

FMDIC, Inc.  
Face-to-Face Meeting  
December 7, 2012

Members Present: Jeff Mansell, TDSHS (Regulatory Co-Chair) - Leader  
Al Alonso, RAPS (Industry Co-Chair)  
Steven Juett, ACCE (Treasurer)  
Sue Thomason, FDA-DALDO (Secretary)  
David Braeutigam, AAMI (pri) - Phone  
Brian Blankenship, AdvaMed (pri) - Phone  
Rebecca Ellis, ASQ BD (pri)  
Mary Ellen Delaney – ASQ BD (alt)  
Randy Thoma, BioAustin (pri)  
Jo Svochak, CLMA (pri)  
David Makanani, OK Bio (pri)  
Audrey Swearingen, RAPS (alt)  
David Arvelo, FDA-SWRO - Phone  
Ricky Rodriguez, FDA-DALDO  
Susan Turcovski, FDA-DALDO  
Tom Brinck, TDSHS (alt)  
John Criscione, Texas A&M University (pri) - Phone

Members Absent: Julie Thomas, TMDA (pri)  
Graham Giesen, FDA-DAL  
Elaine Crosby, FDA-SWRO  
Darrel Arterburn, AdvaMed (alt)

1. Roll call: The results above constituted a quorum of membership.
2. Approval/Correction of September 7, 2012 Meeting Minutes: The minutes were reviewed and discussed. Motion made to amend the Members Present area to reflect Jamie Hughes as representing Ricky Rodriguez during the meeting. Minutes approved as amended.
3. Members: David Arvelo announced his resignation from FMDIC, Inc. due to a change in his position to an extended detail position in the Office of Communications at headquarters as a Communication Specialist. This detail requires him to no longer perform the duties as Small Business Representative for the SWR and may become permanent a position. David distributed his FMDIC, Inc. duties to current members as follows: 123 Sign Up – Treasurer and Secretary; Website – Webmaster needed with Secretary as administrator and will add Jeff as an administrator; Linked-In – Beckie Ellis; and Facebook – Secretary as manager and add others as administrators. David will transfer archival documents to an electronic folder on the website or a USB drive. He will post information on the Federal Register notifications for Devices 101 and the big event.

- Alternates needed
  - CLMA – letter sent for president’s signature
  - ACCE – no action
  - AAMI – no action
  - Academia – no reply after 2 email follow-ups. Jack Hart was suggested as a possible alternate. He’s now retired from UT. He is a member of TX Medical Device Alliance. Ricky – Would he consider leading the academic part of Devices 101? John will talk with him. He may have recommendations for someone else if he declines. Ricky – He could help with disbursement of the scholarship as well. John – Does anyone know an academic in an OK university? Brian will look into it (**ACTION ITEM**)
  - MDMA – Beckie – written 3 times for primary and secondary. Recommendation to drop MDMA from membership if no one nominated by next meeting. Beckie will contact them one more time (**ACTION ITEM**)
  - TMDA – Julie - Their next meeting is in February and will select an alternate at that time. (Update sent via email prior to the meeting.)

### **Review of Action Items from September 7, 2012**

- ACTION ITEM – Jo to follow-up on the appointment letter for CLMA alternate – see above
- ACTION ITEM - Beckie will determine if she can be the primary for MDMA or find another person to be the primary. – see above
- ACTION ITEM - Steve to send forms to Sue to maintain with FMDIC files. Forms received (**CLOSED**)
- ACTION ITEM – Al to give TMDA letters to Jeff for signature. (**CLOSED**)
- ACTION ITEM - Jeff to return signed letters to Sue. (**CLOSED**)
- ACTION ITEM – Sue to send the signed letters to TMDA. (**CLOSED**)
- ACTION ITEM – Julie to seek an alternate for TMDA – see above
- ACTION ITEM – Steve to ask David B to be secondary signature on FMDIC bank account. David B – Not at this time but appreciates the offer. Beckie agreed to be the second signature. (**CLOSED**) Steve will get with her to let her know what might be needed. We are closing the OK bank and open an account in TX. We will add the signatures at that time. (**ACTION ITEM**)
- ACTION ITEM – Randy and the Quality Committee will update the Charter and SOPs to reflect the new corporation. (**CLOSED**)

### **Incorporation Status Report**

- Jeff, Al and Steve are proceeding with incorporation in Texas
  - Documents for review today need to be finalized
  - Working with the CPA to complete the process with the IRS

