

FMDIC Face-to-Face Meeting  
January 17, 2014  
Meeting Minutes

Members Present: Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair)  
Brian Blankenship, AdvaMed (Industry Co-Chair) - Leader  
Steven Juett, ACCE (Treasurer)  
Sue Thomason, FDA-DALDO (Secretary)  
Yadin David, ACCE (alt) - phone  
Rebecca Ellis, ASQ BD (pri)  
Mary Ellen Delaney – ASQ BD (alt)  
Randy Thoma, BioAustin (pri)  
Jamillah Selby – FDA-DALDO  
David Makanani, OK Bio (pri)  
Al Alonso, RAPS - phone  
Audrey Swearingen, RAPS (alt) - phone  
Tom Brinck, TDSHS  
Jonnetta Wheaton, TDSH  
Julie Thomas, TMDA (pri)  
Rafi Baddour, TMDA (alt) - phone  
John Criscione, Texas A&M University (pri) - phone

Members Absent: Darrel Arterburn, AdvaMed (alt) out  
Jo Svochak, CLMA (pri)  
Jeff Mansell, TDSHS  
Susan Turcovski, FDA-DALDO  
Elaine Crosby, FDA-SWRO

1. Roll call: the results above constitute a quorum of membership (10 of 11).
2. Approval/Correction of September 20, 2013 Meeting Minutes: The minutes were approved as written.
3. Members:
  - Alternates needed
    - *Jo will send appointment letter for Jan to Sue when received from CLMA.*  
**Table for next meeting**
    - *Sue to prepare notification letter to MDMA for co-chair signatures dissolving their membership. Letter sent on September 26, 2013 asking for a new appointment or withdrawal of their organization. No response received.*  
**(Closed)**
    - *David M to request OK BIO to submit a letter officially an alternate. David M continues the search. Sherry Stickley is no longer with OK Bio. No word back yet from OK BIO*

- *Steve will contact UTA assistant professor to see if he would like to become a member. Table until the next meeting.*
- *Brian will reach out to OU or OSU as well as Jenna McMillan. Brian reached out 3 times with no response. He will find another contact and try again*
- *Julie knows a UTA research professor and will contact them as well about becoming a member. Julie was unable to find her contact.*
- *Steve to contact local AAMI for a recommended primary and alternate member. **Table***

### **Review of Action Items from September 20, 2013**

- ***ACTION ITEM*** – *Sue to send Facebook information to John. **Will send again***
- ***ACTION ITEM*** – *Sue and Brian to develop scholarship letter. Steve did the letter on our behalf with Jeff's help.*
- ***ACTION ITEM*** – *All members review the Event SOP and respond to Randy by October 4th. Some responses received, edited and sent back out. Review and sent to Randy by January 24, 2014.*
- ***ACTION ITEM*** - *Julie to craft an announcement on the Case for Quality and send to Ricky and Brian for review. Done - Sue to send out and post on 123signup.com and FMDIC website.*
- ***ACTION ITEM*** - *Ricky will create formal letter of invitation to CDRH and send to his contact on Case for Quality. Beckie drafted the letter. Ricky sent the letter to Cynthia Garris at CDRH. **(Closed)***
- ***ACTION ITEM*** - *Sue prepared the co-sponsorship agreement for Ricky and Brian to review and sign. Sue will send the agreement through the Ethics office for approval. Co-sponsorship agreement approved by Ethics office. **(Closed)***
- ***ACTION ITEM*** - *Sue will prepare the Federal Register announcement. Announcement is drafted and will be posted as soon as speakers are confirmed **(Closed)***
- ***ACTION ITEM*** – *Steve to work with Beckie to get her name on the bank signature cards. Steve and Beckie completed the bank cards. **(Closed)***
- ***ACTION ITEM*** - *Ricky and Beckie will work together to finalize arrangement with CDRH. On hold. Ricky has contacted the folks at CDRH and they are interested in working with us. They are working on the update for when they come to Dallas. Speakers have to get approval from Steve Silverman before we get a firm yes. There are new things on the horizon they might want to discuss such as Medical Device Single Audit Program, changes in CDRH staff, Prioritized 483 that's in the works and Using a Risk Measurement (Risk/Impact – Safety/Efficacy). Where we are today and future efforts. Is there 8 hours of work? The plan is for the General session in the morning and breakouts in the afternoon. We need to determine how we will fill an 8 hour day. Adverse events in hospitals as a possible afternoon topic. Top 10 FDA violations is another and we could have Iris discuss topics. There is no firm commitment from CDRH at this time. We need a backup plan and have a general topic title posting then the details on the website with schedule of events. Need to talk about a plan B. Ricky can still do a case for quality element. There is a Pilot in*

one district for voluntary compliance inspections. A company comes forward with an issue and we will not do a surveillance inspection for one year. Al – A company identifies a problem, sends a request to the district to meet with district and discuss remediation plan. Progress reports address issues and FDA agrees not to inspect. CDRH would discuss as the lead. Funding? Probably not an issue for FDA to pay. Scheduling might be the biggest issue. Beckie – Alternate speakers on single audit, notified body audits several years ago. Are there companies going through it now? (**ACTION ITEM** - Beckie will send information to Ricky on this topic.) John - ISO 3045 pilot is another topic and he feels it would be of great interest, especially to start-ups. Both issues are relevant. Brian – Could we move the date of the event? Sue – Not easily or without penalty to the hotel. Ricky – Steve Silverman and Jan Welch could talk off the top of their head on this as well as Bill McFarland. Phil Pontikos and Kim Lewandowski-Walker could also cover these issues. John – Best practices everywhere of value to all industry. Ricky – CDER is doing quality by design and it is evolving into something similar to CDRH. Focus in on right things to maybe change the inspection process to focus on issues that deal with safety and efficacy.

