

**Process Analytical Technologies Subcommittee of the  
Advisory Committee for Pharmaceutical Science**

February 25 - 26, 2002  
Holiday Inn, 2 Montgomery Village Avenue  
Gaithersburg, MD

**AGENDA**

Day 1: Monday, February 25, 2002

- 8:30 Call to Order Thomas Layloff, Ph.D., Acting Chair  
Conflict of Interest Nancy Chamberlin, Pharm.D., Exec.Sec.  
8:45 Introduction, Overview, and Objectives for Subcommittee Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science

**Process Analytical Technologies Applications and Benefits**

- 9:15 Perspective 1 Steve Hammond, Pfizer  
9:35 Perspective 2 Doug Dean, Ph.D., PricewaterhouseCoopers  
9:55 Subcommittee Discussion  
10:30 Break

**Product and Process Development**

- 10:45 Perspective 1 John G. Shabushnig, Ph.D., Pharmacia  
11:05 Perspective 2 David R. Rudd, Ph.D., GlaxoSmithKline  
11:25 Subcommittee Discussion

12:00 Lunch

1:00 Open Public Hearing

**Process and Analytical Validation**

- 2:00 Perspective 1 Robert S. Chisholm, AstraZeneca

2:20 Perspective 2 Leon Lachman, Ph.D., Lachman Consulting  
**Day 1 (continued): Monday, February 25, 2002**

2:40 Subcommittee Discussion

3:10 Break

**Chemometrics**

3:25 Perspective 1 Jerry Workman, Jr., Ph.D., Kimberly-Clark

3:45 Perspective 2 Dwight S. Walker, Ph.D., GlaxoSmithKline

4:05 Subcommittee Discussion

5:30 Adjourn

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**AGENDA**

Day 2: Tuesday, February 26, 2002

8:00 Call to Order Thomas Layloff, Ph.D., Acting Chair

8:15 Charge to Working Groups Thomas Layloff, Ph.D., Acting Chair

8:30 Working Group Discussions (four separate groups)

10:30 Break

10:45 Working Group Discussions

12:00 Lunch

1:30 Open Public Hearing

**Working Group Summaries (joint)**

2:00 PAT Applications and Benefits Arthur Kibbe, Ph.D., Acting WG Chair

2:15 Subcommittee Questions and Answers

2:30 Product and Process Development Judy Boehlert, Ph.D, Acting WG Chair

2:45 Subcommittee Questions and Answers

3:00 Break

3:15 Process and Analytical Validation Leon Lachman, Ph.D , Acting WG Chair

3:30 Subcommittee Questions and Answers

3:45 Chemometrics Melvin Koch, Ph.D., Acting WG Chair

4:00 Subcommittee Questions and Answers

**Day 2 (continued): Tuesday, February 26, 2002**

4:15 Subcommittee Discussion

4:45 Summary

Ajaz Hussain, Ph.D., Deputy Director,  
Office of Pharmaceutical Science

4:55 Closing Remarks

Thomas Layloff, Ph.D., Acting Chair

5:00 Adjourn