QA & REGULATORY

Freezerworks
Sample Management Software

The Role of Freezerworks in CAP Accreditation Success

The College of American Pathologists (CAP) accreditation program for biorepositories is relatively new, having begun in 2012. The **Genetic Resources Core Facility** (**GRCF**) Biorepository and Cell Center at the Johns Hopkins School of Medicine recently became the twelfth biorepository accredited by CAP. According to its **Director, Melissa Olson, PhD**, the process, which she describes as a "major reorganizational effort", was well worth it.

CAP accreditation, famous for its detailed checklists to ensure that quality policies and procedures are in place, offers for the biorepository "an overall outline to look at every aspect of this industry and make sure that all the pieces work together," Olson said. And even though an inspection can sound like a way to ensure sleepless nights, the end result – standardization - is actually stress-reducing.

"Freezerworks was the easiest part of the whole process."

With data management such a vital aspect of biobanking, a fully validated and operational sample management system is an important part of the accreditation process. In 2011, the GRCF installed **Freezerworks Unlimited** (Dataworks Development, Inc., Mountlake Terrace, WA, USA) to manage the biorepository data.

According to Dr. Olson, "As we were going through the CAP inspection and checklist, everything we needed to be able to do was already written into the program. It was very helpful. And because our staff had been using Freezerworks for so long, when [the inspectors] would go up to anyone in the lab and say, 'I need to find this sample, how do I do it?' they were able to [find it]."

Melissa Olsen, PhD
Director, GRCF

Because the GRCF is both a bioprocessing as well as a biostorage center, the day-long inspection was conducted by two laboratory peers. The biorepository inspector was himself a biorepository professional, and focused on specific biobanking procedures. The other inspector was a general lab CAP inspector who focused on the bioprocessing policies and procedures of the center. Accreditation is a two year process. A year after certification, the biobank does a self-evaluation. A year after that, inspectors return for another on-site evaluation.

The GRCF at Johns Hopkins was established in 1989 by **Dr. Margaret Penno** to produce immortalized cell lines from human blood. The center now serves as an on-site biorepository, as well as a bioprocessing center specializing in mammalian cell culture propagation, primary cell establishment, lymphocyte isolation, and LCL establishment. The center has processed more than 25,000 blood specimens and serves approximately 300 investigators, mostly at the **Johns Hopkins School of Medicine**, but from other outside researchers as well. Today, the biorepository stores up to 1 million vials and supports a wide array of research happening at the Johns Hopkins School of Medicine and other research communities.

Olson, who joined the GRCF in 2012, discussed how the CAP accreditation process can make a well-operated biobank even better. "It's a very involved process from which I have learned a lot. CAP provides a guidebook that directs and suggests ways to improve the overall structure and flow of the biorepository. They are there to help you." Olson said. "We've always had SOPs (standard operating procedures) and policies, but the CAP accreditation process helped us to formalize this process and ensure routine revisiting," Olson explained, adding that the process not only helps ensure specimen integrity and storage conditions, but also business development and contingency plans. "It's important to CAP that if and when mistakes happen, and they understand they will happen, there are quality methods in place to track and respond to these situations," she explained.

Specimen Security/Data Security

Sample security and integrity, both in a physical sense as well as the data behind it, go hand in hand. The CAP

inspectors wanted to make sure that samples and their data were protected. With sample security, the inspectors wanted to make certain there were freezer locks, and that the site was secure from unauthorized access. Of great interest was the temperature monitoring, with a reliable alarm system, and data security management. Backups needed to be in place, with guidelines on how often to check temperatures, and alarms that actually worked.

“CAP’s approach is to protect the specimen,” Olson explained. “They want to know you can find a specimen at any time and that the integrity of the specimen is always maintained. For example, if a specimen resides outside of a freezer for any length of time, the environmental conditions of that space must also be monitored.”

Similarly, with regard to data security, the inspectors took special note of whether the software that housed the sample data was safe from intrusions from outside the facility. And, within the facility, that permissions and rights were properly restricted, and that the audit trail could reliably trace the life of each sample and vial.

“The audit trail was really critical to CAP, and something they took great interest in seeing. We were able to demonstrate to their satisfaction that every change made was traceable through an audit trail.” Olson said.

30 Spot Checks, 30 Successes

Olson said the inspectors put the site through “30 spot checks”. Although every inspection is different, part of Olson’s quality control measures are to spot check 30 samples at random weekly. In her case, the inspector wanted to be part of that quality measure. “And we got them, we got all 30 of them,” Olson said proudly.

“They may ask, ‘Tell me – you pulled a sample this week. Go find it in the freezer, and tell me the one that is next to it, and show me that it matches Freezerworks.’ They want to make sure the system you’re using does match your inventory.” Also of great importance to the CAP inspectors, Olson said, was the ability of Freezerworks to restrict data access according to a hierarchy.

“It has to be clear to CAP inspectors what roles various repository members play in specimen management. We showed a defined population of people, based on our structural groups, who could modify data, and others who were ‘read only’.” “It has always been important to our facility that no sample data is ever fully deleted. We took pride in sharing this with our CAP inspectors. Our facility maintains its records by deleting the position information on a vial as it leaves the biorepository, yet retaining all information on that collected specimen.”

Validated Updates are Important

Validated software maintenance releases are also an important aspect of CAP certification. Inspectors want assurances from the software vendor that updates will not adversely affect existing data.

“We had to prove that all Freezerworks updates had been validated, and that we received a specific validation statement with each update that indicated that changes to the software had been validated, and that no changes will affect the current inventory data,” Olson said.

Certification statements are available at Freezerworks.com. All Freezerworks updates are validated according to the **FDA General Principles of Software Development**.

In the end, quality sample management means quality results in research studies. Olson, who came to GCRF from a research background in private industry, appreciates the industry standard CAP promotes, even within basic research. “We are supporting academia, but we are running a business, so we want our standards to be a step higher than the general academic environment.”

“Biobanking is a relatively new field, and there is a lot of variety and diversity,” said **Barbara Glazer**, who, similar to Dr. Olson, has also overseen a CAP biorepository accreditation process, and then later herself served as a CAP inspector.

“Whether the bank is for managing samples for clinical trials, for general population or disease specific studies, academic or industry, what CAP accreditation can do is help develop common standards in this environment that will raise the quality for everyone and ultimately the end-user.”

Certification, however, does not serve as the end in itself but rather a beginning of a process that promises an on-going re-assessment for the facility. Glazer pointed out that the CAP inspection can help a facility develop a quality management plan, in which quantifiable measurements (e.g., number of quality incidents over a period of time) are identified and tracked. But an important part of the re-assessment and re-inspection is to look at the data and trends and determine whether those quality measurements are meaningful, or whether better measurements of quality are needed.

Prior to joining the GRCF, Olson worked in industry as a discovery scientist. To her, the bottom line is that if she were to return to doing research herself, she would put her trust in a CAP accredited biobank. “CAP accreditation is a measure of quality, and if I were an investigator wanting to store my samples in a repository, I would only store in a CAP accredited facility,” Olson said. “It’s important to understand the environment your specimens are in at all times. CAP is vital in making sure that they are under the best possible conditions, and there are plans in place in case something unwanted and unforeseen does happen.”