From: OC GCP Questions
To: [redacted]
Subject: Regarding Quality Assurance
Date: Friday, June 26, 2015 2:05:36 PM

Good morning –

You questions cannot be specifically answered as it depends on the clinical trial, the investigational product and the sponsor requirements. Please see a few FDA guidance documents that might be helpful to you.

http://www.fda.gov/downloads/Drugs/Guidances/ucm070305.pdf

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070337.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf
Please also see footnote 10 on page 4. It references auditing of clinical trials.

Compliance Policy Guides > CPG Sec. 130.300 FDA Access to Results of Quality Assurance Program Audits and Inspections

Kind regards,

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

From: [redacted]
Sent: Friday, June 26, 2015 5:27 AM
To: OC GCP Questions
Subject: Regarding Quality Assurance

Dear Sir,

Greetings!

I am in process evolving our clinical quality control and assurance program and require guidance on following questions:

1. Whom shall QA and QC function report? Is it head of clinical R&D or head of institute?
2. What percentage of clinical study data should be audited for Quality assurance?
3. Can one open the old clinical study reports and subject to intense quality assurance program?, if yes, how to treat the discrepancies, if any in the CSR.

Best regards,
[redacted]