

From: Clegg, Patsy M SCC-CHSE-PC
Sent: Monday, July 30, 2001 1:49 PM (GMT)
To: Cagen, Stuart Z SCC <szcagen@Shell.Com>; Tsai, Shan SP SHLOIL-SPS <sptsai@Shell.Com>
Subject: FW: Benzene Consortia Oversight Mtg - Action Items

Hi Stu and Shan,

Attended the 1st Benzene Health Research Program Oversight Committee meeting Thursday of last week. It was a very productive meeting. We agreed to rotate chair. BP will be chair now with Shell as co-chair. Shell will then become chair. Attached is the long list of action items from the meeting. You might want to review the items titled Technical Committee, Scientific and Ethics Review Panels and Protocol Issues .

In terms of the review process and the timeline, I was not able to get agreement/commitment to slow the process, but I asked a lot of questions that seemed to me to have support from ExxonMobil and, maybe BP. It was kind of hard to gauge. I asked:

1. When in Oct is the U of C IRB? Big difference between the beginning and end of the month? Would there really be a big delay if we waited until the Jan meeting in order to accommodate a more broad-based SRP?
2. When is University of Shanghai IRB review? If it isn't until late 4Q, then what is the rush?
3. Can we not go ahead and be setting up the lab while we are waiting for the IRBs? Irons has said that it will take 6 months to get FDA certification of the lab, which is apparently required. I suggested that the lab get equipped, people trained and certification sought parallel to the IRBs. Patrick seemed to think that there might be a problem with going ahead without IRB approval. It might be perceived as not honoring the process.
4. I reminded them that 2+ years have been invested so far, so why the rush now?
5. I reminded them, with very helpful support from Lynn Russo, ExxonMobil, and chair of the PR committee, that we really needed the expanded review from the beginning. Lynn strongly supported that there were too many Harvard people; the lack of international expertise (except Rice), and the fact that there were no Chinese on the board. We expressed the concern that the whole study might be jeopardized from the beginning without this expanded review board. The suggestion to the Technical committee was made to have at least one expert in all the named disciplines before doing the review.

Hence, we need your help. I know that you made suggestions during your technical call last week. But, now, with the push to internationalize the review board, we need some nominations. Shan, we thought you were in a particularly good position to provide some names from the Chinese scientific community.

Unfortunately, this all has a short time line - I need your decisions by COB Thursday so I can get them to API by Friday.

Thanks for your support on this project.

Patsy

-----Original Message-----

From: Lorraine Twerdok [mailto:twerdokl@api.org]

Sent: Thursday, July 26, 2001 4:42 PM

To: 'pmclegg@shellus.com'; 'Beatty, Patrick'; 'Carol A Fairbrother'; 'BURNETT, Don'; 'lynn.b.russo@exxon.com'

Cc: George Woodall; John Wagner; Lorraine Twerdok; Paula Podhasky; Susan Hahn; Bill Frick; 'Broddle, William'

Subject: Benzene Consortia Oversight Mtg - Action Items

To Benzene Health Research Consortium Oversight Committee:

Thanks to you all for a very productive meeting today. While everything is fresh in our minds, I want to get out the action items we developed today.

ALL ACTION ITEMS ARE DUE FRIDAY, AUGUST 3, unless otherwise indicated.

Consortium Agreement Issues:

1. JOHN WAGNER will write & distribute a one-pager listing the pros and cons for an agreement between companies and API vs incorporation of the consortium to include a contractual agreement between companies.
2. JOHN WAGNER will edit the exiting contract agreement based on comments from today's meeting. John will also list sections to be reworked by the consortium agreement workgroup.
3. OVERSIGHT COMMITTEE (OC) MEMBERS will send Lorraine and Paula nominations (minimum = 1 per company) for a consortium agreement workgroup to be staffed by JOHN WAGNER.
4. PATRICK BEATTY and the Technical Committee will develop a 1-page scope of research work, referencing study protocols, to be added to consortium agreement.
5. LORRAINE TWERDOK will circulate relevant API Policies and Procedures to OC for review.

Technical Committee, Scientific and Ethics Review Panels and Protocol Issues:

1. LORRAINE TWERDOK will transcribe and circulate template for technical issue review and flow of information, e.g. protocol amendments.
2. TECHNICAL COMMITTEE will evaluate QA/QC measures for study conduct and report back to OC (due date to be determined).
3. TECHNICAL COMMITTEE will develop milestones for study progress assessment from study protocols (due date to be determined).
4. The following contacts will be made to seek recommendations for international participants on the Scientific Review Panel (SRP):

Myron Harrison - LYNN RUSSO
 Chris Roythorne - DON BURNETT & PATRICK BEATTY
 Shan Shai - PATSY CLEGG
 Otto Wong - PATRICK BEATTY & GEORGE WOODALL
 Chinese Investigators - PATRICK BEATTY & GEORGE WOODALL
 Jerry Rice - PATRICK BEATTY & GEORGE WOODALL
 concawe - LORRAINE TWERDOK

5. The TECHNICAL COMMITTEE will contact existing list of proposed SRP nominations (due date to be determined).
6. PATRICK BEATTY will contact Rich Irons to find out dates for upcoming U. of CO and Chinese IRB reviews, and also seek advice from Rich on how much "up front" work (purchase lab equipment; train technicians, etc.) is appropriate & advisable before IRB approval is in place.

Communications Committee Issues:

1. SUSAN HAHN of API will contract PR firm with CC guidance (mid-late September timeline).
2. JOHN WAGNER will contract outside council for consortium needs (due date to be determined).

Ad Hoc Consortium Membership Committee - BILL FRICK will spearhead:

1. OVERSIGHT COMMITTEE MEMBERS will submit committee nominations (1/company) to Lorraine Twerdok.
2. GEORGE WOODALL will circulate to OC a list of NGOs & foundations for potential consortium membership.
3. MEMBERSHIP COMMITTEE will develop a list of companies (refining, chemical, other business sectors) , associations, NGOs, Foundations, Agencies, etc, to target for membership "drive." Strategies for contacting the various organizations will be developed. (will be a continuing effort over at least the next few months).

Did I forget anything??

Regards,
 Lorraine

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