

**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 Rick E. Cooley, Eli Lilly

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 WG Chair

2:15 Subcommittee Questions and Answers

2:30 Product and Process Development WG Chair

2:45 Subcommittee Questions and Answers

3:00 Break

3:15 Process and Analytical Validation WG Chair

3:30 Subcommittee Questions and Answers

3:45 Chemometrics 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