

Summary Minutes for the PODP Chemistry Sub Team
Telecon on
26 July 2011

1) The admonition statement was noted and following agenda items discussed:

2) Simulated Study Update
Member has received bottles.

3) Materials Study Reports
Need to see if there is a preliminary report. Will send labels and discs

4) PDA Manuscripts
Member has agreed to move up the template to early September so we can begin to draft.
I corrected the LDPE poster lead

I. Introduction/Commentary-

II. Protocol/Methods

III. Chemistry Extractables Data

a. Controlled Extraction Study on Polyvinylchloride (PVC):

b. Controlled Extraction Study on Rubber:

c. Controlled Extraction Study on Cyclic Olefin

d. Controlled Extraction Study on Polycarbonate

e. Controlled Extraction Study on Low Density Polyethylene:

IV. Toxicology-

5) Plans for Next F2F and t-con

This will be November 1 at USP. FDA rep will be able to attend, HC rep is available. A agenda prepared with-in the next few weeks for comment and sent to Health Canada with a letter of request.

6) New Member Update

Request for memberships from individuals from various companies have been received via PQRI website. PQRI has informed that we are on the home stretch and will be contacting them when we are ready for peer reviews to recommendations in 2012. In the

meantime we will be contact rep from Allergan to help sort out the ophthalmic portion. I have sent another emails to CDRH in response the earlier request to join, once I receive the CV it will be forwarded to SC approval.

Other Discussions: Member presented in Berlin and his presentations shared with the chem. team. Following is a list of upcoming visibility:

2011: RAPRA!Ireland:

PharmEd!Philadelphia-

Pira/Rome-

Med Packaging/Berlin-

AAPS Round Table/DC:

2012: Sartorius:

This is all I know of to date, other than there will be a PharmaPak in Phila in May, I will send in an abstract for this. Also recorder has been tracking Linked-in LIE group. He sent a recent report to the group.