

FMDIC Quarterly Meeting
September 9, 2016
Minutes

Members Present:

CHANGE AS NEEDED

Beckie Ellis, ASQ BD-pri (Industry Co-Chair)
Karen Daugherty (Regulatory Co-Chair)
Steven Juett, ACCE (Treasurer)
Randy Thoma- BioAustin (pri)
Mary Pat Moyer-BioMed SA (pri)
Kelly Sheppard-FDA-DALDO
David Makanani-OK Bio (pri)
Jeff Mansell-TDSHS
Dr. John Criscione- Texas A & M University (pri)
Dr. Wei Chen (pri)- University of Central OK
Jonnetta Wheaton-TDSHS
Don Hurd

Members Absent:

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
Mary Ellen Delaney, ASQ BD-alt (Secretary)

- Roll Call: The results above did constitute a quorum of membership (x of 12).
- Approval of July 22, 2016 meeting minutes. Motion made to approve, (xx, xx). Motion approved.

Review of Action Items

Action Items from December 4, 2015/March 4, 2016 Meeting/July 22, 2016:

1. David Makanani to request OK BIO to submit a letter appointing an alternate representative.- Letter received, person reassigned. David to follow-up for the letter. **Open**
2. 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. Julie to post to the website. **Open**
3. Steve to send Final Finance SOP and SOP/Job Description to co-chairs Karen and Beckie for final signature.
4. Ricky to reach out to David Yadin for contact at BioHouston.
5. Beckie will work on an introduction for Case for Quality and send the information for review.
6. 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.**
7. Diane/ Danieli to obtain a date for 2016 for another FDA 101 at UTD.

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8. Karen- Search for Job descriptions and if not available will need to be developed. **All officers and Typical Chair position will follow the format from the approved Treasurer format.**
9. 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. **Sent out in the meeting**
Chairs and officers to start bullet pointing their roles and responsibilities
10. New Action Items:
 - a. Tom Brink resignation, nomination of Charles Hunter. Voted, approved. Karen to send a welcome and invitation.

New Action item

Committee Reports

- Finance Committee – Steve Juett
- Communications Committee:
- Quality Committee :
- Events Committee:
- Big Event:

Important Dates

2nd quarter

Scholarship Committee Meets

Next meeting date:

Announcements:

9/9/16

Friday, September 09, 2016

7:43 AM

FMDIC Face-to-Face Meeting

July 22, 2016

Agenda

Notes for minutes

Roll call

Diana Easton

Karen Daugherty

Randy Thoma

Lynn Miller, Incell

Jonnetta Wheaton, DSHS

Charles Hunter, DSHS

Don Hurd, realtime

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**John Criscione
Beckie Ellis
Steve Juett**

Absent:

Jeff Mansell in a meeting

Approval/Correction of 6/24/16 meeting minutes.

Action Items from December 4, 2015/March 4, 2016/July 22, 2016 Meetings:

Corrections made to minutes, moved and seconded to accept as corrected. KCD will amend minutes as noted and resent after the meeting.

1. David Makanani to request OK BIO to submit a letter appointing an alternate representative.- Letter received, person reassigned. David to follow-up for the letter. **Open Beckie sent a reminder. He wrote back, thought they were going to sign but since they are a govt. entity, concerned about liability. Action: Beckie will follow up to see if she can move that along.**
2. 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 re-signed by all members at the December meeting. Julie to post to the website. **Open. Jonnetta has picked this up and will replace Julie at this function. Action: Jonnetta will send out a reminder a few weeks before the meeting. Forms are to be returned to Jonnetta, cc: Mary Ellen for uploading to the website.**
3. Steve to send Final Finance SOP and SOP/Job Description to co-chairs Karen and Beckie for final signature. Completed. Beckie has the documents, but Mary Ellen isn't here. Action: Beckie will forward the document (Job Description for the Treasurer and assistant treasurer to Mary Ellen and KCD for electronic signature.
 - a. Goal was to have primary positions likewise completed for the other positions. Neither Beckie nor KCD have completed the job descriptions yet. Mary Ellen likely hasn't either: Action: The other chairs will draft job description.
6. **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. Action: Open, Steve is still working on this.**
 - a. **Diana to obtain a date for 2016 for another FDA 101 at UTD. Diana was wondering about last years conversation with Ricky about some of the things FDA has been seeing as weaknesses in some companies about problem solving. Inquired as to whether there was anything at the university level that taught problem solving skills. Look at what type of problem FDA is seeing and focus the training on that. Last time it was a joint effort with the biomedical group. This would need to be coordinated with Mary Ellen. The FDA101 is a canned package and ready to be used. The other one, the problem solving, we would have to develop curriculum for. The university is going to build a summer short course on problem solving tools and integrating that with CAPA. Diana asked whether any of the other universities had an academic program related to problem solving. Skills and overlaying problem solving skills and root cause analysis and overlaying that with CAPA. John includes root cause analysis with some courses, e.g. quality systems, but not one that is integrated. Sounds like a good FDA201 course.**

