

FMDIC, Inc.  
Face-to-Face Meeting  
June 21, 2013

Members Present: Brian Blankenship, AdvaMed (Industry Co-Chair) - Leader  
Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair)  
Steven Juett, ACCE (Treasurer)  
Sue Thomason, FDA-DALDO (Secretary)  
David Makanani, OK Bio (pri)  
Al Alonso, RAPS  
Jeff Mansell, TDSHS - Phone  
Julie Thomas, TMDA (pri)  
Jane Andrews, TMDA (alt) - Phone  
John Criscione, Texas A&M University (pri)

Members Absent: Darrel Arterburn, AdvaMed (alt)  
Rebecca Ellis, ASQ BD (pri)  
Mary Ellen Delaney – ASQ BD (alt)  
Randy Thoma, BioAustin (pri)  
Jo Svochak, CLMA (pri)  
David Braeutigam, AAMI (pri)  
Audrey Swearingen, RAPS (alt)  
Tom Brinck, TDSHS (alt)  
Susan Turcovski, FDA-DALDO  
Elaine Crosby, FDA-SWRO

1. Roll call: The results above constituted a quorum of membership (8 of 11).
2. Approval/Correction of March 22, 2013 Meeting Minutes: The minutes were approved as written.
3. Members:
  - Alternates needed
    - CLMA – Continue to table until Jo is able to attend
    - ACCE - Steve asked Forrest Fox to be his alternate. He hasn't responded as of yet. He works for Methodist in Houston and was recommended by ACCE.
    - AAMI – Tabled. We need to reach out to David Braeutigam see if he is still interested in representing AAMI. We should get him more involved. The suggestion was made to see if he would do the first presentation? **ACTION ITEM** - Ricky will contact David Braeutigam and see if he wants to continue to represent AAMI and see if he will do a presentation to the group.
    - Academia
    - MDMA
    - OK BIO

**Review of Action Items from March 22, 2013**

- **ACTION ITEM** – John will email Dr. Hart to see if he is interested in becoming the alternate. Dr. Criscione has not yet contacted Dr. Hart. Julie Thomas volunteered to

contact him. **ACTION ITEM** – Julie Thomas to contact Dr. Hart to see if he would like to serve as the academic alternate.

- **ACTION ITEM** – Sue to prepare notification letter to MDMA for co-chair signatures dissolving their membership. Not yet done.
- **ACTION ITEM**- David M to request OK BIO to submit a letter officially naming Sheri Stickley as their alternate. Not yet done.
- **ACTION ITEM** – Steve to work with Beckie to get her name on the bank signature cards. Not yet done.
- **ACTION ITEM** – Schedule Devices 101 Sue to contact Jeff Cole/QA rep at MNTC at 405-364-5763 and the JJ Pickle Center in Austin for availability in July or early August.
  - Get break even amount for both facilities .
  - Completed and scheduled for July 19 and July 26 respectively. For future events, establish minimum attendees threshold to hold the event.
- **ACTION ITEM** - Sue to send Pickle Center estimated costs to Steve for the budget.  
Done
- **ACTION ITEM** – John to find a student to work as webmaster for FMDIC . Done. Lars is now the webmaster. Need to give Facebook access to John to delegate to Lars. Jeff to send FMDIC information to John. **ACTION ITEM**: Sue to send Facebook information to John. Jeff to send FMDIC website information to John.
- **ACTION ITEM** – Sue to update and send Scholarship/Grant and Charter documents
  - Scholarship letter to accompany the letter to grantee. Sue to develop letter giving the scholarship. Steve to write check. John will discuss with grant person at A&M for guidance for Sue on the letter. **ACTION ITEM**: Sue to develop scholarship letter after receiving guidance from John.
- **ACTION ITEM** – Sue to send RFPs, conduct site visits and bring recommendations for venues for the big event. Sue discussed findings of the site visits and the pros and cons of each site. The Wyndham Dallas Suites – Park Central was unanimously selected based on reason, location, internet, room rate for all attendees.

**Incorporation Status Report** – Al – All needed documents for CPA Dan Lassiter have been completed. The Form 1023 was completed by Al and Jeff with the help of the Dan. Documentation for grants, changes to the scholarship document were needed. The various requirements for the scholarship document were discussed and the changes were made to complete the document. Steve will be delivered it to Dan today. Dan will file taxes as our agent. FMDIC, Inc. is registered as nonprofit in the state of TX. We need to complete the 1023 federal form. State forms are completed. Do we owe the Dan? Steve asked him to invoice us for \$400 for his services. Jeff – Once we get the scholarship guideline done, we’re complete. Brian – Do we know how much we owe in taxes? Steve – Franchise tax for TX doesn’t kick in until \$1M or more in holdings. We have to receive exemption first before filing federal taxes. The estimate is \$3800 federal tax owed for last year.

#### Committee Reports

- Finance Committee
  - Treasurer’s Report distributed
  - Budget comments received
    - Budget discussed.
      - Added refreshments
      - 101s added
      - Net from meetings go into the general funds

- \$750 filing fee to be added
  - All motion to approve the report and John seconded
  - Financial report Jan-May
    - Two expenses
    - Check received from 123
  - For the Scholarship letter, Beckie needs to be on the bank cards.
- Communications/Publicity Committee – Julie
  - There is a link on the TMD site for Medical Devices101
    - Ask for direct mailing to TMD members
  - Will work with Lars on the website and other links
    - Work needs to be done to refresh the look of the site
    - Log of work
    - Button to register
- Quality Committee – No report
- Medical Devices 101
  - Iris MacInnes will present for FDA in AUS
  - Maybe Margy in OKC
  - John will do certificates
    - FMDIC, Inc. will pay
- Big Event Committee – Beckie not in attendance
  - Wyndham Dallas Suites – Park Central approved as the venue
  - Date 4/11/14
  - Case for Quality potential topic – Ricky to work with Beckie and take the lead with CDRH to bring the topic here
    - Oct 2011, CDRH strategic plan
    - Move from compliance focus to a quality focus
    - Quality from design phase forward
      - Change the mindset
    - Three groups
      - Transparency
        - Data
      - Focus on Quality (division of enforcement)
      - Stakeholder Engagement (Ricky)

New Items – A request was made to start back having presentations by member organizations during our quarterly face-to-face meetings.

Next Meeting Date – September 20, 2013. Adjourn at 1202.

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- ***ACTION ITEM*** – Sue to send Facebook information to John. Jeff to send FMDIC website information to John.
- ***ACTION ITEM*** – Sue to develop scholarship letter after receiving guidance from John.
- ***ACTION ITEM*** – Ricky will contact David Braeutigam and see if he wants to continue to represent AAMI and see if he will do a presentation to the group.
- ***ACTION ITEM*** - Ricky to contact Beckie and take the lead with CDRH to present Case for Quality at our event