From: OC GCP Questions
To: [redacted]
Subject: Computer System validation used in Sensory Studies
Date: Tuesday, August 26, 2014 9:44:44 AM

Good morning –

Any electronic system that is set up to support FDA-regulated research of drugs, biologics, and devices should be validated and be Part 11 compliant. It is unclear whether the research you are referring to (sensory studies) is FDA regulated. You might want to reach out to OHRP as they deal with more behavioral research than FDA. Please see their contact information below.

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@hhs.gov

The guidances listed below might be helpful to you.

Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

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

From: [redacted]
Sent: Monday, August 25, 2014 3:00 PM
To: OC GCP Questions
Subject: Computer System validation used in Sensory Studies

Dear Sir/Madam:

I wish to present this scenario and ask for your guidance/opinion:

A vendor was contracted to conduct a sensory study for a label claim by an internal Pharmaceutical department. The vendor had been audited prior to the investigation and was denied permission to use its computers to conduct the study. The study could only be conducted on a paper-based system because:

- The vendor's computer system was not validated,
- There were no SOPs to govern its computer processes.

Questions:

- Should sensory studies be equivalent to clinical studies in adherence to all GXP regulations ?
- Must computerized systems used in the conduct of a sensory study be validated in order to operate within a GXP environment?

Thank you,
[redacted]