

FMDIC Quarterly Meeting
June 19, 2015
Minutes

Members Present: Beckie Ellis, ASQ BD-pri (Industry Co-Chair)
Karen Daugherty (Regulatory Co-Chair)
Steven Juett, ACCE (Treasurer)
Mary Ellen Delaney, ASQ BD-alt (Secretary)
Randy Thoma- BioAustin (pri)
Mary Pat Moyer-BioMed SA(pri)-phone
Ricky Rodriguez- FDA-DALDO
Kelly Sheppard-FDA-DALDO-phone
Stacy McAllister -FDA-DALDO
Cymbre Weatherly- FDA-DALDO
David Makanani-OK Bio (pri) phone
Tom Brinck-TDSHS - phone
Jonnetta Whwaton-TDSHS-phone
Jeff Mansell-TDSHS-phone
Julie Thomas-TMDA (pri)-phone
Danieli Rodrigues- University of Texas at Dallas (pri)
John Criscione- Texas A & M University (pri)- phone

Members Absent:

David Yadin-ACCE, (alt)
Lynn Miller, BioMed (alt)
Brian Blankeship- AdvaMed- (pri)
Darrel Arterburn AdvaMed- (alt)
CLMA- Jo Svochak (pri)
CLMA-Jan Svochak (alt)
RAPS- vacant
TMDA- Rafi Baddour (alt)
University of Central Ok- Dr. Wei Chen (pri)

- Roll Call: The results above did constitute a quorum of membership (8 of 11).
- Approval/Correction of June 19, 2015 meeting minutes. Motion made to approve and seconded. The motion carried.

Review of Action Items

From March 20, 2015 Meeting

- **ACTION ITEM:** *Becky will reach out to RAPS for replacement members.* OPEN. To take under discussion- they have not gotten back to Becky. Becky to recontact them again. RAPS discussion group in Austin. They were supposed to talk to their members.
- **ACTION ITEM -** *David Makanani to request OK BIO to submit a letter appointing an alternate representative.* OPEN: New management list and David will start again
- **ACTION ITEM:** *Sue was to check file to see if there are missing Code of Conduct forms and resend the signature page to any still missing.* Some are posted on the website. Need officers to sign Code of conduct annually. Officers to submit to Mary Ellen and then to Julie and Lars to post on the website. Karen to look for signed forms in Sue's files. Steve to make a roster of members of those who have completed the code of conduct, Collect missing forms and send copy of forms to Julie to get Lars to get posted to the website and

new members since 12/14/14 to send to Mary Ellen and copy Steve Juett by 6/29/15. Mary Ellen to maintain a file of Code of Conduct.

- **ACTION ITEM:** Sue to contact Randy to see if he has received and reviewed the Finance SOP. Randy did not receive this. Finance SOP is on the website. **OPEN:** Steve to send Final SOP to co-chairs Karen and Beckie for final signature.
 - **ACTION ITEM:** Randy to send to new co-chairs for signature.
- **ACTION ITEM:** Sue to contact Randy to see if he has received the SOP/Job Description - Treasurer and reviewed the SOP. **OPEN:** Steve to send to Co-chairs.
 - **ACTION ITEM:** Randy to send to new co-chairs for signature.
- **ACTION ITEM:** Beckie (or Brian) to send the email back out with the list of eligible schools with a suspense of 3/31/15. If no one responds, first nominee will receive the grant.
 - **ACTION ITEM:** Scholarship Committee (Steve, Becky and Randy) to meet and review nominees in the 1st quarter of 2015. Selection will be recommended for approval at the next meeting. Table until item above is complete. **COMPLETE**
- **ACTION ITEM:** Brian or Ricky will reach out to BioHouston to see if they want to return to FMDIC. Open- Ricky to reach out to Yadin for contact at BioHouston.
- **ACTION ITEM:** Sue to send information on Case for Quality to Becky who will work on an introduction to the information for Ricky's review. **OPEN:** Becky to work on introduction
- **ACTION ITEM:** Becky to review/revise the 101 slides and let the co-chairs know if she will present at the April 17th event. **DONE**
- **ACTION ITEM:** Ricky will contact BioNorthTX to see if they would like to become a member of FMDIC. **OPEN:** Ricky to followup with BioNorth TX.
- **ACTION ITEM:** Becky will follow-up with Randy when the scholarship/grant recipient is named. **CLOSED**
- **ACTION ITEMS:** Devices 101 Expansion and Partnership with UTD. Brian to contact John to see if he is able to present on April 17th. Ricky to name the FDA speaker. **CLOSED**,
- **ACTION ITEMS:** Device 201 – take another look at it to put together the next steps. Brian and Becky to discuss and reach out to Mary Ellen. Becky to set a meeting to discuss the feasibility of Device 201. Becky will send the link to Small Entity Compliance Guide. **OPEN**
- **ACTION ITEM:** Sue will assist Staci and Cymbre in preparing the Statement of Work (SOW) and the Request For Proposals (RFP).
 - **ACTION ITEM:** Staci and Cymbre will report back at next meeting-Tabled to **EVENTS:**
- **ACTION ITEM:** Award Recognition for Al and Sue. Sue to order the standard recognition award for Al. Brian and Jeff will work on recognition for Sue. **COMPLETED.** Acrylic award was given to Sue and we received Thank you from Sue
- **ACTION ITEM:** Sue to contact those nominated for new officer positions and send out an email to vote on new officers by 3/27/15 **COMPLETE**
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Committee Reports

- Finance Committee – Steve Juett. Committee to select and go forward with the grant. Took some time. UTD: Legal review by UTD and made recommendations to our standard letter. Money for not for profit-edited the document to remove not for profit. Was that appropriate to make that decision to make corrections to the document? Steve to provide a copy of the before and after edits. Presented to the coalition. Letter was reviewed by the CPA (Dan). Have Dan review it to make sure the money is used as stated. Check has been cut.

