

FMDIC Quarterly Meeting
March 20, 2015
Minutes

Members Present: Brian Blankenship, AdvaMed (Industry Co-Chair) - Leader
Sue Thomason, FDA-DALDO (Secretary)
Rebecca Ellis, ASQ BD (pri)
Mary Pat Moyer, BioMed SA (pri) – phone
Lynn Miller, BioMed SA (alt) - phone
Karen Daugherty, FDA-DALDO
Kelly Sheppard, FDA-DALDO - phone
David Makanani, OK Bio (pri) - phone
Tom Brinck, TDSHS - phone
Jeff Mansell, TDSHS - phone

Members Absent: Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair)
Steven Juett, ACCE (Treasurer)
Yadin David, ACCE (alt)
Mary Ellen Delaney, ASQ BD (alt)
Randy Thoma, BioAustin (pri)
Jo Svochak, CLMA (pri)
Jan Svochak, CLMA (alt)
Jonnetta Wheaton, TDSHS
Julie Thomas, TMDA (pri)
Rafi Baddour, TMDA (alt)
John Criscione, Texas A&M University (pri)
Danieli Rodrigues, University of Texas at Dallas (pri)
Wei Chen, University of Central Oklahoma (UCO) (pri)
Darrel Arterburn, AdvaMed (alt)
Elaine Crosby, FDA-SWRO

Guest Present: Staci McAllister, FDA-DALDO
Cymbre Weatherly, FDA-DALDO

- Roll Call: The results above did constitute a quorum of membership (6 of 11). Sue introduced Staci McAllister and Cymbre Weatherly. They will work with the coalition on meeting planning.
 - Sue announced her retirement from FDA at the end of May.
 - Brian read the letter of resignation sent by Al Alonso, RAPS
 - **ACTION ITEM:** Becky will reach out to RAPS for replacement members
- Approval/Correction of December 19, 2014 meeting minutes. Motion made to approve and seconded. The motion carried.

Review of Action Items
From December 19, 2014 Meeting

- **ACTION ITEM:** Sue to prepare acceptance letters for Wei Chen and Lynn Miller the co-chairs' signature. Completed. **CLOSED**
- **ACTION ITEM -** David M to request OK BIO to submit a letter appointing an alternate representative. Letter sent to OK BIO requesting an alternate representative. No response from them to date. **OPEN**
- **ACTION ITEM:** Sue will update the Event SOP with two additional corrections and send for official signatures. Completed. **CLOSED**
- **ACTION ITEM:** Sue will send the Code of Conduct to the new members and contact the current members still needed to submit their signature page. Due date for all forms set for 1/30/15. Sue to check file to see if there are missing forms and resend the signature page to any still missing. **OPEN**
- **ACTION ITEM:** Randy will send the Scholarship SOP to the membership for review and comment. Due to Randy 1/16/15. Completed. **CLOSED**
- **ACTION ITEM:** Steve and Becky will review and make the changes to the Finance SOP and forward to the Quality Committee for review. Reviewed by attendees without corrections.
 - **ACTION ITEM:** Sue to contact Randy to see if he has received and reviewed the SOP. **OPEN**
 - **ACTION ITEM:** Randy to send to new co-chairs for signature. **OPEN**
- **ACTION ITEM:** Steve and Becky will review and make the changes to the SOP/Job Description - Treasurer and forward to the Quality Committee for review.
 - **ACTION ITEM:** Sue to contact Randy to see if he has received and reviewed the SOP. **OPEN**
 - **ACTION ITEM:** Randy to send to new co-chairs for signature. **OPEN**
- **ACTION ITEM:** Members are to review the list of schools and submit their recommendation of an institution to receive the next scholarship/grant. Due to the Scholarship Committee by 1/30/15. Only one nomination received from the Finance Committee.
 - **ACTION ITEM:** Beckie to send the email back out with a suspense of 3/31/15. If no one responds, first nominee will receive the grant. **OPEN**
- **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. **OPEN**
- **ACTION ITEM:** Brian or Ricky will reach out to BioHouston to see if they want to return to FMDIC. Ricky is still looking for the appropriate person to contact. Ann Tabeni and Jacqueline Northcutt were recommended as potential contacts. **OPEN**
- **ACTION ITEM:** Julie will work with Lars to get the information updated. Julie reported the website is up to date. Completed. **CLOSED**
- **ACTION ITEM:** Ricky will take the lead to get the Case for Quality information posted and work with Becky to do an introduction to the information.
 - **ACTION ITEM:** Sue to send information to Becky who will work on an introduction to the information for Ricky's review. **OPEN**

