From: OC GCP Questions
To: [redacted]
Subject: Regarding clinical trial unit
Date: Wednesday, March 11, 2015 9:30:52 AM

Good morning –

It is best to send your question to the Center for Devices (CDRH) at DICE@fda.hhs.gov

Thank you,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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: Tuesday, March 10, 2015 4:46 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Regarding clinical trial unit

To whom it may concern,

Hello, This is [redacted].
We are recently planning to manufacture some clinical trial medical device units, and would like to ask one question.

If we only submit IND (investigational new drug) with the FDA, does the device that delivers drug (respiratory gas) not required to be submitted as it is only to support to trial? We would like to make sure because our site is registered as FDA medical device manufacturing site.

Please let us know. Thank you very much!

Best Regards,
[redacted]