

From: OC GCP Questions
To: [REDACTED]
Subject: GDUFA Self identification requirement
Date: Wednesday, June 27, 2018 12:42:00 PM

Good afternoon –

You will need to contact the generic drug office at E-mail: genericdrugs@fda.hhs.gov or phone: 240-402-7920. [About the Center for Drug Evaluation and Research > Office of Generic Drugs](#)

Also for BA/BE studies, please send your email to the following email address. CDER-OSIS-BEQ@fda.hhs.gov

Kind regards,

The OGCP Group

From: [REDACTED]
Sent: Wednesday, June 27, 2018 12:09 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GDUFA Self identification requirement

Hi,
Good morning,

My self [REDACTED] working as Manager -QA in a CRO from [REDACTED]

I request you to clarify whether "Hospital sites, which are involved in patient based BA/BE studies need to register their hospital sites for FEI number" as per the GDUFA self identification guidance requirements.

Thanks and Regards,
[REDACTED]