- **ACTION ITEM:** *Mary Ellen to work with Danieli to bring 101 to UTD*, Industry speaker needed due to Al's resignation. Becky will see if she can present his portion.
 - **ACTION ITEM:** Sue sent the slides to her during the meeting. **CLOSED**
 - **ACTION ITEM:** Becky to review/revise the slides and let the co-chairs know if she will present. **OPEN**
- **ACTION ITEM:** Ricky will contact BioNorthTX to see if they would like to become a member of FMDIC. **OPEN**

Committee Reports

- Finance Committee – Steve sent reports by email prior to the meeting. Reports approved
 - \$40733.06 ending balance
 - Big event estimate is \$14K
 - Will giving a Scholarship dramatically impact the budget?
 - \$5K is budgeted annually for scholarships
 - UTD Nominated by finance committee to receive scholarship
 - Scholarship committee to decide to accept or look at others
 - **ACTION ITEM:** Becky will follow-up with Randy
- Communications Committee
 - Website updated as per Julie's report
- Quality Committee – no report
- Events Committee
 - Devices 101 Expansion and Partnership with UTD
 - Al resigned. Becky sent the slides to see if she can do his portion
 - Ricky to contact John on the academic side. **ACTION ITEM:** Brian will contact John due to Ricky's schedule.
 - **ACTION ITEM:** Ricky should select an FDA presenter
 - All speakers should be committed to present by 3/27/15
 - Device 201 – take another look at it to put together the next steps.
 - **ACTION ITEM:** Brian and Becky to discuss and reach out to Mary Ellen
 - **ACTION ITEM:** Becky to set a meeting to discuss
 - Jeff - Small Entity compliance guide would be a good start to planning 201 but it is no longer available on line.
 - **ACTION ITEM:** Becky found it and will send the link to the guide
 - The committee will come up with ideas first and then bounce off the concept to FDA
- Big Event
 - Start the process by finding a location
 - Brian recommends Wyndham Dallas Park Central where it was held in 2014
 - Other recommendations
 - OKC Marriott next to Cox convention center
 - Move to other places such as San Antonio, Austin, OKC
 - **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

New Items

- Filling of vacant positions
 - Al
 - Becky to contact RAPS
 - Sue - retiring
- Service recognition awards
 - Al and Sue
 - **ACTION ITEM:** Sue to get Al's
 - **ACTION ITEM:** Brian and Jeff to work on Sue's
- Elections
 - Co-Chairs
 - Regulatory Co-Chair
 - Kelly or Karen – **ACTION ITEM:** Ricky to pick
 - Industry Co-Chair
 - Randy nominated by Mary Pat
 - Beckie nominated by Jeff and is willing to run
 - Mary Ellen nominated by Brian
 - Secretary
 - Julie nominated by Sue
 - Mary Ellen by Beckie
 - Treasurer
 - Steve may want to continue as treasurer
 - **ACTION ITEM:** Sue to contact those nominated and send out an email to vote on new officers by 3/27/15

Next Meeting Date:

June 19th, with June 26th as alternate

Important Dates

2 nd quarter	Scholarship Committee Meets
April 8 th or 15 th , 2016	Big Event

Action Items from March 20, 2015 Meeting

- **ACTION ITEM:** *Becky will reach out to RAPS for replacement members*
- **ACTION ITEM -** *David M to request OK BIO to submit a letter appointing an alternate representative.*
- **ACTION ITEM:** *Sue to check file to see if there are missing Code of Conduct forms and resend the signature page to any still missing.*
- **ACTION ITEM:** *Sue to contact Randy to see if he has received and reviewed the Finance SOP.*
 - **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.*
 - **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.*
- **ACTION ITEM:** *Brian or Ricky will reach out to BioHouston to see if they want to return to FMDIC.*
- **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.*
- **ACTION ITEM:** *Becky to review/revise the 101 slides and let the co-chairs know if she will present at the April 17th event.*
- **ACTION ITEM:** *Ricky will contact BioNorthTX to see if they would like to become a member of FMDIC.*
- **ACTION ITEM:** *Becky will follow-up with Randy when the scholarship/grant recipient is named.*
- **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.*
- **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.*
- **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*
- **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.*
- **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*