

FMDIC Face-to-Face Meeting  
September 20, 2013  
Meeting Minutes

Members Present: Ricky Rodriguez, FDA-DALDO (Regulatory Co-Chair) - Leader  
Brian Blankenship, AdvaMed (Industry Co-Chair)  
Steven Juett, ACCE (Treasurer)  
Sue Thomason, FDA-DALDO (Secretary)  
Darrel Arterburn, AdvaMed (alt)  
Rebecca Ellis, ASQ BD (pri)  
Mary Ellen Delaney – ASQ BD (alt) - phone  
Randy Thoma, BioAustin (pri) - phone  
Jo Svochak, CLMA (pri)  
David Makanani, OK Bio (pri)  
Al Alonso, RAPS - phone  
Jeff Mansell, TDSHS - Phone  
Julie Thomas, TMDA (pri)  
Jane Andrews, TMDA (alt) - Phone  
John Criscione, Texas A&M University (pri) - phone

Members Absent: Audrey Swearingen, RAPS (alt)  
Tom Brinck, TDSHS (alt)  
Susan Turcovski, FDA-DALDO  
Elaine Crosby, FDA-SWRO

1. Roll call: the results above constitute a quorum of membership (10 of 11).
2. Approval/Correction of June 21, 2013 Meeting Minutes: The minutes were approved as written.
3. Members:
  - Alternates needed
    - CLMA –Jan Svochak will be the alternate. Jo will get the appointment letter from CLMA. (**ACTION ITEM** – Jo will send appointment letter for Jan to Sue when received.)
    - ACCE - Steve recommended Yadeen David, PhD from Houston as his alternate and sent ACCE the recommendation to approve his appointment. ACCE asked to send appointment send letter.
    - AAMI – David B resigned. We now need a primary and an alternate member from AAMI. Ricky asked him for a recommended replacement and he said he will provide a name soon. (**ACTION ITEM** - Steve is a member of AAMI and will go to the AAMI group to find someone else.)
    - OK Bio – David M continues the search. Sherry Stickley is no longer with OK Bio.
    - Academia – Julie contacted Dr. Hart and he declined as he is not in academia at this time. John suggested we look at the Dallas area at UT Arlington or UT

Southwestern. Steve knows a UTA assistant professor and will reach out to him to see if he or others would want to join. (**ACTION ITEM** - Steve will contact UTA assistant professor to see if he would like to become a member.) Brian talked with Jenna McMillan, PhD, OK Science Center at 101 in OKC. She was interested in scholarship funds and may be interested in becoming a member. (**ACTION ITEM** – Brian will reach out to OU or OSU as well as Jenna McMillan) (**ACTION ITEM** – Julie knows a UTA research professor and will contact them as well about becoming a member.)

### **Review of Action Items from June 21, 2013**

- **ACTION ITEM** – Julie Thomas to contact Dr. Hart to see if he would like to serve as the academic alternate. Closed
- **ACTION ITEM** – Sue to prepare notification letter to MDMA for co-chair signatures dissolving their membership. Not yet prepared.
- **ACTION ITEM**- David M to request OK BIO to submit a letter officially naming Sheri Stickley as their alternate. OK Bio has reorganized. David will continue to seek an alternate.
- **ACTION ITEM** – Steve to work with Beckie to get her name on the bank signature cards. Steve and Beckie will schedule a time and location to sign the bank cards.
- **ACTION ITEM** – Sue to send Facebook information to John. Jeff to send FMDIC website information to John. Jeff sent website information. Sue needs to find the information and send to John.
- **ACTION ITEM** – Sue to develop scholarship letter after receiving guidance from John. Tabled. Guidance not yet received. Sue will continue to work on letter.
- **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. Ricky contacted David and discovered he could no longer continue in FMDIC and therefore resigned. David said he would send his recommendations to Ricky and AAMI for his replacement.
- **ACTION ITEM** - Ricky to contact Beckie and take the lead with CDRH to present Case for Quality at our event. Ricky will create formal letter of invitation to CDRH and send to his contact on Case for Quality. Sue prepared the co-sponsorship agreement for Ricky and Brian to review and sign. Sue will send the agreement through the Ethics office for approval. Sue will prepare the Federal Register announcement. Case for Quality presentation and format discussed. CDRH would come here to present since they haven't been to the middle part of the country. Ricky and Beckie will work together to finalize arrangement with CDRH.

**Incorporation Status** – Steve stated we are incorporated in TX as a not for profit organization. CPA Dan Lassiter went to the comptroller office to discuss taxes. We paid our fees and penalty. On the federal side, we are applying using the 1023 form checklist. Looking at the form checklist, there are forms we have not yet filled out. Power of Attorney Form 2848– Steve will be listed as the taxpayer as the treasurer and Dan will be our representative. Form 8821 Tax Information Authorization is needed for Dan. Form 5768 needs to be completed if we will have a representative to lobby congress. Our part should wrap up pretty quickly. The process to

complete can take up to 18 months once forms are received. We do not owe federal tax due to the fact we have no employees. Estimated cost to submit the forms is \$750. Steve received approval by a majority vote to cut the check for US Treasury to have documents processed.