### **Committee Reports**

- Finance Committee
  - Treasurer’s Report

- Distributed and reviewed
- IRS 1023 form for non-profit organization to be recognized by IRS as tax exempt. Move forward? Get with CPA for end of year tax preparation. Ricky - Approximate cost? The Form 1023 - \$15. Dan (CPA) – Will let officers know about the cost and approval of filing forms. Franchise tax – state related, 6 months to a year to file. Have to report even it is zero dollar reporting. Ricky – Is there a penalty? OK dropped. New one franchise tax and agree to meet the rules. Rollover funds may be taxed. Need to get the Form 1023 in fast to file against or we'll have to pay.
- Communications Committee – No Report
- Quality Committee
  - Randy sent documents electronically last week for everyone's review
  - We will focus on SOP, Charter and Scholarship.
    - Changed all documents to reflect the new name
    - SOP – responsibilities
      - Gatekeeper not necessary - Strike
      - Reaffirmation of primary and alternate representatives no longer needed. Ricky – We need to concentrate on inactive member associations. Tom – Removal members if not attending. Beckie – as the coalition, we can contact inactive members to see if they want to continue.
      - Tom – format of the agenda should match the bylaws.
      - Randy proposed, based on amendments, we approve as it is amend. Sue to make changes in documents, get them signed and distributed. (**ACTION ITEMS**)
      - Jeff – Let's keep moving on all the documents today so we can concentrate on getting the bylaws to pass today. Conflict of interest and scholarship guidelines need to be reviewed. We need those documents for the packet approved today. Audrey – De we need the By-laws, event planning, etc? Jeff – We need some of these to be submitted with the non-profit application. Form 1023 application asks for a lot of the documents. Randy – Could we eliminate the SOP if everything covered in the by-laws.
      - Let's modify the responsibilities in the SOP
        - Hold for now until bylaws reviewed
      - Hard signatures on the documents are needed
        - Co-chair 1 and co-chair 2
    - Charter
      - Election of officers discussed
      - Tom – coalition terminology. Do we use the organization title or can we use “further refer to “coalition” statement”
        - Coalition is in the title and indicated cooperation between government and industry.
    - Scholarship
      - How will we be reminded when the scholarships are due?
      - It is a line item in budget that's reviewed annually

- SOP is written now as bi-annual distribution
- Steve - EOY budget review decide on whether we will fund for that year. 1<sup>st</sup> quarter budget review. Delay until after review complete
  - Ability to award scholarship will be determined during the 1<sup>st</sup> quarter budget review and assigned as an action item to the scholarship committee.
  - Grant to a student recommended by John. Write the check to the university for the student's use upon their need. Grant to the university.
- Educational Event Planning – table for further work on Devices 101.
  - Al asked Ricky to name someone to work on Devices 101 at least 6 months out. Target to hold the next one in June?? Ricky - A basic medical device investigator would be able to do it.
- By-laws on the screen
  - Board of directors not needed in the state of TX. Can be management by members only. Functionally we can exist the same either way. (TX code). Very similar to how we've been operating for years. We can change the certificate to management by members for \$15. Need to vote to change if so desired. Board can be the current officers. Steve – we can add advisors. David M – What are the down sides? Jeff – President/secretary minimum if you name officers. Can select a committee to serve the function of a president. Structurally can set by-laws to operate either way. Al – The greater the number harder to get a decision. Officers – fewer numbers to make the decision. In the past, everyone had a say. Jeff – We're still set up that way and most things still call for a vote by the members. Bylaws could be shorter if members instead of board. Benefit for board we may be close to finishing the by-laws and submit. Steve – Voting today doesn't prevent us from changing our minds later on. Jeff did a push to get legal zoom to provide us with a Texas document. Compare with what we have now. Steve \$99 and included access to other documents \$200 at the most to get reference documents. It outlines all these piece for which we have responsibility to the state. Calendar with deliverables to the state and IRS. Beckie – stay compliant. Ricky – \$99 to get in and \$99 to continue? Steve – annual \$99 fee. One year to get it and determine our structure. They are willing to be the registered agent to keep us compliant on our required reporting. Calendar of events really helps me. Jeff – would like to have had the document months ago. We

really need to get it moving and file this year. Get in great shape - great. Hold off mailing to IRS until we are satisfied with the documents. Steve – use just to help us with the taxes. Audrey – go through the bylaw and get it in place.

- Who would take this action? (2<sup>nd</sup> para by-laws) Tom – board of directors
  - Board of directors (officers)? Described in the document
  - John voice concerns about organizations being members with representatives. He feels the representatives are the members and not the organization they represent. Jeff – member list (Discussed)
  - Are the members' actions actionable?
  - See yellow highlighted areas (in the by-laws) for discussion and recommended changes to the by-laws.
  - Finding out what the requirements of Title 5 Chap 555 are and identify our exemptions. More research needed to make sure we are not in violation. Registration is considered a service and receipt of government funds. Beckie will write an SOP on compliance with the TX open meeting act in lieu of a footnote. ACTION ITEM
  - Add financial limits in a procedure and not in the by-laws
  - Beckie voted in by all as assistant treasurer
  - By-law as amended. Beckie motioned Randy 2<sup>nd</sup> passed carried by voting members.
- ACTION ITEM - Sue to resend electronic documents to Randy
  - Publicity Committee – No Report
  - Big Event Committee – No Report necessary

New Items –

- The next Devices 101 course – Requested for the agenda by Julie Thomas.
  - Table until Event SOP finalized

Next Meeting Date – March 22, 2013, 9:00 am, Dallas District Office (announced after the meeting via email from Jeff)

### **Important Dates**

2<sup>nd</sup> quarter

Scholarship Committee Meets