

# Leaning QC: Lonza Rolls Out Raman for Materials ID

After evaluating technologies, Lonza Biologics is implementing a Raman-based raw materials identification process.

BY PAUL THOMAS, SENIOR EDITOR

**AS PART** of an effort to Lean its raw material QC process, Lonza Biologics' Portsmouth, New Hampshire facility evaluated several new spectroscopic technologies—Raman, NIR, and FTIR handheld or portable devices—for rapidly verifying incoming raw materials. The manufacturer sought to shave significant time off its compendial, lab-based sampling and analysis of materials, without sacrificing ID accuracy and specificity.

Ultimately, Lonza selected handheld Raman devices (TruScan, marketed by Thermo Fisher Scientific) to roll out in Portsmouth, and to extend this implementation worldwide to all of its biologics facilities.

A key factor was the need to have a more transparent supply chain and harmonized processes, says senior QC manager for raw materials, Derek Hubley. Increasingly, customers prefer materials testing and specifications to be consistent from one site to the next, he says. We spoke with Hubley about the project.

**PhM:** *Was raw material ID an obvious candidate to be leaned, and if so, why?*

**D.H.:** Both sampling and testing are the lengthiest activities in the raw material receipt to release process. So, streamlining this portion was obvious. By decreasing the sampling and testing of raw materials, the supply chain process becomes more flexible—ultimately, allowing for a significant reduction in inventory carrying costs and raw material lead times.

**PhM:** *Why were inventory carrying costs a problem?*

**D.H.:** Basically, everything has a lead time associated—ordering, sampling, testing, and release are all part of the chain of events. So, decreasing the sampling and testing times would result in a decrease in the inventory required for the processes. For example, if we apply a three-week lead time from the vendor and a three-week lead time for sampling and testing, we would need to keep six weeks of materials on-site to support the processes. Using our new method, we can keep the three-week lead time from the vendor, but decrease the sampling and testing time to one week. This results in the need to carry only four weeks of materials on-site to support the manufacturing processes.

In this case, the inventory carrying is cut by two weeks, and in the case of high-dollar materials this can be a tremendous savings on the total inventory carrying cost.

**PhM:** *For accuracy and sensitivity, you found Raman and NIR to outperform FTIR for various materials. Can you explain this difference?*

**D.H.:** The main reason Raman and NIR showed better accuracy was the design of the study. The study was designed to eliminate the need for sampling raw materials for identification testing. Therefore, the Raman and NIR could scan through packaging resulting in greater accuracy and sensitivity. The final conclusion of the study showed the Raman having the greatest accuracy and sensitivity and this was because of its ability to scan through multiple container types.

An exercise showing the types of materials that were active using the three technologies showed most materials were active with all three technologies. However, this would be if the analysis was done in direct contact with the material. There were a handful of materials that were active with Raman and NIR, but not FTIR.

**PhM:** *What surprises did you encounter in terms of how any of the technologies handled specific materials (salts, sugars, solvents, etc.)?*

**D.H.:** I guess the biggest surprise was the ability of both Raman and NIR to distinguish between hydrate forms of materials such as dextrose, sodium phosphate monobasic  $\text{XH}_2\text{O}$ , and sodium phosphate dibasic  $\text{XH}_2\text{O}$ . All other materials functioned as expected based on the activity of the materials in the facility based on literature review.

**PhM:** *One of the parameters that you evaluated was the ability to create reference scans. Were all three technologies capable in this regard?*


**D.H.:** Yes, all three technologies had the ability to create reference scans. Both Raman and FTIR only required one lot of material to create the reference scan. FTIR required direct contact with the material, which we wanted to avoid, as the ultimate goal is to limit the contact with

the material. The Raman reference scan could be created using a single lot of material. However, to make it robust, the reference scan was created in each of the different container types in which the material could have been received into the facility. For example, a reference of an amino acid (dry powder) was created in a poly bag, glass container, and a HDPE bottle; and the reference scan of Polysorbate (liquid) was created in a clear glass container and an amber glass container. As for NIR, although the capability is there, it was not evaluated during this study. This is because it takes more than one lot of material to obtain a robust library.

**PhM:** *Your ultimate goal is to process incoming materials with no sampling, but are there still some materials you're testing via traditional sampling?*

**D.H.:** Yes, there are still some materials that would require sampling. This is ultimately based on where the material is used in the process or if there is a critical attribute that needs to be analyzed for each shipment. For instance, microbial safety testing would always need to be performed if the material is capable of supporting microbial growth. Also, excipients require more testing even if the material is qualified for a reduced testing strategy. Excipients require 100% container ID, so the time saved by not needing to sample 100% of the containers is significant; the remaining attribute testing would be performed using the number of containers required per our statistical sampling plan.

**PhM:** *To what extent has harmonization across sites been realized?*

**D.H.:** Currently the technology is being rolled out to the biopharmaceutical divisions. The materials across the facilities are common, making the harmonization efforts less challenging. In addition, these facilities have begun harmonizing specifications and testing procedures so the challenges were expected. Thus far, we have approximately 10 harmonized raw material specifications, which are shared between sites in the biopharmaceutical division, and have deployed the Raman units to five sites. 

## OUTSOURCING NEWS AND NOTES

A study of 381 pharma and biotech executives conducted by **Marks & Clerk** showed that drug companies are becoming increasingly dependent on patent-term extensions. Eight out of 10 execs believed that they will not be able to innovate enough to compensate for drugs going off-patent. Seven out of 10 said that an increase in acquisitions within the industry was inevitable. These manufacturers "are determined to cherry-pick the best targets, while increasing reliance on patent term extensions buys them some vital time ahead of making a move," said Gareth Williams, Partner at Marks & Clerk. "What is being predicted is not necessarily driven so much by desire as urgency."

Nearly two-thirds of respondents indicated that the U.S. intellectual property system has better managed to reward innovation than that in Europe. "This optimism emerges despite the impact of (President Barack) Obama's recent healthcare reforms," the report said.

**Baxter and Halozyme Therapeutics** recalled Hylenex, used for pediatric rehydration, due to possible glass contamination within the vials that was identified in routine stability testing. Halozyme delivered a "notice of breach" to Baxter regarding its fill-and-finish issues, which Baxter must remedy within 120 days.

**DSM Biologics** announced that it had successfully scaled up its XD technology from 2L to 50L—XD aims to boost bioprocess yields. DSM Biologics also recently purchased the Rhobust chromatography platform from **Upfront Chromatography**. The Rhobust and XD will combine for yield improvement.

**Pfizer** has expanded its contracts with India's **Strides Arcolab** to manufacture and supply generics for various markets.

**GlaxoSmithKline** has contracted with **Johnson Controls** for the provision of workplaces services such as energy management and technical and engineering support. The move is part of GSK's strategy to outsource more functions and simplify its operating model.

**Quintiles** has partnered with **Kaiser Permanente's** Southern California Permanente Medical Group (SCPMG) to collaborate on clinical research. Also, Quintiles has hired an entire U.K.-based Healthcare Solutions Team from **Nycomed**. After the team's transfer to Quintiles, it was contracted back to Nycomed to complete work it had been doing.

R&D specialist **Parexel Consulting** has opened two more offices in China, in Chengdu and Guangzhou.

Indian CMO **Kemwell** has opened a 31,000-square-meter manufacturing plant in Uppsala, Sweden, to increase its tablet, capsule and suppository manufacturing capacity in the E.U. Also, **Patheon** and Kemwell have announced that they have formed a co-marketing alliance.