## Committee Reports

- Finance Committee
  - Treasurer's Report – distributed and reviewed
  - \$47,011.42 start
  - \$47,907.71 end
    - \$4457.51 Devices 101 income
    - \$3061.22 Devices 101 expenses
    - \$1396.29 net on Devices 101
  - Two reimbursements issued for John (Austin – \$115.50 travel and OKC \$483.20 travel and hotel), One for Lars (travel to Austin and hotel \$278.00) and one to Al (OKC \$503.58 travel)
  - CPA fees of \$400
  - Cover letter to go with scholarships issued will need to be added to the guidance. (**ACTION ITEM** - Brian and Sue will work on letter and updating the guidance.)
  - Beckie and Steve to go to the bank on the signature cards. They are open on Saturdays.
  - Steve will file the Form 1023
  - Treasurer's report accepted by a majority vote.
- Communications Committee – Julie
  - Devices 101 covered some with the web site
  - Lars is back at school and will get back up to speed soon.
  - Next announcement is the big event
    - Sue – The Federal Register announcement takes 3 months to publish
    - Members should announce on association web sites
    - Mary Ellen – ASQ World Conference is scheduled for 5/5-7/14. We should announce early so members will have a choice of which event to attend.
    - How can we advance the publicity to those members? Mary Ellen has announced to local groups. We need to post the ASQ meeting on the FMDIC web site. Can Lars post the May meeting? Go to the ASQ website and link that meeting on our website. John will ask Lars to post. We can request ASQ posts the Case for Quality on their website. Do a short statement for all members for them to post on their websites. (**ACTION ITEM** - Julie to craft an announcement and send to Ricky and Brian for review.)
- Quality Committee – Randy
  - Got status of each SOP from Sue
  - We need to finish the one for the event planning.
    - Timing, responsibilities and procedures for Devices101 are still needed. He will send it back out to the group for review and update. Due to Randy

October 4<sup>th</sup>. Track changes format. (**ACTION ITEM** – All members review the Event SOP.)

- Publicity Committee – Julie - Combined with communications
- Big Event Committee – Cost estimates reviewed and explained.
  - Need to determine how much we will charge for this event.
    - Case for Quality – all FDA speakers? Ricky – They typically have 2 from industry and we should offer to fund them to attend this meeting. Ricky will need to check with CDRH for the industry speakers. (**ACTION ITEM**- Ricky to check with CDRH for recommended industry speakers)
    - Brian – Considering the subject, we should charge \$200 for industry and adjust for government and students.
    - Ricky – We will need breakout rooms. Discussion ensued on how best to handle breakout sessions
      - Pre-select sessions at registration
        - Focus on Quality – asks attendees what FDA can do about focusing on quality instead of compliance discussion group
        - Data transparency – center receives a large amount of data Highlight what's going on in their own industry. Look at proactive instead of when MDR reports come in. Put usable data on dashboard. Has to have a story behind it.
        - Stakeholder engagement – Government agencies that pay for medical devices - Identifying what they look for to determine what they buy. Risk managers, etc. Industry feedback to FDA - how the focus can be on quality
    - Challenges of breakouts discussed. Three sessions, 1 hour each then rotate. Color dot attendee rotation. Close out session. Recommendation made to rotate speakers instead of attendees. Assign room colors for the afternoon breakout sessions.
    - (**ACTION ITEM** - Sue to contact the Wyndham for availability of breakout rooms and to see if we would be tax exempt.)
    - Publicize 200 attendees but allow for 240 maximum. 2 breakout rooms and the 3<sup>rd</sup> in the ballroom area.
    - Co-sponsorship by the end of next week to Sue to finalize and forward to ethics.

#### New Items:

Feedback on Medical Device 101s - Austin had 40 attendees; Oklahoma City had 19 attendees.

- Brian - Austin went really well. Is there a video to tell a story? More active demonstrations would be a good addition to the slides. Adds to questions.
- Al – Austin - Venue, location, food, everything went well. Participation was good. Good cross section of attendee experience. OK – excellent venue as well. Room to grow in both locations.
- Areas of Improvement
  - Al - incorporate Redi conference slides and have readable labeling example.

- Brian – show and tell on design controls? Growth - how to get the word out better.
- Steve – look at bad examples to illustrate what should be done.
- Beckie - volunteered to be on a team to look at a Medical Device101 rewrite. Brian also volunteered to be on the team.
- Julie – Cards from Redi conference. She reached out to both on how to plug into FMDIC and become members. Mary Pat’s email bounced back. Kay was contacted.
  - Mary Pat is a friend of Randy and a member of SALSA group in San Antonio. She would be a valuable resource for FMDIC.
  - (**ACTION ITEM** - Julie to send email to Randy and he will contact Mary Pat on behalf of FMDIC.)
  - Kay is BIO Fort Worth. Mary Pat also involved in BIO San Antonio. (**ACTION ITEM** – Julie will call Kay again.)
- Jeff – Final code of conduct signatures? Everyone on FMDIC needs to sign the code of conduct annually. Latest version of code of conduct guidance has the page to sign. (**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.)
- Steve – Is the website being maintain and update or will Lars do a rewrite? John – Lars just to maintain at this time. We need to consider mobile users when we do a rewrite. Meeting minutes should match incorporation date. John will have Lars take a look at the website and come back with suggestions. (**ACTION ITEM** – Add to agenda for the next meeting.

Next Meeting Date – 6 December 13

### **Important Dates**

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

Scholarship Committee Meets  
FMDIC Educational Forum

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- **ACTION ITEM** – Steve to contact local AAMI for a recommended primary and alternate member.
- **ACTION ITEM** – All members review the Event SOP and respond to Randy by October 4th.
- **ACTION ITEM** - Julie to craft an announcement on the Case for Quality and send to Ricky and Brian for review
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- **ACTION ITEM** – Julie will call Kay again
- **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.
- **ACTION ITEM** – Add website discussion to the agenda for the next meeting.