

**Chapter Board Meeting
March 10, 2005
5:30 PM @ Genentech, SSF**

Board Members Present: Peter Rauenbuehler (President), John Ferreira (President Elect), Michael Place (Treasurer), Kristina Nordhoff (Secretary), Elizabeth Leininger (Member-at-Large), Randall Tedder (President Emeritus)

Distribution: Board Members, WCC-PDA Files

ORDER OF BUSINESS

January Chapter Dinner Meeting / Chapter Board Officer Elections

The January 20th dinner meeting at the Clarion Hotel-Burlingame was considered a success, from break-even and electoral standpoints.

Martin Van Treiste (Bayer HealthCare-Biologicals) spoke about new FDA Guidance Document on Aseptic Processing. Feedback regarding the presentation was very positive.

Following the presentation, Officer Elections took place, where all nominees were accepted and vacancies filled. Randall remains on Board as “President Emeritus”.

Chapter Charter Review

Board reviewed the Chapter Charter that was revised by National PDA in 2004. Randall had signed the new bylaws and sent them back to National but has not received confirmation that it was received.

Action Item: Board to review the bylaws offline and provide comments to Peter.

Action Item: Randall to check with National about status of Chapter Charter that he submitted.

PDA National Annual Meeting

Peter will attend the National PDA Annual Meeting in Chicago 4/3-4/5, which includes the Officer’s Meeting, where he will benchmark with other chapter officers for their best practices.

Action Item: Peter asked the Board for any areas of interest that he might investigate at the annual meeting. (Update: Following the Board meeting, Peter thanked the group for their support and feedback, stated that he had a clear agenda to take to the Chapter Council Meeting on April 3rd, and the group was off to a good start.)

Upcoming Dinner Meetings

Board decided to postpone originally scheduled March dinner meeting to ensure speaker availability. Due to various conflicts, the third Thursday in May (19th) was chosen as the next best date. Subsequent meetings for the remainder of the year are tentatively scheduled for July 21, September 15, and November 17.

Action item: Randall to ask Natalie Saldou-Holtz to reserve Clarion Hotel, Burlingame for 5/19. (Update: Reservation confirmed at Clarion for 19-May-2005. Contract being reviewed.)

Upcoming Dinner Meetings, continued

May 19, 2005 – “Managing Quality Oversight”

John Ferreira (Bänziger Systems) is scheduled to present a review of regulatory requirements for assuring product quality, a look at major operations that support drug manufacturing, and explore strategies for the gradual introduction of balanced quality oversight. John will provide examples of new facilities in which integrated compliance strategies and risk assessment minimize costs without diminishing cGMP compliance. The presentation will be geared towards project managers, quality managers, senior and executive management exploring risk based compliance strategies, but all are encouraged to attend this special engagement.

Action Item: John to provide presentation overview and brief biography to Kris for review and distribution. (Update: Overview and biography received and reviewed. Preparing for chapter announcement.)

Other Dinner Meetings - TBD

Hot topics suggested and discussed for future meetings:

- Current Trends/Inspections (7/21?)
- Cold Chain Management
- Supplier Quality/RM Suppliers
- Contract Manufacturing/ISPE
- Quality Agreements
- Viral Clearance
- FDA/Regulations
- Process/Equipment/Facilities Validation
- Current/Upcoming Technologies
- Environmental Monitoring
- Developing Validation Plans
- Critical Process Parameters
- Process Analytical Technology in Biotech
- Operations & Quality Systems

Speaker considerations for future meetings:

- Possible conflict for availability of speakers with National's plans.
- Suggestion to have every other meeting with three-member panels: Discussion, Q&A (staged, audience): Solicit panelists from Genentech, Chiron, BioMarin, Consultants, etc.
- Local or Former FDA or Small Business representatives

Other considerations:

- Board strongly recommends back-up/contingency plans in case speaker(s) cancel. Alternative is to have speaker(s) forward their presentation materials in advance and/or nominate delegates/stand-ins. Cancellation insurance?
- There is a lot of overlap/competition with National in regards to topics and training. Need to know boundaries/regional limitations for inviting speakers/audience, and what the chapter's attendance area is.

Action Item: Peter to get a feel for competition of speakers/topics and Chapter's regional restrictions at PDA Annual Meeting.

Chapter/Meeting Attendance

How to get former members involved? How to rekindle member interest in attending events on West Coast/Bay Area rather than East Coast/DC Area? How to get Academic interest? There remains competition for jobs/local talent. Revisit National “Chapter Points” incentive program?

WEST COAST CHAPTER – PARENTERAL DRUG ASSOCIATION (WCC-PDA)

Symposiums / Workshops

- National no longer owes local chapter money from last symposium. A financial accounting of the December 31, 1999 event indicates a loss for the chapter, not the profit expected.
- Board to revisit: one day event(s) to raise money for the chapter. Dates, Topics, Locations: open.
- Possible Speaker(s): Frank Matarrese (GxP Consulting, Biotech Interest Group)
- Leverage past Board presidents (“Call in the chips”)
- Consider inviting Vendors to sponsor tables, present displays; “Job Postings” Board

Action Item: Board to review the Profit & Loss Statement to see where adjustments can be made to make future symposiums more profitable.

Dinner Meeting / Symposium Reservations System

Board discussed applications used by other organizations to electronically capture dinner reservations and payments via email and/or internet. Kris suggested that the Board investigate and consider <http://www.acteva.com/index.cfm>, which is the system that the American Society of Quality uses. After learning about an event, participants visit the Active Page web pages that we would create and register and pay for the event. Acteva processes and confirms registration and payment information (for a small fee) immediately and sends an electronic ticket confirmation to the registrant by email. Attendee check-in lists and name tags can be generated from the site.

Randall suggested linking a FileMaker Pro database to the WCC-PDA website.

Action Items: Kris and Randall to come-up with ideas for how to handle registrations. Randall to investigate process for utilizing FM Pro database from the website. (Update: Investigation is in progress.) Kris to check with other organizations to see how their online registrations work.

Web Site

Board discussed the proposal of a new website address. Randall presented information to the Board that states that the Board’s preferred choice “www.wccpda.org” is available. The new web address will be easier to remember and brings brand identity to the chapter. The domain name would cost the chapter \$20/year with a 2-year minimum. Hosting with e-mail functionality would cost \$30/month, to be prepaid quarterly or yearly. The Board considered researching other options, but the offer that Randall presented was considered acceptable. Ideas for the new website include “hit counts”, posting a newsletter, invites to the site, soliciting volunteers, etc.

Action Item: Randall to purchase domain name and establish website hosting. Kris and Randall to work together to develop updated website and enhanced functionality, and coordinate website hosting.

Chapter Stationery

Board reviewed and accepted proposed template for new chapter “letterhead” created by Kris per Peter specifications. A few corrections were identified to update the list of Board members. A new logo to create brand identity for WCC-PDA is in the works, which may include a sailboat or Golden Gate image. Suggestions are welcome!

Next Board Meeting, Close of Business

Next Board meeting is scheduled for April 21, 2005 with the location to be determined. Possibilities include meeting in San Francisco and/or near a BART station for those attending from the East Bay.