Letter from IRS with penalty for \$249.40. for 2013. Form needed to be filed which was filed in 2014. Dan, CPA to send the check. Steve to talk to Dan for when that will be paid.

Motion : Suggestion for Treasurer to make the payment. Wait 5-10 days (by 6/29/15) for Dan to resolve then, Then Steve to make payment. Expecting 250.12.

Authorize treasurer to make a payment by 6/29/15 up of \$260 So moved.

Closed with \$40,253.70 this quarter, 2 awards for Sue and Al.

Motion accepted finance report: Becky, Randy.

Future: Due to issue of our TX franchise payment due by November: need addresses of new officers.

Karen to get addresses by end of the June 30, 2105.

➤ Communications Committee

- Website updated

Julie: Action item: Will do Updates to include new officers and meeting minutes, and code of conducts.

Remove old announcements.

Need for new Communications Chair/ Website. Julie communicates with LARS takes @ 1-2 hours a month.

Action Item: Julie to send out an email to communicate the need for a replacement. Lars will be able to continue with FMDIC per Dr. Criscione.

- Requested Secretary to publish minutes 2-3 weeks after the meeting.
- Motion to approve, Steve, Ricky- Approved.

➤ Quality Committee – no report (Randy) SOPs to go through Quality committee to ensure consistency in parallel with approve. Action Item: Randy Will send new email address to Steve and Mary Ellen

➤ Events Committee

FDA 101 presentation was held 4/17/15 at the University of Texas at Dallas. 100 students registered and 60 students attended. Feedback was very positive. More condensed information suggested, Friday is good day for students, Saturday may be better. Students information presented.

Action item Danieli: to obtain a date for 2016 for another FDA 101.

Action item: 101 Committee: Beckie to send out email for the committee and see if there is interest in certain areas. Send a Survey for 101/201

➤ Big Event:

➤ Action item: Need to make decision by July 20, 2015

Looked at 4 hotels : Karen to look at hotels with Cymbre and Staci to make a recommendation before 7/20/15.

1. Doubletree by Hilton-DFW North- undergoing renovations
2. Wyndham Dallas Suites- Park Central
3. Doubletree by Hilton Dallas Near the Galleria
4. Courtyard & TownePlace Suites DFW Airport North/Grapevine

TOPIC>> Effectiveness Checks, Supplier Qualifications and/or Vendor audits, Design Changes, 803/806/Corrections Removals, Recalls, CAPA- knowing when it needs to be elevated to a CAPA.

Action item: *Beckie to send email for a list for topics and for formation of a committee.*

New Items: None

Next Meeting Date: September 11, 2015

Beckie, Ricky to adjourn 11:32am

Important Dates

2nd quarter
April 8th or 14th, 2016

Scholarship Committee Meets
Big Event

Action Items from June 19, 2015 Meeting

1. Becky will reach out to RAPS for replacement members.
2. David Makanani to request OK BIO to submit a letter appointing an alternate representative.
3. Code of Conduct forms need to be completed by the officers (and annually by all members) and posted on website by Lars.
4. Mary Ellen to maintain a copy of the Code of Conducts by members.
5. Steve to send Final Finance SOP and SOP/Job Description to co-chairs Karen and Beckie for final signature.
6. Ricky to reach out to David Yadin for contact at BioHouston.
7. Beckie will work on an introduction for Case for Quality and send the information for Ricky's review.
8. Ricky will contact BioNorthTX to see if they would like to become a member of FMDIC
9. Steve to provide a copy of the before and after edits of our standard Grants letter.
10. Steve to have Dan review standard grants letter to make sure the money is used as stated.
11. Steve to make an IRS payment by 6/29/15 up to \$260.
12. Karen to get officer addresses by end of the June 30, 2105 for TX franchise which is due November.
13. Julie/Lars do updates to the website to include new officers and meeting minutes, and code of conducts.
14. Julie to send out an email to communicate the need for a replacement with job descriptions for Communications Chair
15. Randy will send new email address to Steve and Mary Ellen
16. Danieli to obtain a date for 2016 for another FDA 101 at UTD
17. Beckie to send out email for the committee and see if there is interest in certain areas for FDA 101.
18. Beckie to send a Survey for 101/201.
19. Becky to setup a meeting to discuss the feasibility of Device 201. Becky will send the link to Small Entity Compliance Guide.
20. Karen to look at hotels with Cymbre and Staci to make a recommendation before 7/20/15, Venue date needed by 7/20/15.
21. Beckie to send email for a list for topics and for formation of a committee.
22. Mary Ellen to post meeting minutes 2-3 weeks after each meeting.