Summary of Meeting, September 17, 2008 - Menveo

Summary of Meeting

Discussion points are in italics.

17Sept08, 3:00 pm WOC – 1

BLA 125300_0

Novartis ACYW-135 Mening Vaccine

C. Fiore – Primary Reviewer

1. Introductions

We went around the room and introduced all present committee members. The attendees are listed below:

Al-Humadi, Nabil x - Tox
Austin-Hansberry, Lori x - OBE - reg coor
Bash, Margaret x - Clin
Blake, Milan x - DBPAP Dir (cc)
Burns, Drusilla - Assay Validation
Campbell, Karen x- DPQ
Devore, Nicole x - Prod coord trainee
Fiore, Cara x - RPM
Freedberg, Daron x - Product
George, Joseph x - Facilities
Green, Martin (Dave) Tox Chief (cc)
Gruber, Marion - Repro tox
Krasnicka, Barbara x - Stat
Lee, Martha x - Stat – assay
Lee, Robert x - Product
Lynch, Christian x -hSBA Product
Meysick, Karen x - Assay Validation
Miller, Catherine x- APLB
Pratt, Doug - Clin Chief (cc)
Richman, Paul- Branch Chief (cc)
Roecklein, Tina x - Product Coord
Schwab, David- Elect. Integ
Sutkowski, Liz (Branch Chief)
Sun, Wellington - Div Dir (cc)
Trudel, Nicole x - Facilities
Vann, Willie x - CHAIR
White, Janet- BIMO
Wise, Robert- OBE
Woo,Jane x - PMS
Shone, Deanna x - dvrpa
McCormick, Bill X - DPQ

2. Monthly team Meeting (telecon/face to face)

Future meetings will be via telecom or face to face, unless there are urgent issues that require extensive discussion (ie – that may be face to face only.)

3. FDAAA – what it mean to reviewers – moves schedule up. Documentation is are posted on the web, PMC, labeling, etc (see "FDAAA Implementation" on our intranet).

The facilities reviewer and the Chair clearly state the review deadlines may not be attainable. This is a point of concern for the primary reviewer and she will further explore these dates with management. These dates were set by a pre-programmed Gannt chart on BLA timelines in draft form by OVRR in order to conform with FDAAA.

4. Documents – Reviews, memos, telecons, emails, meetings summaries, etc.
    a. All deadlines include uploading **signed, certified pdf with attached Word doc** into EDR. See instruction handout. If you have problems, please email david.schwab@fda.hhs.gov and cc me (cara.fiore@fda.hhs.gov).

Please do not upload any document without the stamp, attached Word doc and certification. Deanna Shone is here to answer any questions, as well as I have provided you with a hand out.

5. Communication with sponsor

Please include the primary reviewer on all communications. If you request Cara to set up a telecom, and therefore she sit in on it to assure proper documentation of the communication. There are a couple exceptions that are listed in the BLA SOPP.

6. Committee assignments, Roles and Responsibilities (SOPP 8401)

Al-Humadi, Nabil- Tox
Austin-Hansberry, Lori- OBE - reg coor
Bash, Margaret- Clin
Blake, Milan-DBPAP Dir (cc)
Burns, Drusilla- Assay Validation
Campbell, Karen- DPQ
Devore, Nicole- Prod coord trainee
Fiore, Cara- RPM
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Schwab, David- Elect. Integ
Sun, Wellington - Div Dir (cc)

Trudel, Nicole- Facilities
Vann, Willie- CHAIR
White, Janet- BIMO
Wise, Robert- OBE
Woo, Jane x - PMS

7. Major Due Dates are on Table below
8. Responsibilities

Milestones	**Date**
STN Assignment	11Sept08
Committee Assignment	11Sept08
1st Committee Meeting	17Sept08
VRBPAC Determination	12Oct08
Filing Meeting	>13Oct08
PeRC – schedule pres. If needed	27Oct08
Filing Action	>28Oct08
Deficiencies identified	>11Nov08
Draft Reviews Due/Mid Cycle review	**25Jan09**
VRBPAC planning meeting	26Nov08
PREA determination	25Jan08
Final Reviews Due	**26Mar09**
PMC to FDAAA Safety WG	06May08
Package to Branch Chief	27May09
Final Action Due Date	**29Jun09**
Action Package Posting	**01Jul09**
Monthly Meetings (Team)	Every Month
IOD Monthly Update (WV/CF)	Every Month

9. Questions/Comments/Concerns?

None. The Chair added no comments. The meeting ended at 3:25.