

FMDIC Face-to-Face Meeting  
September 19, 2014  
Agenda

Members Present: Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair)  
Brian Blankenship, AdvaMed (Industry Co-Chair) - Leader  
Sue Thomason, FDA-DALDO (Secretary)  
Steven Juett, ACCE (Treasurer)  
Yadin David, ACCE (alt) - phone  
Rebecca Ellis, ASQ BD (pri)  
Mary Ellen Delaney – ASQ BD (alt)  
Mary Pat Moyer, BioMed SA (pri)  
Jo Svochak, CLMA (pri)  
David Makanani, OK Bio (pri)  
Tom Brinck, TDSHS (alt)  
Jonetta Wheaton, TDSHS (alt)  
Julie Thomas, TMDA (pri)  
Danieli Rodrigues, University of Texas at Dallas (pri)

Members Absent: Randy Thoma, BioAustin (pri)  
Al Alonso, RAPS (pri)  
Rafi Baddour, TMDA (alt)  
John Criscione, Texas A&M University (pri)  
Jeff Mansell, TDSHS  
Darrel Arterburn, AdvaMed (alt)  
Elaine Crosby, FDA-SWRO

1. Roll Call: the results above did constitute a quorum of membership (9 of 11).
2. Approval/Correction of June 20, 2014 minutes. Correction made to reflect 2014 instead of 2011. Approved as corrected.

**Review of Action Items**  
from June 20, 2014

- **ACTION ITEM** - David M to request OK BIO to submit a letter officially an alternate. **(OPEN)**
- **ACTION ITEM** – Steve and Yadin to contact local AAMI for a recommended primary and alternate member. <Note: Since the meeting, Albert DeWeese [[albert.deweese@goodautomation.com](mailto:albert.deweese@goodautomation.com)] has had an interest in joining and was referred to AAMI to get a letter recognizing him as a member. > Contacted by AAMI representative, Allison (Whitaker) Rafti in Arlington, VA expressing interest in renewing their membership. She wanted more information on FMDIC and to update their logo on our web page. No decision has been made for Mr. DeWeese's membership. Sue provided dial-in information for her to dial-in to this meeting.
- **ACTION ITEM** – All members review the Event SOP and respond to Randy. **(OPEN)**

- **ACTION ITEM:** Randy will resend SOP and all members are to respond to him by July 31, 2014. **(OPEN)**
- **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:** Jeff to verify this is an annual requirement. Confirmed it is an annual requirement. **(CLOSED)**
  - **ACTION ITEM:** Sue to send out the form with the agenda for the official annual meeting by July 18, 2014. Sent. **(CLOSED)**
- **ACTION ITEM:** Add website discussion to the agenda for the next meeting **(CLOSED)**
- **ACTION ITEM:** Randy to review Scholarship SOP and send out to members for review. **(OPEN)**
- **ACTION ITEM:** Al will prepare a thank you letter for Dan Lassiter. Letter sent and signed by co-chairs. **(CLOSED)**
- **ACTION ITEM:** Sue to order FMDIC plaque for Dan. Suggested wording reviewed by those in attendance. Sue will place the order. Steve and Ricky will present the plaque and letter to him once the plaque is received. **(CLOSED)**
- **ACTION ITEM:** Steve to prepare an SOP for the treasurer's position Steve distributed the proposed SOP for the members in attendance to review. Steve will forward the SOP to the Quality Committee for final approval. **(OPEN)**
- **ACTION ITEM:** Brian to search websites for examples and send to Julie. Julie and Brian to discuss and send recommendations to Lars. **(OPEN)**
- **ACTION ITEM:** All members need to review the Event SOP and send their recommendations to Randy by 7/31/14. **(OPEN)**
- **ACTION ITEM:** Ricky to review the Big Event responses and send to the group for their input. **(CLOSED)**
- **ACTION ITEM.** Sue to send email notifying attendees of aggregate of information from Big Event. **(CLOSED)**
- **ACTION ITEM:** Sue to find a venue Houston on Friday, August 22, 2014. Selected the Norris Conference Center Houston/Westchase for Devices 101 event. **(CLOSED)**
- **ACTION ITEM:** Steve and Beckie work together on Scholarship for next year. **(OPEN)**

## **Committee Report**

- Finance Committee
  - Treasury's report distributed
  - Ending balance as of 8/31/14 - \$38,737 with an estimated \$1,870 more income to be released by 123SignUp
  - John and Al expense received for Devices 101 in Houston
  - Hats off to Staci and Sue on reducing expenses and working with the venue.
  - No expenses for Brian or Steve.
- SOP for the treasurer position – Hard copies reviewed, recommended changes made.
  - Financial reporting grid attached.
  - Finance committee prepares reports with tax filing assistance from the CPA.
  - Julie – Recommend to label tables as the attachments. Attachment A - really aren't due dates. Recommend removing due date from A.
    - Capialize Resources and move to the left.

- Version changes in footer to make uniform. **ACTION ITEM:** Steve to change and send out. Members to vote on line
- Communications Committee –
  - Website - Julie - Sprucing up the website and making changes to what is public and what is private. Brian and Julie will work on it.
    - Decide as a group what needs to be public.
      - Brian everything is open to see except the SOPs and scholarship information.
      - Ricky post only after finalized. Remove signatures and state the signatures are on file.
    - BIOMedSA information is needed for the membership area.
      - Should Bio Houston be a member? Sue reached out to them before the 101 but did not get a response. **ACTION ITEM:** Brian or Ricky will reach out to BioHouston to see if they want to return to FMDIC. Yadin has a contact and will help with communication. Yadin will be backup if Brian or Ricky are not successful.
    - Julie update areas of the website. Post minutes up to point of incorporation. **ACTION ITEM:** Sue to review website to see what minutes are needed and forward to Julie to have Lars post.
- Quality Committee – Randy – No Report
- Event Committee
  - Devices 101 Report
    - Brian – 14 registered with 1 walk-up.
      - Wide range of experience. From years to brand new. Lots of good questions. Venue was very good. Met criteria of education and was very well received.
  - Beckie – Will there be a Devices 201? Format should be more than basic 101 but not to the extent of the big event. We need something in-between like a how to or what it is? A transition from knowing the regulation to the implementation phase. Brian – can we make it happen? Ricky – The expertise is in the room. Brian – take 4 or 5 pieces of QSIT. Ricky – This is what we’ve done for our big events. **TABLE** –for the next meeting.

#### New Items

- Danieli – I’m looking for ways to connect students with the industry real world after graduation. We need to close the gap between university learning to real world application. Can FMDIC meet with the department head in an effort to show the importance of compliance? Beckie – We could do a special seminar day and have Device 101 as a part of that seminar day. We could put an emphasis on local resources. Steve - Use class room as a source to present FMDIC 101. Mary Pat – Education is a part of our goal. How can we provide the tools to the students to prepare them for industry? Danieli – She’s flexible to develop a course. Mary Pat – internships. We need to try to address this need.

Next Meeting Date  
December 12, 2014

2<sup>nd</sup> quarter

**Important Dates**  
Scholarship Committee Meets