

FMDIC Face-to-Face Meeting Minutes  
June 1, 2012

Members Present: Al Alonso, RAPS (Industry Co-Chair) - Leader  
Jeff Mansell, TDSHS (Regulatory Co-Chair)  
Steven Juett, ACCE (Treasurer)  
Sue Thomason, FDA-DALDO (Secretary)  
David Braeutigam, AAMI (pri)  
Brian Blankenship, AdvaMed (pri)  
Mary Ellen Delaney – ASQ BD (alt)  
Randy Thoma, BioAustin  
David Makanani, OK Bio (prim)  
Audrey Swearingen, RAPS (alt)  
David Arvelo, FDA-SWRO (by phone)  
Tom Brinck, TDSHS (alt)  
John Criscione, Texas A&M University (pri)  
Graham Giesen, FDA-DAL

Members Absent: Rebecca Ellis, ASQ BD (pri)  
Jo Svochak, CLMA (pri)  
Ricky Rodriguez, FDA-DALDO  
Susan Turcovski, FDA-DALDO  
Elaine Crosby, FDA-SWRO  
Darrel Aterburn, AdvaMed (alt)

1. Roll call: The results above constituted a quorum of membership. See member list

- Graham Giesen was introduced as the newest member representing Dallas District. Graham is the new Medical Device Program Manager

Approval/Correction of March 9, 2012 Meeting Minutes - Steve Juett motioned the minutes be approved. Tom Brinck seconded the motion and the minutes were approved.

#### Members

- Alternates needed
  - CLMA – has one but name not submitted to Sue to do the letter of membership.
  - ACCE – not yet Steve is still looking and hopes to get one soon.
  - AAMI – not yet. David B is still looking for a local alternate.
  - Academia – Emails were sent with no response. Graham will give recommendations at the next meeting.
  - MDMA – Mary Ellen to check with Beckie to see if she will represent MDMA and then Mary Ellen will move to the primary for ASQ.

## Review of Action Items from March 9, 2012

- Incorporation Status – Brian or Steve
  - Al is working with Jeff and they have a meeting today with the CPA.
    - Recommendations
      - Dissolve the old FMDIC
      - Take penalties from IRS
      - Start fresh with new organization
    - Will work with CPA to start process
      - All financial documents were sent to CPA
      - CPA says we don't exist on IRS roles
    - Al and Jeff will report back following their meeting with the CPA (**Action Item**)
  - Steve – Finance committee discussed the process
    - Decision and recommendation
      - Al – officers given the approval process in this issue
      - Jeff – file in TX, proceed in TX and fire Jon T
      - Dissolve in OK and file paperwork in TX
      - Decision made by officers
        - Dissolve OK FMDIC after filing taxes and incorporating TX
        - Resolve taxes
        - Establish address in TX
        - Name responsible person
        - Bylaws, officers, annual meeting designation
        - Minutes at each meeting
        - Decisions made by officers and finance committee

## Committee Reports

- Finance Committee
  - Treasurer's Report - Distributed
  - Activities – Mail box but not PO box obtained through UPS services and acceptable as a business address. Saved 20% by purchasing for a year. 4447 N. Central Expressway, Dallas, TX 75205.
  - With Bank of America required 3 trips to get Bill off the account
    - Bill still on as primary
    - Access on web but no ownership on account as treasurer
    - Steve is the only one with signature capability
      - Brian's signature is not currently on and he doesn't have access to the internet account
  - Requested EIN information
  - Deposits
    - Big event registrations and one check deposited
  - Expenses

- Legal fees paid and the firm fired
    - Scholarship distributed
    - Reimbursed Jeff for food
    - Plaque for Michael
  - Next quarter financials – big event expenses and completing IRS obligations
- Communications Committee – David Arvelo
  - Advertising event
  - Building bios and website
  - New emails out
- Quality Committee - Randy
  - No specific activity other than draft of SOP for events
  - Need feedback
    - Take another look at timeline
    - Include 101 in review
  - Al – Do we need to meet after the big event to update timeline?
  - Let Randy know about changes to the status of the organization to update SOPs
  - John – run both corporations?
    - Steve – run both until the end of the year.
    - John – do it and get everything transferred as soon as possible. File today with articles of incorporation.
- Publicity Committee- David A (see above)
- Big Event Committee – Al chair
  - Venue report – 2 wireless microphones requested and no need for an all day technician
  - Al – has gotten with Graham and the other speaker
  - Pre-event dinner discussed
  - Randy – get with Scott to introduce to his counterpart
  - Agenda – Changes will update beforehand
    - Drop dead date? David – today
    - Template FMDIC out to speakers? Randy sent to Scott. Al sent to David Furr. Graham to get FDA presentations on template. David A will send template to FDA. COB on Friday, June 8.
    - Agenda reviewed
    - Confidence monitor?
    - Evaluation form – David A
    - Drop WiFi and all day tech in room
    - CEU Form – John. Will check with office to get the form.
    - Graham – Advertised to local engineering programs? North TX Bio Association local announcement made. John - Can offer course credit if student enrolled (future)
    - Consent decree – still keep? Al explained reason behind having it on the agenda. Deal with WL only? Run by Ricky to make sure info will be agreeable. **Action Item - AL**
    - Recap just before Q&A
      - David – Explained what will happen
      - Cards to be distributed

- Panel discussion with Ricky as moderator
- Hold cards and write their answer on the card
- Post Q&A if possible.
- Mention 101? Information for attendees.
- Student rate – Motion to keep the early rate for the students
  - Graham motioned. Jeff seconded. The motion passed with one dissention
- Graham - Last topic title – focus on 483 and WL. **Action Item** – Sue will arrange a conference call for R3/AI/David F/Graham

New Items –

- Consideration of Texas Medical Device Alliance as a member of FMDIC – Dr. Criscione
  - Spoke there on behalf of FMDIC in February
  - Interested in what we're doing
  - Jack Hart device companies in TX will help getting the word out
    - Can capture the Austin crowd
    - Former professor at UT and helped organize their program
    - Started TMDA
  - Julie Thomas nominated as their primary member
  - John motioned to accept the membership of TMDA. Randy seconded the motion and the motion passed. **Action Item** – John to ask TMDA to submit formal appointment letter to Sue. Sue to prepare membership letters for TMDA.

Next Meeting Date – Conference call next Friday? David A June 8 at 9:00. Subcommittee reports needed

Next Quarterly Meeting – September 7<sup>th</sup>. This meeting will count as the Annual Meeting for incorporation purposes.

### Important Dates

2 <sup>nd</sup> quarter	Scholarship Committee Meets
June 15, 2012	FMDIC Educational Forum