

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** GCP Question  
**Date:** Wednesday, January 08, 2014 8:18:34 AM

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Good morning –

As you note 24/7 hotline is not required under FDA regulations. My office does not handle international or global issues. You may wish to contact someone in FDA's Office of International Programs (OIP). Please see the link below. Please see the panel on the lower right-hand side of the page to contact someone in OIP.

[International Programs and Activities](#)

Kind regards,

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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.

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**From:** FYXUMXQ  
**Sent:** Tuesday, January 07, 2014 10:33 AM  
**To:** OC GCP Questions  
**Subject:** GCP Question

Good morning.

I wanted to reach out to you as I work in strategic development for a UK based company that offers Emergency response medical information for global clinical trials. Due to the strict legislations with in the EU's GCP and ICH policies, European Pharmaceutical companies are required to cover their trial subjects with a 24/7 Serious Adverse Events (SAE's) hotline.

I am aware that in the USA such strict legislations are not in force in this area, does your department cover this particular area and can you offer any official advice as to how the FDA view The need for Pharmaceutical companies in the USA to provide this service or if there is a global alignment due to be placed in the future?

If this is not the correct area please can you advise me on who I need to contact.

Thanks in advance.

Kind Regards k