Breakout Session: Manufacturing Science

Questions for Manufacturing Sciences Workshop:

- Manufacturing Science and Related Regulatory Processes
  - How do we define manufacturing science?
  - Which regulatory processes are directly related to manufacturing science?
  - What is the current state of the relationship between manufacturing science and the associated regulatory processes?
  - What is the desired state of the relationship between manufacturing science and the associated regulatory processes?

- Facilitating Change
  - In moving toward the desired state, what can be accomplished within the existing regulatory framework and what will require changes in regulations?

- Risk
  - What is the perceived risk of implementing new technologies?
  - What is the perceived risk of not implementing new technologies?

- Knowledge Sharing
  - What is the level of knowledge/information FDA will need to adequately categorize the risk associated with a specific product/process?
  - How should this information be conveyed to FDA?