

FMDIC Face-to-Face Meeting

28 April 2017

Agenda

Roll call

ACCE	Steven (Steve) Juett	X
ACCE	Yadin David	
AdvaMed	Brian Blankenship	X
AdvaMed	Abbie Dunagan	X
ASQ- Bio	Rebecca (Beckie) Ellis	X
ASQ- Bio	Mary Ellan	
BioAustin		
BioAustin	VACANT	
BioMedSA	Mary Pat Moyer	
BioMedSA	Lynn Miller	X
CLMA	Naomi (Jo) Svochak	
CLMA	Jan Svochak	
OKBio	David Makanani	X
OKBio	VACANT	
RAPS	VACANT	
RAPS	VACANT	
TDSHS	Jeff Mansell	X

TDSHS	Jonnetta Wheaton	X
TDSHS	Meagan Snyder	X
TDSHS	Charles Hunter	X
TMDA	Julie Thomas	X
TMDA	Rafi Baddour	
Academia (A&M)	John C. Criscione	X
Academia	Lars Kuslich	
Academic (UTD)	Diana Easton	X
Academic (UCO)	Dr. Hari Kotturi	X
BioNT	Don Hurd	X
BioNT	Shawn Beddes	
GOV	Karen Daugherty	X
GOV	Cymbre Kooker	X
GOV	Elaine Crosby	
GOV	Kelly Sheppard	
GOV	Iris MacInnes	X

Approval/Correction of 20 January 2017 meeting minutes.

Read and approved, second

Action Items pending from last meeting

OPEN ACTION ITEM:

1. David Makanani to request OK Bio to submit a letter appointing an alternate representative. Pending since 7/22/2016 meeting. **OKBio received a template from David and they are reviewing**
2. Beckie sent out Code of Conduct Forms that needs to be completed by the officer and annually by all members. Forms to be returned to Jonetta by 1/31/2017. **Have 9 forms. Will review with Jeff and attempt to post on the website.**
3. Beckie forwarded the Treasurer Job Description and Assistant Treasurer Job description to Mary Ellen and Karen Daugherty for electronic signature. **Complete.**
4. Committee Chairs and officers to start bullet pointing their roles and responsibilities and return by 2/15/2017. Committee chairs to complete job descriptions. Beckie to target individuals. **Steve will assist.**

5. Steve to provide a copy of the before and after edits of our standard Grants letter. Steve to send Word and PDF version to Lars for posting to the Members only page. **Jonetta will coordinate with Lars. Steve to look and confirm.**
6. Diana to obtain a date for 2017 for another FDA 101 at UTD. Mary Ellen is willing to continue as an alternate for the biomedical division and to help coordinate 101. Beckie will reach out to Diana and ask for date, and coordinate with Mary Ellen. **Follow up**
7. John and Diana will work together on developing an FDA201 course and consider doing it as a roadshow. **Diana will reach out to John to begin working on this next week. Yadin David has agreed to assist with this.**
8. Randy to write up the job description for the Quality Committee chair so that we can seek a replacement. Yadin is interested in the position. Nominations from the floor were made enthusiastically. Yadin to reach out to Randy to discuss the status of the position and the time involvement. Nomination from the floor to make Yadin our Quality Chair and Yadin does not object. The nomination was enthusiastically and unanimously agreed to. Yadin to reach out to Randy to discuss the status of the position and the time involvement. **No response**
9. Jonetta is going to ask Lars how long he will be available to us and come up with a transition plan if we need to. Our transition plan is for Jeff Mansell to provide assistance. Jeff has been able to update the website, and Jonetta has experience uploading documents to other platforms. Lars has been helpful for AV coordination on big events; if we aren't able to find someone to assist on this, we will have to budget for it. **Graduating in August, paid hourly position John/ David. Work as a committee to discuss and come back with options**

Committee Reports

1. **Finance Committee**
2. **2016 EOY Expense Statement reviewed and approved**
3. **Scholarship grant was voted to not fund on 2017**
4. **Table the purchase of Flash Drives**
5. **Finance Report motion David, second Beckie**
1. Proposed change: removing \$4000 expense for flash drives. We need to determine whether that quote is based on a bulk order and printing set up charges. KCD moved to remove this line item from this year's budget and otherwise approve the budget as written; Jonetta 2nd. Approved. **We will not purchase more drives at this time.**
2. **Grant SOP that addresses the scholarship** – discussion around the language assuring that the amount of the scholarship is not fixed. Jeff will review the SOP and submit it to Yadin for approval. We think it is currently flexible, but Jeff will confirm. Scholarship grant guidelines state that we aware a grant of up to \$5000 may be made – wording allows for variation in amount and whether award will be given in a particular year. May want to modify to include consideration of the account balance. **The SOP is not fixed, it is optional.**
3. **Consider adding a low balance cutoff to the budget** so that we maintain a minimum balance in our account. Possibly a mark of \$30,000. Jeff will speak with Steve about this.

Note a discussion – SOP amend to state to review at budget time the balance and ability to fund the grant

4. Communications Committee

Website – as discussed, Jeff has been able to make changes and corrections made today can be incorporated on the website. Made changes to Website, members, please review and share with Johnetta feedback. Member Orgs please send updates, events, and distribution list changes to Johnetta. Jeff sent out a request to review the Website member's area. Steve suggested that Communications Committee round up the files and documents to go to the website, then issue them to Web Master for posting.

Cymbre – received emails and notifications for Facebook, not may 'likes' to the page. Copy these communications to Staci/ Cymbre to post on Facebook.

