

FMDIC Annual Meeting
December 19, 2014
Minutes

Members Present: Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair) - Leader
Brian Blankenship, AdvaMed (Industry Co-Chair) - phone
Sue Thomason, FDA-DALDO (Secretary)
Steven Juett, ACCE (Treasurer)
Yadin David, ACCE (alt) - phone
Mary Ellen Delaney – ASQ BD (alt) - phone
Randy Thoma, BioAustin - phone
Mary Pat Moyer, BioMed SA - phone
Karen Daugherty, FDA-DALDO
Kelly Sheppard, FDA-DALDO - phone
Tom Brinck, TDSHS (alt) - phone
Jeff Mansell, TDSHS - phone
Jonetta Wheaton, TDSHS (alt) - phone
Julie Thomas, TMDA (pri) - phone

Members Absent: Rebecca Ellis, ASQ BD (pri)
Jo Svochak, CLMA (pri)
David Makanani, OK Bio (pri)
Al Alonso, RAPS (pri)
Rafi Baddour, TMDA (alt)
John Criscione, Texas A&M University (pri)
Danieli Rodrigues, University of Texas at Dallas (pri)
Darrel Arterburn, AdvaMed (alt)
Elaine Crosby, FDA-SWRO

Guest Present: Wei Chen, University of Central Oklahoma (UCO)

Wei Chen – Recommended as an academic representative for UCO. He thanked the coalition for the support of students with a grant. The grant was used to fund a student project. UCO's focus is on research and invention. Dr. Chen also gave a brief summary of his credentials and experience.

Ricky gave a brief explanation of Dr. Rodrigues' and Dr. Criscione's role as members and explained the focus of FMDIC is on quality, and quality of medical products. We seek ways we can start at the college level to build in a quality focus and welcome Dr. Chen's input as well.

- Roll Call: the results above did constitute a quorum of membership (8 of 11). Ricky introduced Karen Daugherty, Director Investigations Branch and Kelly Sheppard, Medical Device Program Manager and Supervisor as the newest FDA members of the coalition.
 - Dr. Wei Chen, University of Central Oklahoma, has requested membership as a third academic representative to the coalition.
 - Mary Pat Moyer recommended Lynn Miller as her alternate representing BioMedSA

- **ACTION ITEM:** Sue to prepare acceptance letters for the co-chairs' signature.
- Approval/Correction of September 19, 2014 meeting minutes. Motion made to approve and seconded. The motion carried.

Review of Action Items
from September 19, 2014

- **ACTION ITEM** - David M to request OK BIO to submit a letter officially an alternate.
Table
- **ACTION ITEM** –Randy will resend Event SOP and all members are to respond to him by July 31, 2014. A majority of members reviewed the document and responded. Members present voted to approve the Event SOP with the recommended changes.
 - **ACTION ITEM:** Sue will update the SOP with two additional corrections and send for official signatures.
 - Page 2 of 5 – “Prepare a Notice of Public Workshop.....” area of responsibility, add FDA member
 - Page 3 of 5 – Add 5-6 months in the Time until Even column, third block down
 - Page 3 of 5 – Delete Treasurer in Activity column, 4th block down and add Treasurer to the responsibility column
 - Page 3 of 5 – Delete the entire row, duplicate entry
 - Page 4 of 5 – Under Registration, Give-a-ways, change 802s to 820s
- **ACTION ITEM** - Steve to send out the Code of Conduct. Everyone should sign the signature page of the document and return it within three weeks. All Officers signed and submitted their Code of Conduct. Sue sent the Code of Conduct to the members who had not yet submitted their signature page.
 - **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**.
- **ACTION ITEM:** Randy to review Scholarship SOP and send out to members for review. Scholarship SOP, dated 3/27/13 needs to be reviewed.
 - **ACTION ITEM:** Sue will send the Scholarship SOP to Randy for review.
 - **ACTION ITEM:** Randy will send the Scholarship SOP to the membership for review and comment. Due to Randy 1/16/15 in order for the SOP to be used in the upcoming scholarship selection process.
- **ACTION ITEM:** Steve to prepare an SOP for the treasurer's position. Steve prepared and provided two documents: SOP – Finance and SOP/Job Description – Treasurer. Both documents were discussed and changes recommended.
 - **SOP – Finance:** The SOP-Finance is a “how to” guide for the position.
 - The question about defining due dates discussed. Steve will add any known dates to the SOP.
 - A recommendation was made to add “report in a timely manner” to the General Timeline of Activities section.

