously expected to be used for process characterization alone.

CP: *Are there specific challenge areas where sponsors seek solutions?*

MS: Support for process development (analytical testing of in-process samples) also is seeing increased demand as customers improve and optimize complex CGT manufacturing processes. Many sample types are analyzed with fit-for-purpose methods. Quick turnaround is needed for decision-making.

CL: Challenges come with optimizing analytical methods, which inherently have higher variability, such as cell-based methods, during process development. This involves focusing on fit-for-purpose methods that easily can discern the impact of process changes, but can be quickly fine-tuned for routine use when process development is complete. Part 11-compliant solutions are still needed for certain instrument software and require continued partnership with software developers to avoid procedural means to address.

CP: *What do real-time lab services entail?*

MS: Real-time lab services will harness technologies like RPA to improve efficiency and reduce potential for error by eliminating repetitive inputs and touchpoints, automating events and enabling collaboration with customers. A laboratory information management system (LIMS) system will provide customers access to real-time updates on testing progress, as well as access to their data. Data models that predict upcoming work and effort will ensure highly skilled staff are available to meet demand. Real-time monitoring of key performance indicators for timeliness and quality will replace annual reviews and ensure customer deliverables are met.

CL: Faster laboratory turnaround time will be needed to support patient dosing for certain CGT therapies. For some analytical methods that currently span weeks to generate data, there must be shorter versions developed with equivalent, robust performance. **CP**

CATHERINE LILOIA, cell lab director in the PPD Laboratories GMP Lab, has 20 years of experience in the biotechnology industry across manufacturing, quality control and process development functions. In her most recent role in contract testing, she leads a team that supports method development and routine testing associated with monoclonal antibodies, proteins, and gene and cell therapies in Phase I – commercial testing.

MARY SCANLAN, Ph.D., is a director in the biopharmaceutical department in the PPD Laboratories GMP Lab. She builds and leads teams that support testing for cell and gene therapy (CGT) products. Prior to her work in CGT, Mary led teams focused on small molecule products.

RYAN ELLEFSON is an associate director of laboratory informatics in the PPD Laboratories GMP Lab. In that role, he builds and leads teams to serve as application product owners, business system analysts, data analysts and system configuration specialists for data management systems. His teams drive data automation and innovation with a focus on rapid user adoption through merging process excellence with technology.