**Incorporation Status** – Steve – We are incorporated. We’re working on federal taxes and trying to get an exemption because we do not have employees. The 1023 issued back in August and we should have a response soon. It could take 18 months to complete. Brian - Will we file 2013 taxes? Steve – This is discussed in the financial report. Tom – What about State purposes? Steve – We’re in good shape. We have no tax liability to the state.

## **Committee Reports**

- Finance Committee
  - Treasurer’s Report – distributed and reviewed.
    - Beckie is on the bank account.
    - 1023 fee change occurred \$850 vice \$750 in the last meeting notes.
    - \$47,501.82 beginning balance
    - \$41,185.18 ending balance
      - Correction needed in event expense total
    - Grant of \$5,000.00 went to University of Central OK.
      - Will change school in the report
  - State of TX tax in good standing
    - CPA talked to comptroller and paid fees
    - Filing fees of \$50 and late filing fee of \$50
  - Projected budget for 2014 distributed and reviewed
  - Projected cost for big event?
    - estimations for big event based on 2012 event spending
      - projecting income \$45K
      - expenses \$36K
      - net projected of \$9K
    - Scholarship next year of \$5k to issue.

- Can send in April 14
    - Will move expenses to April time frames.
  - Beckie motioned to approve 2014 Budget and Randy 2<sup>nd</sup>
    - The budget is approved
- Communications Committee – Julie
  - Lars is back at school and will get back up to speed soon.
  - Next announcement is the big event
    - Sue – The Federal Register announcement takes 3 months to publish
    - Members should announce on association web sites
    - Mary Ellen – ASQ World Conference is scheduled for 5/5-7/14. We should announce early so members will have a choice of which event to attend.
    - How can we advance the publicity to those members? Mary Ellen has announced to local groups. We need to post the ASQ meeting on the FMDIC web site. Can Lars post the May meeting? Go to the ASQ website and link that meeting on our website. (**ACTION ITEM** - John will ask Lars to post link to ASQ meeting.) We can request ASQ posts the Case for Quality on their website. Do a short statement for all members for them to post on their websites.
- Quality Committee – Randy
  - We need to finish the SOP for the event planning.
    - Need to add Pre-Event dinner.
    - He will send it back out to the group for review and update. Track changes format. (**ACTION ITEM** – All members re-review the Event SOP.)
- Publicity Committee – Julie - Combined with communications
- Big Event Committee – (See above in Action Item discussion)

#### New Items:

- Acrylic Award for David Arvelo – Sue recommended we purchase an acrylic award for David and present it at the Big Event. (**ACTION ITEM** – Sue to order award)
- Brian – Would like to give hand-outs/gifts to attendees at our Big Event. We've given ink pens in the past and pads of paper. Several suggestions were made. Brian is to look for items costing approximately \$2/each (**ACTION ITEM** - Brian will research items and send information to members for a vote.)
- Steve – Is the website being maintain and update or will Lars do a rewrite? John – Lars just to maintain at this time. We need to consider mobile users when we do a rewrite. Meeting minutes should match incorporation date. John will have Lars take a look at the website and come back with suggestions. (**ACTION ITEM** – Add to agenda for the next meeting.)

Next Meeting Date – February 7, 2014 Conference Call

2<sup>nd</sup> quarter

**Important Dates**  
Scholarship Committee Meets

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- **ACTION ITEM** - Steve will contact UTA assistant professor to see if he would like to become a member.
- **ACTION ITEM** – Brian will reach out to OU or OSU as well as Jenna McMillan
- **ACTION ITEM** – Julie knows a UTA research professor and will contact them as well about becoming a member.
- **ACTION ITEM** – Sue to send Facebook information to John.
- **ACTION ITEM** – Steve to contact local AAMI for a recommended primary and alternate member.
- **ACTION ITEM** – All members review the Event SOP and respond to Randy
- **ACTION ITEM** - Ricky and Beckie will work together to finalize arrangement with CDRH and discuss plan B
- **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.
- **ACTION ITEM** – Add website discussion to the agenda for the next meeting.
- **ACTION ITEM** - Beckie will send information to Ricky on single audit/notified body audits
- **ACTION ITEM** - John will ask Lars to post link to ASQ meeting.
- **ACTION ITEM** – All members re-review the Event SOP.
- **ACTION ITEM** – Sue to order award for David Arvelo
- **ACTION ITEM** - Brian will research items and send information to members for a vote