From: OC GCP Questions
To: [redacted]
Subject: Diluent
Date: Thursday, March 08, 2018 7:52:00 AM
Attachments: [redacted]

Good morning –

FDA regulations and guidance do not specifically address your question.

I spoke to a few colleagues here in OGCP. The answer is -- it depends. If a specific diluent is shipped along with the IP and must be used for the dilution then it might be a good idea for record documentation to include batch number, shipment method etc. However, if the IP can be used with a non-specific diluent (normal saline, sterile water, etc) then this type of tracking may not be necessary.

It is probably a good idea to get the opinion of the Center for Drugs (CDER) at druginfo@fda.hhs.gov and/or the Center for Biologics (CBER) ocod@fda.hhs.gov

Kind regards,

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Office of Good Clinical Practice
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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, March 07, 2018 12:55 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Diluent

Good Afternoon,

I have a question regarding investigational products and *trial-related materials*. In the execution of a clinical trial, the batch numbers of the investigational product and trial related materials are required to be documented to allow for tracking/traceability, etc. to each patient. In the case of diluent , is it necessary to keep information such as batch number, method of shipment etc, as patient level data also within the TMF for US sites? I cannot find specific guidance relating to this.

Thank you for any additional clarity you can provide.

Kind regards,
[redacted]