FDA's Advisory Committee for Pharmaceutical Science

The Subcommittee on Process Analytical Technologies (PAT): Closing Remarks

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Why were we here?

- To find a better way to serve our customers
  - Improving our manufacturing and associated regulatory processes
  - “Gap analysis”
- Understand the (potential) role PAT can play
  - develop a “common” understanding (same page)
  - identify real and perceived “regulatory hurdles”
  - initiate the process of finding “win - win” solutions

"Unable to determine the structure of this byproduct by spectroscopic methods, Nathan resorts to chemical degradation."

Expectation & Challenge

- At the end of this meeting:
  - Topics to be covered in the guidance (outline)
  - Layout general principles for setting specifications, validation, chemometrics
  - Consensus on benefits, definitions, terminology
- Different perspectives, expertise, and affiliations - can we come on the “same page” by the end of this meeting?

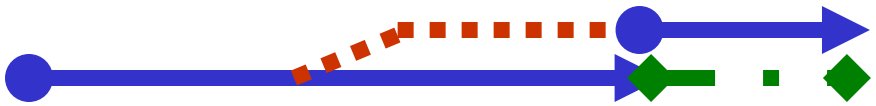
Accomplishments?

- “Same page”
- Topics to be covered in the guidance
- Consensus on “benefits”

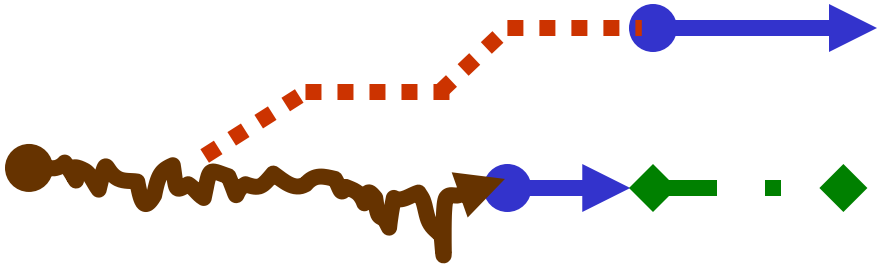
PAT?

- Systems for continuous analysis and control of manufacturing processes based on real-time measurements, or rapid measurements during processing, of quality and performance attributes of raw and in-process materials and processes to assure acceptable end product quality at the completion of the process.
- *Tools and systems that utilize real-time measurements, or rapid measurements during processing, of evolving quality and performance attributes of in-process materials to provide information to ensure optimal processing to produce final product that consistently conforms to established quality and performance standards.*

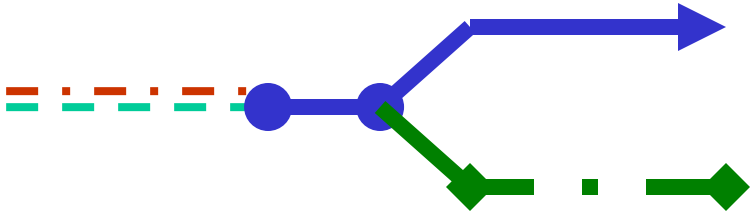
Options for Introducing PAT



A. Currently marketed “robust” products. PAT to improve efficiency (minimal improvement in quality assurance)



B. Currently marketed products that need improvement. Step wise PAT approach - first improve quality and then improve the efficiency



C. New products. PAT utilized throughout development and scale-up. Lab based tests to ensure shelf-life and/or for establishing “public standards.”

Next Steps

- ACPS meeting May 7 and 8, 2002
- PAT Subcommittee meeting (June 02)
  - More focused discussion
  - Examples?
- What can I do to prepare for the 2nd meeting?

Win-Win Solution

- FDA
  - Unambiguous regulatory process for PAT
  - General Guidance for Industry
    - Regulatory position on PAT, expectations and regulatory process
  - Collaborate with industry and academia
- Industry
  - Willingness to improve and change
  - Technical know-how (good science) and applications
  - Collaborate with FDA and academia
- Academia
  - Knowledge (public domain)
  - Provide future experts and leaders