

From: OC GCP Questions
To: [REDACTED]
Subject: Work Instruction deviating
Date: Wednesday, June 07, 2017 9:09:00 AM
Attachments: [REDACTED]

Good morning –

Every effort should be made to follow the site's own standard operating procedures. However based on the limited information in your email, if and FDA inspection occurred at your site, I don't think FDA would consider this a significant deviation.

Kind regards,

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Office of the Commissioner, FDA



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Monday, June 05, 2017 2:39 PM
To: OC GCP Questions
Subject: Work Instruction deviating

Hi,

My question is: if a Work Instruction states that employees must use the date format DDMMYYYY and they do not always follow this format, would that be considered a deviation that the sponsor should write up every time they do not make the employee correct the date format? Or is it so insignificant that it does not matter if it is written up?

Thank you.

[REDACTED]