

IPAC-RS Conference  
6-8 November 2006

## Breakout Session Track C Feedback

Moderators:

Michael Golden, GSK  
Dan Norwood, BI

## Questions & Feedback

IPAC-RS Conference  
6-8 November 2006

- Y What issues do industry and FDA face today with respect to control strategies (e.g., redundancies, unnecessary testing)?
- Ø Agreement on and recognition of redundancies, e.g.:
    - PNA and nitrosamine controls on elastomers and drug product;
    - Multiple controls on spray pattern (plume geometry, orifice diameter, spray pattern, etc);
    - Excessive/unnecessary quality testing for excipients
  - Ø Make proposal to FDA to reduce redundant/unnecessary testing – bring data!
- Y How can the FDA/industry interaction process be improved?
- Ø Need for more clarity in process for requesting meetings and in expectations for meetings
  - Ø More frequent communication
  - Ø Use different modes of communication, e.g., telecon, potential for in-depth PAI-style meetings

Y How do you link control strategies to safety and efficacy?

Ø No one could suggest realistic way of linking Q to E

Ø Challenges

- Using clinical program to link these is not realistic – too resource intensive
- Clinical instrument is too blunt to link Q and E

Ø PQRI L&E WG is example of linking Q to S

Ø Potential to use PQRI L&E approach to clarify link between one quality attribute (e.g., fine particle mass) and efficacy?

Ø More academic research is needed on linkage of Q to E

• Additional issue: Statistical power

Ø To define design space and link it to S and E requires more use of high level statistics

Ø Is there sufficient statistical capacity and expertise at FDA and industry?

Ø Need for more extensive statistical training

- In FDA and industry
- For chemists, reviewers, product development experts

**IPAC-RS Conference  
6-8 November 2006**