

# *FDA PAT Guideline Review*

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PPAR 2004

Discussion Moderator: Andrew Lange



# Overview

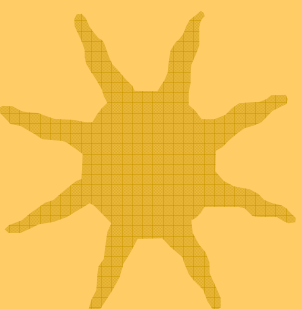
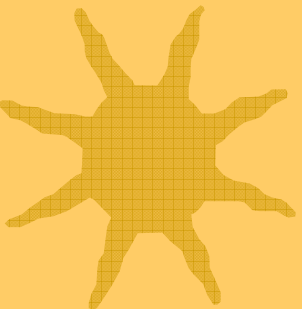
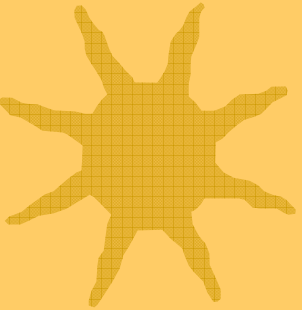
- ★ Introduction
- ★ Guidance Development Process and Scope
- ★ Background
- ★ PAT Framework
  - Process Understanding
  - Principles and tools
    - PAT Tools
    - Risk-Based Approach
    - Integrated Systems Approach
    - Real Time Release
  - Strategy for Implementation
- ★ PAT Regulatory Approach



# *Introduction*

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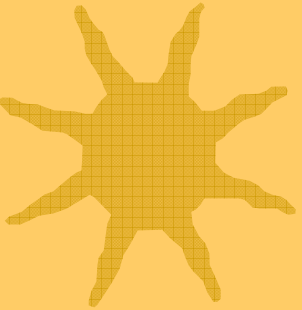
- ★ Guidance should be viewed as recommendation



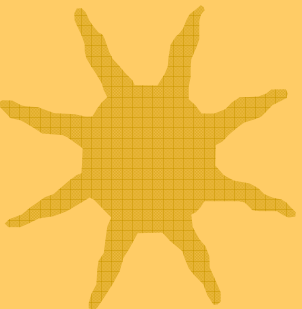


# *Scope*

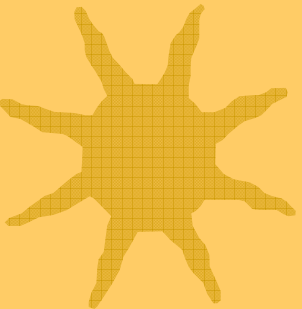
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- ★ Set of scientific principles and tools supporting innovation
- ★ Strategy for regulatory implementation that will accommodate



- ★ CDER & CVM



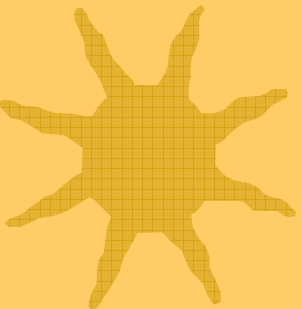
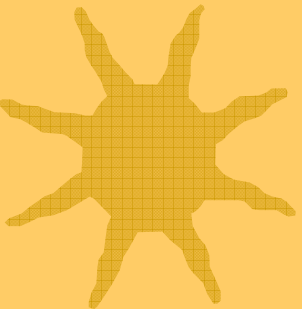
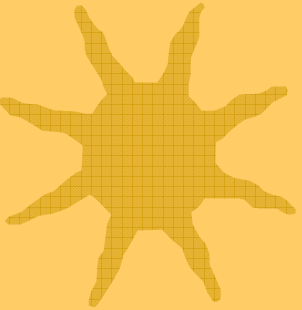
- ★ Voluntary!



# *Background*

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- ★ Historically: batch mfg. and lab testing
- ★ Industrial Hesitance
  - Regulatory is perceived barrier
- ★ Risk-Based Guidance (Aug. 2002)
- ★ Effective use of process design and scientific knowledge

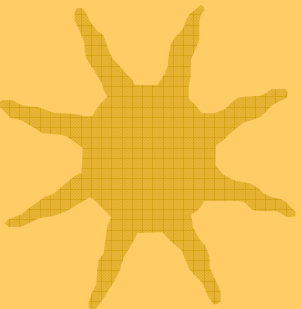
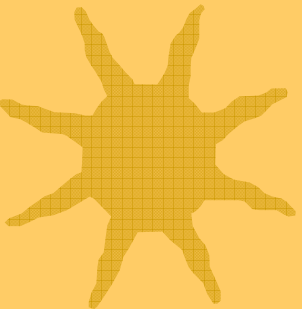
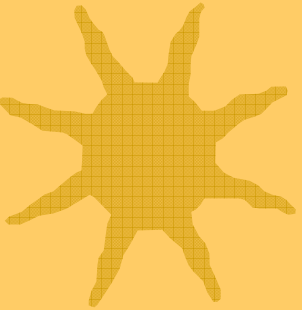




