Sample tracking: are you leaving too much at risk?

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Abstract

This white paper examines the importance of tracking biological materials and samples as they move through laboratory processes, and looks at the possible consequences of undertaking this kind of procedure incorrectly. It discusses the use of electronic systems to ensure each and every sample is accounted for, and some of the major issues to consider when selecting software for your laboratory.

Introduction

Sample tracking is an aspect of Good Laboratory Practice (GLP) that has received a great deal of attention since the introduction of computer-based Laboratory Information Management Systems (LIMS). In life science institutions, especially those which use human material, it is vitally important to be able to name and trace biological materials. The successful implementation of a suitable tracking system not only ensures that all materials are easily found and traced, but can help guarantee the regulatory compliance and the value of a laboratory and its results.

What can be gained from sample tracking?

Careful tracking and monitoring of samples within a laboratory delivers a number of significant benefits. Initially, it helps to meet contractual requirements when applying for grants and patents, or tendering for contracts. In such situations there are often explicit obligations that must be met concerning the production and sharing of detailed records. All candidates submitting funding proposals to the Medical Research Council in the UK for example, must include a Data Management Plan as an essential part of the application.

In addition, comprehensive tracking software establishes and encourages good working practices. Comprehensive records allow the creation of formal reports and presentations, and assist when assigning credit and responsibility to individual lab members. They can also contribute to avoiding fraud and maintaining the integrity of the lab and its results.

Finally, most laboratories must specify and validate the complete chain-of-custody. While certainly true when dealing with forensic and human samples, this can also be crucial to other applications; for example, when pioneering new products, pharmaceutical manufacturers may need to defend their interpretation of clinical trial data. Accurate records eliminate any uncertainties regarding the integrity of specimens and analysis results, demonstrating through a complete chain-of-custody that the samples used during trials could not have been compromised.

What can happen if samples are not monitored?

Cases of missing samples have occurred across several applications throughout the years. It was reported in 2006 that a National Institutes of Health (NIH) official had provided a pharmaceutical company thousands of samples without prior consultation. Although nothing suggested the company obtaining the material was aware of any questionable activity, 3,200 vials of human spinal fluid and 388 tubes of plasma were transported with no kind of government disclosure or approval. Obtaining the tissue materials alone cost the US government $6.4 million, and so this was an understandably huge loss to the NIH.[1]

The case placed a huge focus on the handling of human tissue, with questions being raised on how large organisations maintain formal inventories and use tracking systems to highlight anomalies as they occur. An increased amount of attention was also placed on the level of sample control required when using human tissue samples.[2]

This was not the only occurrence of samples going missing that attracted media attention. An audit in December 2011 revealed that hundreds of moon rocks and samples, some collected by Apollo astronauts, were missing from NASA's inventory. These samples were unique and, due to their source, held a great deal of potential. However, their misplacement made their use in research and education impossible[3].

Another such incident took place in India in 2012. Samples of unsafe food articles and edibles sent to a laboratory in Mysore were declared missing, although the required forms arrived intact. If available, these samples could have played a role in the convictions of those responsible for the production and sale of these items.[4] Laboratory samples are often relied on quite heavily in court, with many sentences being passed on evidence from forensic and chemical analysis. Any loss or misplacement of such samples, therefore, could have dramatic consequences.

Finally, in March 2013 it was revealed that a vial containing the Guanarito virus, the cause of haemorrhagic fever, went missing from a research facility in Texas[5]. It was suspected that the vial was destroyed during the lab's cleaning processes. However, as the virus is classified as a 'Category A Priority Pathogen" by the National Institute of Allergy and Infectious Diseases, the whole situation was understandably an area of great concern.

Moving from paper to computer systems

As these cases show, it is essential to track all of the material held during scientific research. According to regulatory agencies and laboratory managers, this is best done with a complete, auditable and easy to use system. Laboratories will vary in their procedures for obtaining the required levels of tracking, with systems ranging from simple laboratory notebooks to completely computerised, automated software depending on lab size, type, and sample and storage requirements.

Traditionally, many laboratories have used paper reporting to keep track of their specimens, or have employed simple software solutions such as Excel. However, this creates considerable scope for error and exposes laboratories to the risk of losing materials, with potentially serious consequences

both for their research and financially. On top of this, any inability to prove the source and movement of specimens could lead to their confiscation, with severe implications for institutions.

Laboratories are increasingly looking to implement electronic systems for this purpose. These are particularly useful when a large number of samples are being handled, or when they are being kept in multiple locations. An electronic, computer-based system allows the monitoring of more complex data with a significantly reduced risk of error. There is also less opportunity for the loss of information, as software can be backed up in a way that is not always possible with paper records.

Selecting an appropriate tracking system

Despite the increasing popularity and convenience of electronic systems, they are infinitely more complex than their paper predecessors. Therefore, a range of factors must be considered during their purchase. This selection process is one that requires careful thought and deliberation - investing in the right software can be hugely beneficial in improving lab efficiency, whereas committing to unsuitable solutions can cost huge amounts of money, and actually have a negative effect on the day to day running of the laboratory.

- The choice of tracking software may be influenced by existing software and hardware, customer support and training, flexibility and additional features. The software should ideally be compatible with existing packages and hardware. Anyone investing in new laboratory software wants to be sure that it is rapidly accepted into routine use and that all users in the laboratory quickly become comfortable with its operation. Comprehensive training supports the integration of the new software, which should be incorporated into existing systems and practices, eliminating the risk of losing any previously tracked samples. This streamlines software adoption and minimises the time required to move it into routine use as a valued tool in managing laboratory workflow:

- Furthermore, a manufacturer with a strong focus on providing excellent levels of support should be able to confirm that customers can easily reach a technical support contact, even in the case of 24-hour laboratories or those in different time zones. A variety of channels, such as email, telephone and text message, means the process can become as efficient and pain free as possible.

- The balance between flexibility and affordability is also a real factor to consider. For many smaller labs, there is a common problem in finding affordable software which does not over-service their needs. In many cases, laboratories are buying a large system for a high price and applying cost-saving measures such as using shared logins, which can compromise security. By offering real choice and flexibility, manufactures can ensure that users get exactly what they need from their tracking and monitoring, with no additional costs or complications. There may be an option available to upgrade or add to a system should it become necessary.

Conclusion

Sample tracking systems must prove the definite connection between results and the samples from which they were obtained. In addition, the original source of the material must be recorded and linked

with the related data, as well as providing a complete chain-of-custody. In this way, laboratories can avoid the financial and scientific implications of losing track of their samples.

Although there are many tracking systems available, computerised systems are becoming increasingly commonplace. These provide the levels of security, reliability and flexibility that many laboratories need to guarantee sample safety. Selecting a piece of tracking software which directly meets the needs of their laboratories allows life scientists to continue with their work with confidence, knowing that all their records and samples are safe and secure.

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