
Report of Telephone Conversation

Date/Time of Call: March 24, 2012 @ 2:41 PM EDT

CBER Representative(s): Richard Heath Coats, Biologist, OCBQ/DMPQ

Organization Representative: Kim Sullivan
Vice President Research and Regulatory

Organization: SmartPractice

Subject: Request for SOPs regarding Purchasing Controls

STN: 125579

Background:

DMPQ phoned Kim Sullivan to request recently revised and created SOPs called out in a Gap Analysis performed by the firm. These SOPs are:

- SOP #343 for Suppliers of Services
- SOP #199 for Purchasing of Raw Materials and Packaging Materials
- SOP #357 for Supplier Audits

Ms. Sullivan did not answer the phone and a voice message was left. Ms. Sullivan followed up with Elizabeth Valenti who instructed Ms. Sullivan to submit English translations of the procedures as an official amendment to BLA 125579/0.