# *PAT Framework*

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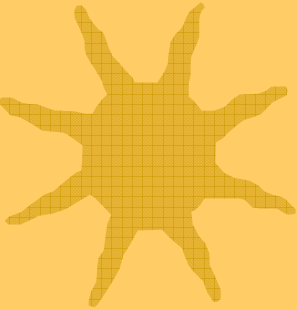
- ★ PAT is a system
- ★ Quality is built into products via process understanding
- ★ Understanding and controlling variability
- ★ Predefined quality at the end of the process by designing and developing well understood processes





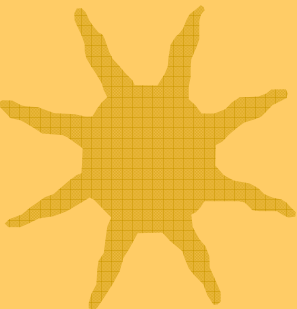
# *PAT Framework*

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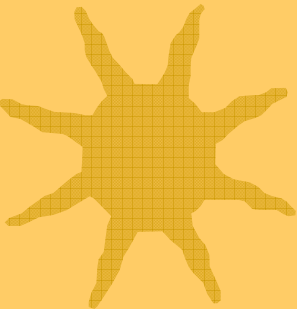
## ★ Process Understanding

- Variability understood and controlled
- In the absence of process knowledge, test-to-test comparison



## ★ Principles and Tools

- multivariate tools
- Analyzers (process signature)
- Control tools
- Continuous improvement and knowledge management tools



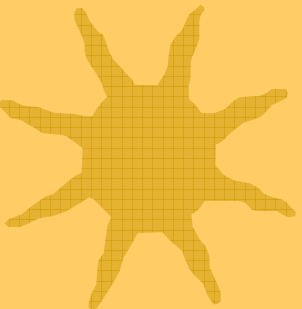
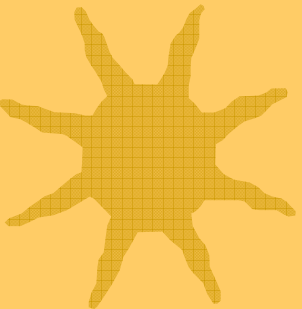
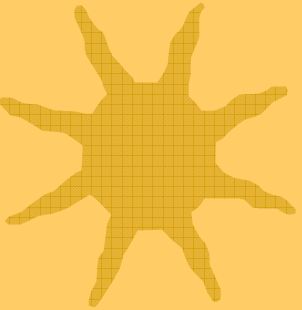
## ★ Risk-Based Approach



# *PAT Framework*

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- ★ Integrated Systems Approach
  - Upper management and inter-departmental
- ★ Real Time Release
  - Was termed “parametric release”
  - Agency approval should be received prior to implementing

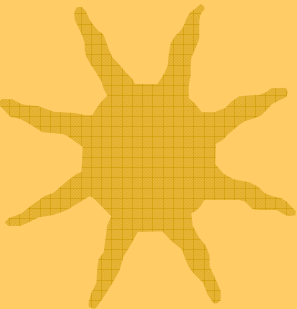
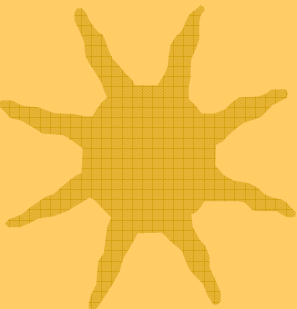
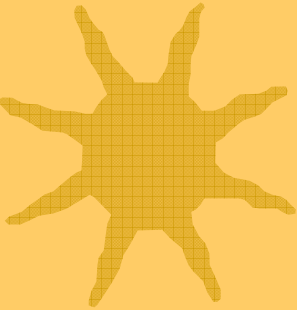






# *Strategy for Implementation*

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- ★ Current regulations are sufficiently broad
- ★ Ideally, PAT introduced in development phase
- ★ Working with the FDA up front
- ★ “Research Exemption”



# *PAT Regulatory Approach*

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- ★ Manufacturers should communicate with FDA in a timely manner
- ★ Possibilities:
  - PAT implemented inside company's quality system
  - Supplement
  - Comparability Protocol
- ★ Pre-operational Review

