

FMDIC Quarterly Meeting
October 2, 2015
Minutes

Members Present:

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
Kelly Sheppard-FDA-DALDO-phone
David Makanani-OK Bio (pri) phone
Tom Brinck-TDSHS
Jeff Mansell-TDSHS
Dr. John Criscione- Texas A & M University (pri)- phone
Dr. Wei Chen (pri)- University of Central OK-phone

Members Absent:

Ricky Rodriguez- FDA-DALDO
David Yadin-ACCE, (alt)
Lynn Miller, BioMed (alt)
Brian Blankeship- AdvaMed- (pri)
Darrel Arterburn AdvaMed- (alt)
Jo Svochak (pri) CLMA
Jan Svochak (alt) - CLMA
RAPS- vacant
Rafi Baddour (alt) TMDA
Beckie Ellis, ASQ BD-pri (Industry Co-Chair)
Julie Thomas-TMDA (pri)
Danieli Rodrigues- University of Texas at Dallas (pri)
Stacy McAllister –FDA-DALDO
Cymbre Weatherly- FDA-DALDO
Jonnetta Wheaton-TDSHS

- Roll Call: The results above did constitute a quorum of membership (8 of 11).
- Approval of June 19, 2015 meeting minutes. Motion made to approve, (Randy, Jeff). Motion approved.

Review of Action Items

Action Items from June 19, 2015 Meeting

1. Becky will reach out to RAPS for replacement members.- Sherry Keramides, RAPS to submit nominations to Chairs for recommendations.- OPEN
2. David Makanani to request OK BIO to submit a letter appointing an alternate representative.- Letter received, person reassigned- OPEN
3. Code of Conduct forms need to be completed by the officers (and annually by all members) and posted on website by Lars. Forms to be resigned by all members at the December meeting- OPEN
4. Steve to send Final Finance SOP and SOP/Job Description to co-chairs Karen and Beckie for final signature.- OPEN

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

New Action item

1. Karen- Search for Job descriptions and if not available will need to be developed
2. Steve – To draft Job descriptions for Treasurer and Assistant Treasurer and Jeff to assist with referencing the bi-laws and will review at the next meeting
3. Chairs and officers to start bullet pointing their roles and responsibilities.
4. Karen to follow up with Beckie on Big Event Topics by end of October and to review Educational Event Planning SOP.

Committee Reports

- Finance Committee – Steve Juett
 Financial report ending 9/30/15. No expenses reported from Device 101. Received the IRS letter for penalty of not reporting on time. Steve reached out to the CPA and Dan contacted IRS- Payment was made and an inquiry was sent to the IRS.
 Dan does not have power of attorney. Penalty was removed and reimbursement was received (including postage costs). Dan said all returns have been filed and accepted.
 Proposal for 2016 event expenses reviewed and hotel ok with holding reservation \$834 below the budget to date. Balance \$34320- with no expenses at this time.
 Venue proposed at \$14,000 from 3/2015 meeting minutes.
 Steve has requested an audit from the CPA.
 Job Descriptions are needed for Finance SOP
 Motion to move budget to the 4th quarter meeting. Motion approved (Steve, Mary Pat).
 Motion to approve Finance report with corrections (Steve, Randy) Motion approved
- Communications Committee: no report
- Quality Committee : no activity to report
- Events Committee: no report
- Big Event: no report

New Items:

201- Want more advanced topics. Kelly offered to take on and organize. Dr. John offered to assist.

Next Meeting Date: December 4, 2015

Important Dates

2nd quarter
April 8th or 14th, 2016

Scholarship Committee Meets
Big Event

Announcements:

Wei Chen- Intentions to step down as primary due to being the interim Dean of the University. Associate Biology Professor Dr. Harry Kotturi to replace Dr. Chen and he may remain as alternate. He will send a letter of resignation with the CV of the new nominee.