From: OC GCP Questions
To: [redacted]
Subject: GCP applicable to eCTD/ESG submissions vendors?
Date: Tuesday, February 14, 2017 12:05:00 PM
Attachments: [redacted]

Good afternoon –

This is not the correct office to answer your email question. Please see the information below.

Here's the website with some information on eCTD -- http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm .

The following information is at the bottom of the page:

If you have questions for CDER, please contact the CDER Electronic Submission (ESUB) Support Team at esub@fda.hhs.gov .

If you have questions for CBER, please contact the CBER ESUB Support Team at esubprep@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, February 14, 2017 9:49 AM
To: OC GCP Questions
Subject: GCP applicable to eCTD/ESG submissions vendors?

Dear FDA GCP,

Can you please clarify whether ICH E6 applies to vendors hired to prepare FDA submissions according to electronic Common Technical Document format and to submit to CDER or CBER through FDA's Electronic Submissions Gateway? These vendors take finalized documents and put them in eCTD backbone of INDs, NDAs, BLAs and amendments/supplements.

Regards,

[redacted]