7. We were talking about an advanced class, FDA201, about how to resolved the issues when you find that. So we need to develop that. We could regularly do FDA201 for RCA and CAPA. John thought the presentation at the big event was good and we could branch off of that. **ACTION: 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.**

8. Karen- Search for Job descriptions and if not available will need to be developed. **All officers and Typical Chair position will follow the format from the approved Treasurer format. Closed. Randy sent an email that he wants to participate but feels that he will not be able to fill the position of the Quality Committee Chair because he doesn't think he will be here often enough. Beckie asked Randy if he could write up the job description for the quality Committee chair so that we can seek a replacement. ACTION: Beckie will copy of the job description to Randy for the format so that he can write the job description, and then we'll look for a replacement.**

9. 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. **Sent out in the meeting. Completed.**
Chairs and officers to start bullet pointing their roles and responsibilities Open
10. Tom Brink resignation, nomination of Charles Hunter. Voted, approved. Karen to send a welcome and invitation. Letter not sent, but Charles is with us.

Committee Reports

- Finance Committee
- **Steve has the financial component available. Event net amended to reduce total by 50.00 Moved, voted to unanimous to accept as amended.**
- Communications Committee
 - Website Jonnetta will be added the minutes we just voted on, and will update the website so that the big event is not still showing as upcoming, and will also post events for our organizations. By December will be ready with a plan to update our social media to incorporate that in our communication. Jonnetta is going to ask Lars how long he will be available to us and come up with a transition plan if we need to. John asked us to let him know if we want to continue with Lars or add someone to be paid by FMDIC. Steve said that we would need to know what those costs would be so that we could add it to the budget. John said that he can get us historical numbers, and can also look at getting another student to work on an hourly basis. A&M has been supporting this function. Diana said that UTD has a lot of student at the engineering school that are volunteering to be interns as something to put on their resume. That might be a way to do this in a way that doesn't cost anything. Steve said that was the original goal and A&M jumped in, and we've had Lars serving us for a long time now. There are several opportunities, including maintenance of the website. Lars also runs our AV for our events, and that is another activity that could be used in that capacity.
- Quality Committee
Randy had to leave the call, no report.
- Events Committee:
- Beckie will send a separate note to Mary Ellen for an update, we will table this report for now.

New Items:

The next AFDO meeting is next June in Houston. Tom Brinck just reminded me that FMDIC partnered with AFDO a few years ago when they met in Plano. Since there is no big event next year, it could be a great opportunity to collaborate on that again.

Jonnetta said that we sponsored a lunch presentation and handed out pocket 820s. AFDO attendance is split into 2 tracks - food and medical products.
Action Item: KCD will send a link for the AFDO conference and will speak with Randy Young about getting a preliminary agenda and find out how they would like us to support.

For next meeting, Steve requested that Staci take inventory of supplies for next year so we can work into the budget. We've got pamphlets, flash drives, pens, note pads. We will need to vote on the continuing expense. We got a particular type, logo, etc., so we'll need this on the December agenda.

Steve received a letter from Bank of America stating that they had an incorrect email; Steve believes that he was the cause of that because his email did change. Steve confirmed Beckie's email and will correct that.

Round up review of all of the membership contacts. We've usually had the list provided when we've had a membership change. Recommend that we have this available at the December meeting for update. Beckie will send an email to her to find out if we can do this and get this updated.

Continuing Items: Steve was thinking that since we have many new representatives. Previously when we had a lot of new people, we had a roundtable of sharing. We had each association have a meeting date and had each explain what their associate did and what that meant to the FMDIC. The association sponsored these and had discussions, whether they made a presentation of brought in a speaker. This was done at regular quarterly meetings, and did this in alphabetical order. Steve moved resume doing, and I seconded. I agreed that this was a great idea, and Diana agreed. Steve said that he could start with December meeting, and we could go alphabetically. Steve suggested that even Staci. Steve moved, seconded. Unanimous to resume these presentation, starting with Steve in December.

Next Meeting Date: December 16th meeting is our annual meeting. The secretary or co-chair needs to send out an invitation at least 2 weeks prior, required by our Texas incorporation. We have voting, code of conduct meetings. Beckie will send an email to pull a copy of the records. There are no finite limitations. Randy will write the job description.

Discuss the FD201 concept at the next meeting, and finalize the date for the FDA101.

Diana will be working on a date with Mary Ellen. The District has provided speakers for FDA101 in the past.

Motion to adjourn, seconded, adjourned at 10:25 a.m.

Important Dates

2nd quarter Scholarship Committee Meets