



January 14, 2010
PQRI Teleconference Summary Minutes
9:30-11:30 EST

9:30-9:45: **Call to Order/ Minutes of November F2F**

9:45-10:00: **Review Q1 and Q2 Objectives**

2010 PODP Goals

AET Models and Identification of Best Demonstrated Practices
Development of Safety Concern and Qualification Thresholds
Harmonization and Consensus (Thresholds and Best Practices)
Develop Strategies for Ophthalmic and LVP Thresholds

2010 Toxicology Goals

Agreed on approach to classify leachables
DEREK → Cramer Classification → Literature review
Present to Regulatory Authorities for Feedback

This item was emphasized as a key milestone for the team.

Tox team to meet F2F on January 26 in Jersey City (Forest) to solidify approach.

Targeting an overview with Chemistry Team in early Feb (date TBD). Targeting audience with KOL from FDA to be arranged via FDA rep around March 29 (TBD).

Determine appropriate toxicity classifications based on data
Classification of L&E chemicals list based on agreed approach

General agreement from the team that goals were achievable.

2010 Chemistry Goals

Acquire, Collate and Evaluate Extractables Test Data
Develop an AET Model Approach for Leachables
Report Preliminary Recommendations to Regulators
Develop Plan for Ophthalmic and LVP Dosage Forms

General agreement from the team that goals were achievable, though the group was generally aware that individual business needs are unpredictable and can challenge completion of the proposed laboratory work.

10:00-10:20: **Tox Update**

Results of Silico Analysis

analyses performed in house at Pfizer. Initial results fed back to Tox Team late 2009. Data are intended to be used to construct a

classification table with a separate category for genotoxic chemicals based on alerts.

Subteam looking at sensitization/irritation threshold and if a rationale can be developed to support a stand-alone classification of these chemicals similar to what is proposed for genotoxic chemicals.

Subteam looking at developing threshold doses for leachable classes.

F2F mtg Jan 26 intended to determine how much additional effort / resource the team will need for literature searches to support a valid classification table.

Presentation to the FDA

Targeted for approximately March 29 (leveraging attendance to the ELSIE meeting occurring in Washington DC). In parallel will present proposal to HC for their comments.

10:20-10:40: Chem Update

Status of Lab Studies –

Protocol is complete, per Dec 3 2009 email

Affirmed that all test articles were received. Verified receipt of polycarbonate, but will need to verify the other materials. Most team members were unable to confirm a schedule, though it was reported that the inorganic analysis would be complete by end of March.

Member reported that he was funded by Baxter to provide analytical support and would be able to fill-in any gaps left by the other laboratories.

Next Steps

Chem Team members to forward questions / issues on the protocol to Dennis by end of January for an early February teleconference (date TBD) to determine next steps.

10:40- 10:55 Applicants for Toxicology and Chemistry Team

Tox Team believed it had already reviewed and made a “no” determination– will review and verify on January 26 F2F meeting.

Team felt that current Tox core team was adequately staffed and felt that the January 26 F2F meeting determine how much additional help would be needed for lit searches.

Chem Team to discuss any other Chem applicants during early Feb T-Con.

10:55- 11:05 Tentative 2010 F2F meeting for 2010

Tentative Location and Dates (March/September/December)

January 26, 2010: Tox Team F2F (Forest Labs,)

Finalize approach to be presented to Chem Team and FDA / Health Canada

Early Feb, 2010: Chem Team T-Con

Questions / issues w/ protocol

Discuss applicants to team

Hear an overview of Tox Team plan

Feb – Mar 2010: Full team meeting, preferred F2F to address concerns / issues with Tox Team plan?

~ March 29, 2010: Tox Team meeting w/ FDA. If possible, a representative of the Chem Team should participate.

11:05-11:20 Industry Presentations for 2010

Opportunities/Venues and Content

Potential for poster presentation at RAPRA (UK) and PDA(DC) mid September

Potential for PQRI Workshop in end Dec or early Jan 2011

PODP update given in Dublin Dec 2010 showed interest from Europe.

The presentation or PQRI poster can be given at other European venue if opportunity is recognized.

11:20-11:30 File Sharing Capability/Other

Both Tox and Chem Teams feel that data archival and sharing will be critical as data are generated. Chair to follow up with PQRI / AAPS on potential turn-key solutions.

BI rep reminded the team that he planned to convene a subteam to determine a format for sharing data generated by the protocol.

Action Items

| Item | Owner |
|--|------------|
| Propose dates to Chem Team for early Feb T-Con. Anticipated agenda: Questions / issues w/ protocol Discuss applicants to team Hear an overview of Tox Team plan | |
| Chem team to forward questions or issues on protocol to Dennis prior to Feb T-Con | Chem Team, |

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|---|--|
| Review second tier team applicants and prepare a list for next F2F | |
| Check with PQRI (Vicki, Reggie, Frank et al) regarding availability of file sharing / data archival solution | |
| Contact Frank Holcombe to request meeting with FDA in the March 29 2010 timeframe. Clarify FDA needs for briefing packet prior to meeting. | |