

FMDIC Face-to-Face Meeting  
February 7, 2014  
Face-to-Face Meeting

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  
Mary Ellen Delaney – ASQ BD (alt)  
Randy Thoma, BioAustin (pri)  
Jo Svochak, CLMA (pri)  
David Makanani, OK Bio (pri)  
Al Alonso, RAPS (pri)  
Audrey Swearingen, RAPS (alt) - phone  
Tom Brinck, TDSHS (alt)  
Julie Thomas, TMDA (pri)  
Rafi Baddour, TMDA (alt) - phone  
John Criscione, Texas A&M University (pri) - phone  
Jamillah Selby, FDA-DALDO

Members Absent: Darrel Arterburn, AdvaMed (alt)  
Rebecca Ellis, ASQ BD (pri)  
Jeff Mansell, TDSHS - Phone  
Susan Turcovski, FDA-DALDO  
Elaine Crosby, FDA-SWRO

1. Roll Call: the results above constitute a quorum of membership (9 of 11).
2. Approval/Correction of January 17, 2014 Meeting Minutes. The minutes were approved as written

**Review of Action Items**  
from January 17, 2014

- **ACTION ITEM** – *Jo will send appointment letter for Jan to Sue when received from CLMA. Received. CLOSED*
- **ACTION ITEM** - *David M to request OK BIO to submit a letter officially an alternate. OPEN*
- **ACTION ITEM** - *Steve will contact UTA assistant professor to see if he would like to become a member. Declined. CLOSED*
- **ACTION ITEM** – *Brian will reach out to OU or OSU as well as Jenna McMillan. CLOSED*
- **ACTION ITEM** – *Julie knows a UTA research professor and will contact them as well about becoming a member. No response. Will try to find another contact. OPEN*
- **ACTION ITEM** – *Sue to send Facebook information to John. Sent. CLOSED*

- **ACTION ITEM** – Steve to contact local AAMI for a recommended primary and alternate member. **OPEN**
- **ACTION ITEM** – All members review the Event SOP and respond to Randy Some members still need to respond. **OPEN**
- **ACTION ITEM** - Ricky and Beckie will work together to finalize arrangement with CDRH and discuss plan B. Ricky – Received confirmation from CDRH they will attend as well as Kim Ledowski-Walker. Agenda is coming together very nicely for the speakers. Ann Feritter, CDRH to firm the agenda. There will be 8 hours of material. To Yadin David - Would there be an objection to have you speak at another time? He agreed. **CLOSED**
- **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. **OPEN**
- **ACTION ITEM** – Add website discussion to the agenda for the next meeting. **OPEN**
- **ACTION ITEM** - Beckie will send information to Ricky on single audit/notified body audits. **OPEN**
- **ACTION ITEM** - John will ask Lars to post link to ASQ meeting. Completed. **CLOSED**
- **ACTION ITEM** – Sue to order award for David Arvelo. Completed **CLOSED**
- **ACTION ITEM** - Brian will research items and send information to members for a vote. Recommended thumb drives sent by Brian through email. Brian to order and ship to Sue. **CLOSED**

## **Committee Reports**

### Finance Committee

- Budget edited as noted and added 2<sup>nd</sup> plaque.
- Motion to approve 2014 budget passed

### Communications Committee

- No report

### Quality Committee

- No report

### Big Event Committee

- Tentative Agenda
  - Start at 8:00 am with Welcome and Housekeeping
  - 8:10 to 9:00 - Case for Quality
  - 9:05-9:50 - Prioritized FDA 483
  - 9:50-10:50 – Tabletop discussion stakeholder input/feedback.
    - Will have a list of questions at each of the tables.
    - Randy recommended a numbering system for each table to start in different place.
    - AI – Is this a concept or this is real?
      - R3 – Concept needing feedback from industry. Depends on feed back at this meeting.
    - Questions are not set in stone at this time.
    - FMDIC Members – If you have questions/suggestions for improvement about the 483, submit them to Ricky for consideration. **ACTION ITEM**

- Each table to have a flip chart and markers, recorder and presenter. Sue to check on room set up to make it interactive session. **ACTION ITEM**
- 10:00-12:00 - Report outs from tables and Q&A's.
  - Need to capture report outs and charts from each table. CDRH will take back as a work product to incorporate into the development of the product.
    - Julie – Breaks?
      - We will have to structure the agenda with a break.
    - Beckie – wrap up conversation at the end, talk through the process so people can understand what happens to the information.
    - Tom – how many people to a table? Sue - 6 in crescent, 10 in full banquet.
    - Al- what if we don't get the Q&A to fill an hour.
      - Ricky - Been through this before and he feels it will fill the hour.
- 12:00-1:00 lunch
- 1:00-1:30 – Data transparency and matrix. CDRH's handling of information they are receiving from industry and what they're doing to make it available to industry.
- 1:30 2:45– Tabletop discussion on matrix for measuring sets of questions.
  - How does industry currently measure quality, ID trends like yours?
  - How will data assist you in identifying trends in your products?
- 2:45 – 3:30 - Report outs
- 3:30 – 3:45 - break
- 3:45 – 4:00–Recall and enhancement guidance
- 4:00 – 4:15 – Voluntary compliance and inspection guidance
- 4:15 – 4:45– Single audit program
- 4:45 – 5:00 – Reorganization office of compliance
- 5:00 – 5:30 - Closing statements, next steps and summary of the day. Recap of information from industry.
- Agenda changes discussed
- Sue to check with hotel to see if we can extend time in the room. **ACTION ITEM**
- Ricky with work on the agenda and send it to Julie for review/input
  - Ricky will send the agenda to CDRH Team. **ACTION ITEM**

#### New Items

- Membership
  - New - BioMed SA
    - Mary Pat Moyer – Primary representative
    - New member accepted by unanimous vote
  - Audrey Swearingen resigned as alternate RAPS member
    - Sue will order plaque for presentation to her at the April event (**ACTION ITEM**)

Next Meeting Date – June 20, 2014 unless another update call is needed prior to the event.

2<sup>nd</sup> quarter  
April 11, 2014

**Important Dates**  
Scholarship Committee Meets  
FMDIC Educational Forum