How to Implement/Strengthen Pre-Filing Strategies

Mark J Goldberger MD MPH
FDA Alumni Association International Network

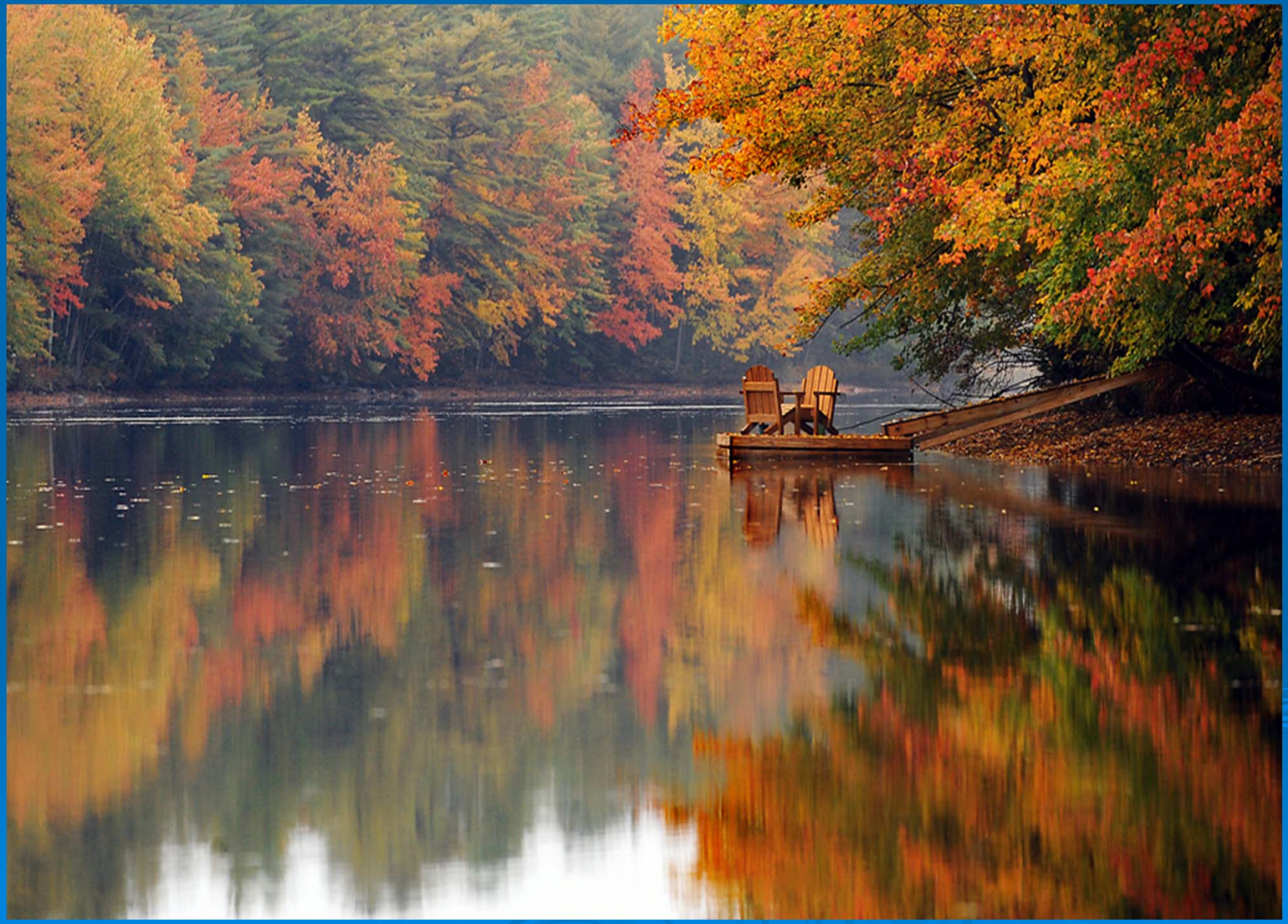
November 7, 2012

APEC Meeting

Taipei

Disclaimer

- I am an employee of Abbott, My travel expenses travel are being paid by Abbott
- I worked at the U.S. Food and Drug Administration (FDA) in various capacities in the past;
- I am a member of FDA Alumni Association (FDAAA). The following are my views and not necessarily the views of FDAAA or FDA.



The Big Picture

- We have talked about the approaches to interacting with the sponsor to achieve a high quality application
- What do you need to do within your Agency to enable this?

Overall Mindset

- Interacting with sponsors should be thought of as an investment
- Meeting preparation takes time
- Not meeting ultimately consumes more time

More Than Just Meeting Preparation

- Reviewers need the appropriate skills
- Reviewers need the appropriate tools
- Division of labor: sponsor vs. agency
- Don’t always “reinvent the wheel”
- Learn from experience

Reviewer Skill-Sets May Depend on Circumstances in Your Agency

- What level of staffing is available
- What mix of products will reviewers be presented with?
- How can you get the most value, minimize the most important risks with your product mix?

Review Tools

- Templates
- Guidance
- Paradigms
- Electronic

Analyses: Sponsor or Agency

- At the US FDA we were in the fortunate position of having sufficient resources to redo may sponsor analyses as well as additional analyses of our own
- Most agencies won't have all these resources
- If the assumptions are understood and the questions clear, the sponsor can supply the great bulk of the analytical muscle

Don’t Re-Invent the Wheel

- The same types of issues in product development and review occur and reoccur
- Thinking about dose-finding
- What type of analysis is most appropriate?
- What does this type of adverse event suggest?

Learn from Experience

- “What is the use of experience if you do not reflect”
- To most effectively utilize experience you need to be aware of it
- Ideally there should be a central repository of review documents
- Much experience is in the minds of your fellow workers – how to access this?

FDA Regulatory Briefing

- Similar in some ways to an “internal” advisory committee
- A voluntary process for divisions and offices who have potentially difficult questions
  - Approval decisions, labeling issues, risk management issues, study design issues
- Broad representation of senior managers across the Center participate including Center Director and Deputy Center Directors and senior managers of all review offices

Harness the Experience of Staff

- Utilize the collective experience to inform and harmonize decision-making
- Group decisions combine the strengths and the different perspectives and experiences of the group members in providing overall recommendations

Structure of a Regulatory Briefing

- Pre-Reads provided ahead of meeting
- Questions submitted by the presenters describing the advice their office/division needs
- Focused presentation at the meeting
- Ample time for discussion
- To facilitate easy scheduling of such meetings on short notice if necessary, a time slot is reserved in advance on most weeks.

What's Available on the "Web"?

- US FDA
  - Reviews
  - Product labels
  - Advisory committee materials – FDA and sponsor
  - Guidance
- EMA
  - EPAR
  - Product labels
  - Guidance

What Other Help is Available

- Academic institutions
- Trade associations
- Other regulatory agencies
- Other organizations

In Summary

- No “one size fits all” review model
- Identify and train on the reviewer skills most appropriate for the reviewer and product mix
- Try to standardize the approach to review
- Take advantage of the collective expertise of staff
- Take advantage of the resources and assistance of other agencies/organizations