

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

June 12 – 13, 2002
Gaithersburg Hilton, 620 Perry Parkway
Gaithersburg, MD

AGENDA

Day 1: Wednesday, June 12, 2002

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|-------|--|---|
| 8:30 | Call to Order | Thomas Layloff, Ph.D., Acting Chair |
| 8:40 | Conflict of Interest | Kathleen Reedy, Pharm.D.,
Executive Secretary |
| 8:50 | Introduction, Overview, Training
and Objectives of Subcommittee | Ajaz Hussain, Ph.D., Deputy Director,
Office of Pharmaceutical Science |
| 9:35 | Subcommittee Discussion on Training | |
| 10:20 | Break | |
| 10:35 | Regulatory Affairs Perspectives | Four Industry Speakers |
| 11:30 | Subcommittee Discussion on Regulatory Risk | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | Subcommittee Discussion on Regulatory
Risks and Training | |
| 3:00 | Break | |
| 3:15 | Subcommittee Discussion | |
| 4:30 | Working Group Sessions and Strategy | |
| 5:00 | Adjourn | |

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AGENDA

Day 2: Thursday, June 13, 2002

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| 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 | |
| 10:00 | Break | |
| 10:15 | Working Group Discussions | |
| 11:15 | Consensus and Summary Preparation | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| | Working Group Summaries (joint) | |
| 1:30 | Product and Process Development | WG Chair |
| 1:45 | Subcommittee Question and Answers | |
| 2:15 | Process and Analytical Validation | WG Chair |
| 2:30 | Subcommittee Question and Answers | |
| 3:00 | Break | |
| 3:15 | Subcommittee Discussion | |
| 4:15 | Summary | Ajaz Hussain, Ph.D., Deputy Director,
Office of Pharmaceutical Science |
| 4:25 | Closing Remarks | Thomas Layloff, Ph.D., Acting Chair |
| 4:30 | Adjourn | |