- An additional Attachment needs to be added describing the Banking Procedures and resources. Signing of bank cards will be added in that attachment.
 - **ACTION ITEM:** Steve and Becky will review and make the changes to the Finance SOP and forward to the Quality Committee for review.
 - **SOP/Job Description – Treasurer:** The SOP/Job Description -Treasurer is a basic guide to the responsibilities of the treasurer position.
 - The group recommended the addition of “Assistant Treasurer” to the title information. This should cover both the treasurer and the back-up treasurer.
 - **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:** Brian to search websites for examples and send to Julie. Julie and Brian to discuss and send recommendations to Lars. Brian and Julie determined the current website is okay. **CLOSED**
- **ACTION ITEM:** Steve and Beckie work together on Scholarship for next year. Scholarship tabled to the next meeting. Steve sent a list of 46 schools in Texas, Oklahoma, Arkansas, Louisiana and New Mexico who participate in educational programs geared toward careers in the medical device industry.
 - **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.
 - **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.
- **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. **TABLE**
- **ACTION ITEM:** Sue to review website to see what minutes are needed and forward to Julie to have Lars post. **CLOSED.**

Committee Reports

- Finance Committee – Steve Juett
 - Steve will present the letter of appreciation and a plaque to Dan Lassiter today
 - Financial report distributed and discussed. All reports were approved.
 - Dr. Chen asked how the coalition is funded. Steve explained registration fees from the educational events we present provide the funds. Monies go toward education and scholarships/grants.
- Communications Committee
 - Website – Julie Thomas
 - Requested changes made were made by Lars
 - Members only tab was added.
 - Grant/scholarship letter template were added
 - About section – organizations, officers, logo, minutes and documents

- More areas need to be updated
 - New and noteworthy needs updating
 - Organizations need to be made current
 - Take down AAMI until they are an official member again
 - FMDIC email distribution list needs updating
 - Jeff to work with Julie to update
 - Julie to send changes to Lars and copy John
 - **ACTION ITEM:** Wei Chen asked to send logo to Sue for UCO. Sue will forward to Julie for updating the website
 - Mary Pat asked if the site could be updated sooner.
 - **ACTION ITEM:** Julie will work with Lars to get the information updated. Updates will depend on his school schedule.
 - Julie asked if someone else would consider being the Communications chair. Ricky reminded the group elections will be held at the March 2015 meeting. Everyone should consider becoming an officer. Brian and Ricky's time as co-chair will be over in March. Let Brian and Ricky know if you are interested.
- Quality Committee – Randy Thoma
 - Event SOP and Scholarship SOP discussed earlier.

New Items

- Were the Case for Quality table summaries posted on website? Ricky – We will post after names are removed.
 - **ACTION ITEM:** Ricky to take the lead to get the information posted. Ricky will work with Becky to do an introduction to the information
- Devices 101 Expansion to 201 and Partnership with UTD - **TABLE**
 - Beckie and Danieli not here to discuss with MaryEllen; however MaryEllen has been working with Danieli to set up a student chapter of ASQ at UTD.
 - Brian keep on the list for the next meeting
 - Mary Ellen informed the group she is working with Danieli as a part of ASQ Biomedical Division to bring more students into ASQ. She feels if we can partner with UTD for space, there is a potential ASQ would pay for food for the event.
 - There would be no charge for students
 - We could explore a follow-on event open to public at UTD
 - **ACTION ITEM:** Mary Ellen to work with Danieli to bring 101 to UTD
 - Student 101 - invite other students from area schools
 - Wei March 16-20 spring break for UCO
 - Weekends are better for students to minimize the cost
 - A very basic course might attract graduating students.
 - Faculty as well might be interested.
 - Wei will work with UCO for their interest.
 - Speakers need to be contacted as to their availability for 101.
- JJ Speckle of BioNorthTX contacted Ricky to see if he wanted to become a member. Is there anyone else familiar with this group? Would BioNorthTX be a potential member of FMDIC?
 - Mary Pat said they are trying to get the group started again but she is unsure of their status at this time

- **ACTION ITEM:** Ricky will contact him to see if they would like to become a member of FMDIC
- Big Event for 2016
 - Be prepared to start planning for the next big event at the March meeting.
 - Should we go back to CAPA, Recalls, 806, MDRs?
 - Becky would have topics as well such as management responsibility and quality audits
 - Mary Pat suggested combination products
 - Julie suggested software used in medical devices
 - Ricky states we may be able to get speakers from the centers for more complex topics
 - We will need to request speakers very early on to get through the speaker appearance request tracking system
- Medical Devices 201
 - Mary Pat would like to participate in 201 discussions with Brian and Becky

Next Meeting Date

- March 6th based on the potential UTD 101. Back up meeting date is March 20th.

Important Dates

2nd quarter
April 2016

Scholarship Committee Meets
Big Event

Adjourn at 11:15.

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from December 19, 2014

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