

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Phase 1 Clinical Trials Compliance
Date: Friday, June 12, 2020 9:53:00 AM
Attachments: [REDACTED]

Good morning –

Thank you for your inquiry. It is best to send you query to the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on electronic records, Part 11 compliance and validation in clinical trials.

Additionally, this office does not have the expertise to answer your question on media for environmental monitoring. Perhaps CDER OMP can assist you.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration



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: Thursday, June 11, 2020 12:00 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Phase 1 Clinical Trials Compliance

Hi,

My name is [REDACTED] I am the manager of a [REDACTED] that is preparing to conduct phase 1 clinical trials. My background is in Pharmaceuticals so I have a few questions about certain aspects of the guidance to ensure that we are in compliance. My first question is about Validations. The guidance for process validation references 21 CFR 211 on several occasions. As phase 1 clinical trials are exempt from 21 CFR 211 are we required to perform process and/or equipment validations?

My second question involves growth promotion testing for media. We will be conducting

environmental monitoring to ensure the area is within control. The only reference to growth promotion I could find in the CFR was 21 CFR 610.12 which involves sterility testing. Our sterility tests will be performed by a third party, not in house. In this case, will the media for environmental monitoring need growth promotion testing? If so, where is this required in the CFR? If not, what are some general requirements for incoming media (sterility, visual inspection, etc.)?

I appreciate any help you can offer.

Thanks,

[REDACTED]