Taking the Mystery Out of the Chain of Custody

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How many times have you received a phone call or email from your laboratory asking for additional information which was not included on the chain of custody or to let you know that what was noted on the chain of custody was not what was actually received? Unfortunately this is a common problem, but taking the time to properly complete the chain of custody will aid in lessening the frequency of these calls and emails.

To some the chain of custody is cumbersome and in some ways mysterious. However, this document is essential to ensuring that the test samples are tested appropriately and in a timely manner. Some may be asking why we need to completely fill it out every time. The laboratory should know that we always send samples that require the same type of testing. This may be true, but the laboratory should not make any assumptions regarding the test samples or the testing required. This is why the chain of custody is so crucial.

According to Dictionary.com, the definition of chain of custody is "the unbroken trail of accountability that ensures the physical security of samples, data and records." In other words the chain of custody that is submitted to the laboratory is the contract between the certifier and the laboratory. The information contained on the form must be correct and thorough in order to be sure that the laboratory received everything that they were supposed to and that the samples are correctly processed.

Proper FDA documentation and compliance with GMP's are of utmost importance when completing the chain of custody, particularly when working with sterile compounding pharmacies or pharmaceutical manufacturers. In cases where the FDA might be involved, they would be auditing against the CFR's and all other general chapters contained in the USP that they would consider relevant. Therefore your compliance with these documents, as well as your laboratory, is essential to meeting your client's needs, especially if they find themselves or you find yourself in an audit situation.

Some laboratories have ISO (International Organization for Standardization) or other accreditations that require the submission of these forms to meet the standard's requirements. ISO/IEC 17025:2005(E) states the following: "The laboratory shall establish and maintain procedures for review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that the requirements, including the methods to be used, are adequately defined, documented and understood. Any differences between the request or tender and the contract shall be resolved before any work commences." Therefore the laboratory's quality systems require the use of these documents.

Since each individual chain of custody is the contract for testing a particular set of samples, it is the responsibility of the customer to thoroughly complete the chain of custody and specifically document the request for testing procedures as well as the regulations to be followed by the laboratory. Without specific direction, the laboratory cannot start the incubation of the samples and in some cases all discrepancies need to be resolved before proceeding with any testing. Also, depending on your laboratory's reporting procedure, any information that you supply on the chain of custody may be included on the final report.

So what are the critical pieces of information that need to be included on the chain of custody? Some are obvious, such as the company name making the submission, but others are often missed, which may be equally or even more important. The items listed below are some of the critical pieces that the laboratory will need. Keep in mind that each laboratory's requirements are different.

Sample description or sample identifier – Including this information on the chain of custody allows the laboratory to confirm that what was written on the samples is correct and that all the samples were received.

Sample date – Including the sample date helps to differentiate sample sets, if multiple sets were taken at the same location. It also can be an indicator as to whether there was an issue with shipping. In most cases samples are shipped for next day delivery, but if the laboratory notes a large time difference between the sample date, the shipping date and the date of receipt, they should contact the client as this delay could have a negative impact on the samples. Another issue may be that samples were held for an extended period of time prior to shipping. Notifying the client of this may be useful to them as it could indicate that additional training of technicians may be needed.

Air sampler used – If the laboratory will be performing a final calculation for reporting, it will be necessary for them to know which air sampler was used, as many of the samplers have their own unique correction factor which must be applied in order to determine the most probable number. Sample volume or area – For laboratories that report a final calculation for air samples based on sample volume, this piece of information is crucial. The sample volume must be included for each air sample taken, as in some instances different sample volumes must be taken in order to meet acceptance criteria. For surface samples, including the area sampled, especially for swab samples, is important for accurate reporting.

Acceptance criteria or the ISO classification of the area where the samples were taken – In cases where the laboratory is including acceptance criteria on the final report, performing a calculation to determine the final result and assigning a Pass / Fail status, the chain of custody must include this information for each sample. For the testing of <797> samples, ISO classifications may be sufficient, as the acceptance criteria are provided in the USP chapter. However, if the samples are to be tested according to another compendial method, acceptance criteria would need to be provided, as these tend to be trended based on past environmental monitoring data.

continued on page 12

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The Chain of Custody

continued from page 7

Method requested or laboratory testing code – This piece is critical and is absolutely necessary to ensure that samples are tested properly. A compendial method such as USP<797> or ISO 14698 needs to be included as the incubation temperatures and times are very different depending on the method required. The other option would be to include the laboratory's specific test code that clearly indicates the testing required. Not including this information could cause a delay in the testing of the samples.

Other information – Each laboratory has their own chain of custody or sample submission form, which may have other items that will need to be completed. Some examples may be the type of media used for testing and the lot and expiration dates, the number of controls submitted, contact information, invoicing information, and requests for expedited testing.

Filling out a chain of custody can feel overwhelming, especially if it is not something that you are required to do regularly. However, it cannot be emphasized enough how critical a thoroughly completed chain of custody is. Depending on the laboratory, you may be able to design your own chain of custody or submission form, as long as all of the pertinent information is captured. Whether you choose to use your laboratory's existing chain of custody or opt to create your own, always take advantage of the support of your laboratory and contact them if you are unsure of the information required or how to fill out the form. They will be more than happy to help solve the mystery.