

Draft Redacted Minutes



Summary Minutes PQRI PODP Leachables and Extractables WG Meeting, June 24, 2008

Meeting started at 08:30 AM EST

- The chair the admonition statement
- The team, reviewed the PQRI Process
- The team looked at getting agency representation from FDA on the team
- The team reviewed the OINDP Process and reviewed the current milestones set out for this team.

I.

II. The QbD Relationship

HC Rep gave an overview of the relationship of QbD concepts to Extractable /Leachable determination in a container closure system. She detailed the potential application of QbD concepts, and discussed whether they should be incorporated into the plans of the WG. There was agreement that the QbD terminology should be included into the work plan. Her presentation is attached in appendix III.

III. Toxicology Team Update

Rep gave an overview of activities which have occurred with the Tox subteam. To date there have been 2 telecons to go over the work plan, review membership, and to review deliverables for this year. Rep took an action to send minutes to secretary for redaction and for filing.

IV. Chemistry Team Update

Rep gave a chemistry team update. Today the subteam has held a telecon on understanding external resources may be required. The subteam planned to follow up at today's face to face meeting. Rep took an action to send minutes to secretary for redaction and for filing

10:45- 4:00

V. Chem- Tox Break Outs

See below.

4:00- 5:00

VI. Summary of Breaks-outs

The focus of the toxicology sub team breakout session was to review the current work plan and determine how the sub team will complete deliverables in the intended time frame. Sub team members were assigned tasks to review existing documents on safety thresholds and determine

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how these thresholds will be applied to L&E in PODP. The sub team will reconvene in an August, 2008 teleconference to review the data collected by sub team members and how we will use these data to develop a threshold rationale for L&E in PODP. Minutes from the toxicology sub team are in appendix IV.

The chemistry sub-team planned to investigate the possibilities for acquiring a unique six component container closure system in which the individual components would be profiled as well as conducting a leachable study on the assemble system. The system would be representative of base thermoset and thermoplastic materials, adhesives, overwrap and labels. The materials would be consistent with a combination of those used in each of the four categories and would serve as a model to acquire data to demonstrate a controlled extraction study followed by a leachable study. Six solvents are currently being considered for the study with special attention given to aqueous systems. Headspace sampling and inorganic methodology are also being considered. Commitments from material suppliers and processors for radiation services are being pursued. Laboratory resources will then be assigned. The plan and protocols for Best Practices are scheduled to be completed by the end of September. Minutes from the chemistry sub team are in appendix V.

VII. Schedule Next Meeting

A full WG telecon will be held in August wit the next face to face meeting scheduled for October.

Meeting concluded at 05:00 PM EST.