Steve- typically we do not respond to info@fmdic.org external email to minimize spam. This should be internally communicated and discussed prior.

Cymbre – requests for joining from Facebook, discuss internally.

Beckie – Need the organization to recommend to FMDIC the representative. We do not take self-nominations to the FMDIC. They need to go through their organization.

Jeff- suggests adding a link on the Website to the next events, we agree.

5. Quality Committee

New chair of the committee is Yadin David. He will work with Randy on the details of the position. Yadin has already reached out to Randy. No response

6. Events Committee

We do not have a report from the events committee. Beckie will follow up and will include Yadin on response. As discussed, Mary Ellen is willing to assist. No committee response. Federal Register requires a 6mo notice.

Liked near the airport, considering venue. Have 6 months to prepare for 2018.

Need co-sponsor agreement. No theme, topic currently, open or suggestions.

Topic request –

Committee Review – Don Hurd volunteered to participate on the committee, Beckie is on the committee, John, Diana would do the 101 and 201 events.

Jonnetta will participate, Jeff will assist (not lead).

Jeff - Circuit of America as a potential venue in Austin – maybe for 201?

David – Cowboy training center as a potential venue

Cymbre/ Staci – Venue support

John is happy to develop subject matter for 101/ 201 and present

Cymbre to send feedback to Beckie. Beckie will send out an email for discussion.

7. Replacement of Secretary

Beckie will write an email requesting nominations for a secretary. Karen has indicated that she is trying to work with Bill Shackelford and ask if he would be willing to serve as Secretary. No confirm commitment. Beckie to send a separate request at FDA (Bill, for example). Cymbre will consider and seek approval comments.

8. Replacement of Primary Representative for AdvaMed

Darrell Arterburn is no longer a member. Brian d to be backup and to have Abbie Dunagen, the Quality Systems Manager for Smith and Nephew/Oklahoma City take over as Primary. Brian proposed Abbie as alternate of the primary, and Brian as the backup. Brian isn't sure what Darrell submitted. He is trying to get information on what was done in the past – Beckie sent example, but what is needed is something on AdvaMed letterhead recommending Abbie as primary and Brian as alternate. Secretary maintains document as an archived form. **We need a AdvaMed letter.**

8. We need the same thing from Mary Pat and Lynn for their change. **We need a AdvaMed letter.**

9. Replacement of Karen Daugherty as Regulatory Co-Chair

a. Her position is changing and she is looking for a replacement. Date is not confirmed; regulatory co-chair is not required to come from FDA. This could be a DSHS representative. Recommendation from the floor that we use a senior member. Nomination from Meghan for Jeff to be chair, KCD seconded. Historically regulatory co-chair has been a senior member of the organization. Jeff is agreeable to the chair if the secretary is someone from FDA, in order to maintain the relationship. Karen will reach out to Bill Shackelford in regard to serving as Secretary. **Offered to represent AFDO and reaches out to FMDIC. Touch base with Karen to let her know they are going. Jeff will take on the Regulatory C-Chair position.**

10. Annual Meeting was scheduled for December 16th, which was postponed. Invitation to annual meeting must go out at least 2 weeks prior to the Annual Meeting. Next annual meeting set for April 28, 2017. **Annual meeting completed 4/28**

11. Discuss the FD201 concept. John and Diana were not present at January 2017 meeting. Tabled to April 28 meeting **John is happy to develop subject matter for 101/ 201 and present. Too late for a 201**

12. Finalize date for FDA 101 which Diana will work on with Mary Ellen. Mary Ellen has indicated she is willing to do this. Will FDA provide speakers? This was tabled. **Content is well defined. More emphasis on venue and date. 101 does not require a federal register notification. Need a date, use local mailing list, choose a venue, UTD was for students. John's summer is open. Beckie will work with the Events committee. Beckie will start the conversation.**

13. Scholarship committee needs to meet 2nd Quarter. Tabled, no scholarship offered this year. Discussion regarding the fiscal implications of scholarship in light of the current budget. Considered either reducing or foregoing a scholarship for the current year. We don't have an obligation to offer a scholarship per the current scholarship. **Therefore the committee agreed that no scholarship will be issued in 2017.**

NEW BUSINESS.

- 1. Annual Meeting Review** – Steve Juett to conduct. **Complete**
- 2. AFDO in June** – we do not currently have anyone appointed to birddog the event and get us involved. At the last one, we set up a table and put out some 820 booklets, but didn't necessarily have a manned booth. Jonetta remembers that we co-sponsored the drug/device track lunch. Karen will get the contact information for Randy Young to Jonetta.

- Alena King and Randy Young from AFDO have asked Karen to provide a FMDIC update at the AFDO Conference during the Drug, Device and Cosmetics Committee Meeting on Sunday, 6/18/2017 from 11:15-11:30 a.m. She doesn't know if we have anyone from the Board planning to attend. Karen will have already resigned as co-chair before the conference, and this would be a great opportunity to let additional folks know about FMDIC .Karen has indicated that she is willing to go and talk to AFDO about FMDIC at that meeting on Sunday,
 - **Beckie will reach out to those volunteers**
- 3. Items from the Floor**
- **Brian Blankenship send Beckie the membership letter for Abby.**
 - **Academics Representative, request a primary, discuss a time frame. Report Primary role and alternates.**

Review of Discussion

Selection of Next Meeting Date

June 16, Jeff by conference call

Move to adjourn

David moved, Don seconded

Meeting adjourned