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# **Regulatory Compliance Challenges in IND & IDE Clinical Trials**

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# AGENDA

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- ▶ Regulatory Agencies
- ▶ Framework
- ▶ Challenges
- ▶ Case Study

# Regulatory Agencies

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- ▶ **Global Agencies**

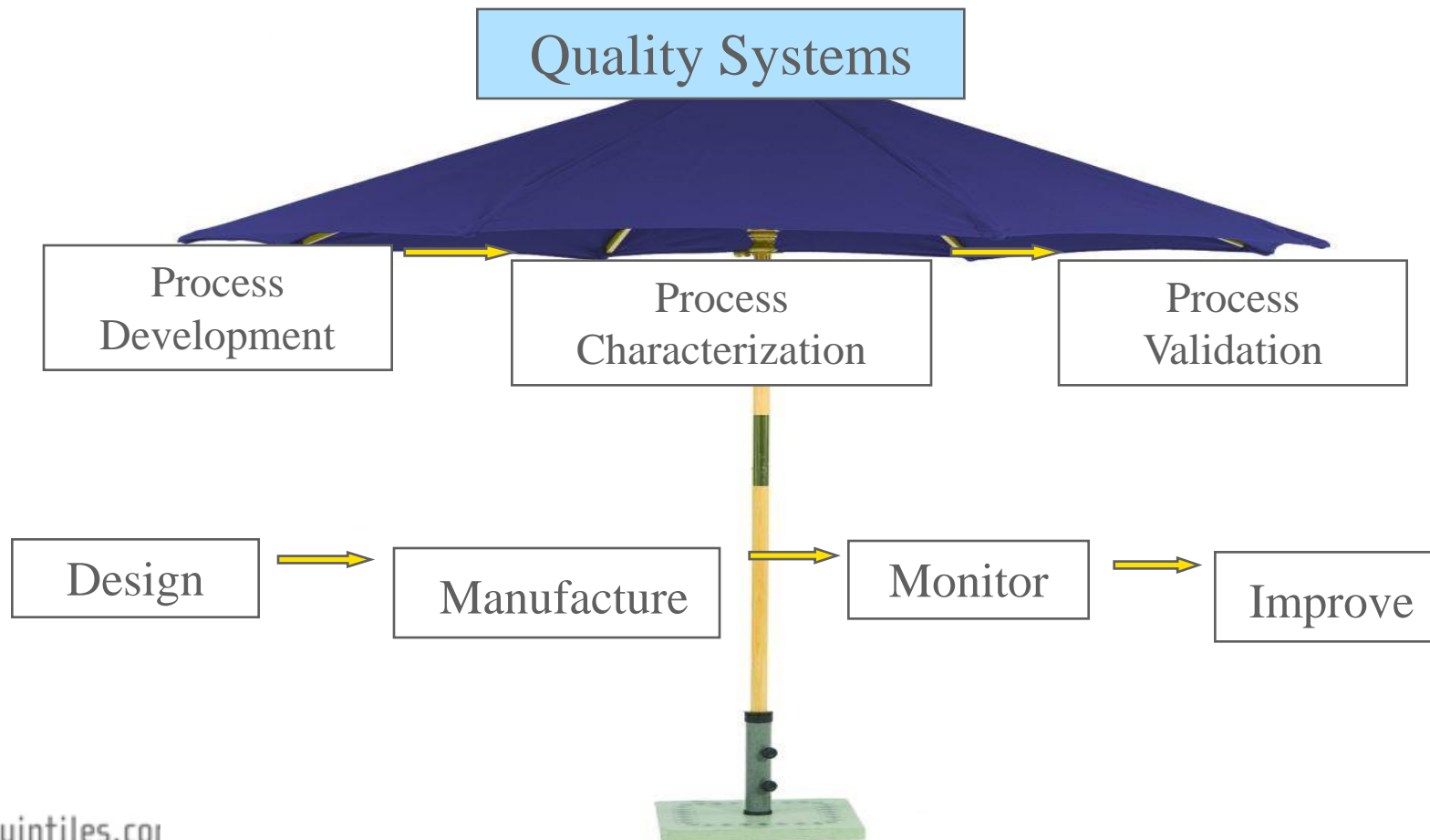
- ▶ **FDA**
- ▶ **EMA**  
**Japan**
- ▶ **Australia**
- ▶ **Canada**
- ▶ **CAP**

- ▶ **Policies**

- ▶ **GxPs**
- ▶ **ICH**
- ▶ **MCC**

# Framework

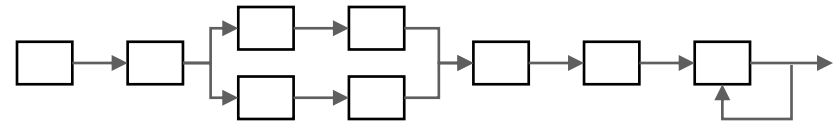
- ▶ Establishing a process to facilitate
  - ▶ Quality By Design is the activity of establishing customer needs and developing the process and products required to meet those needs.



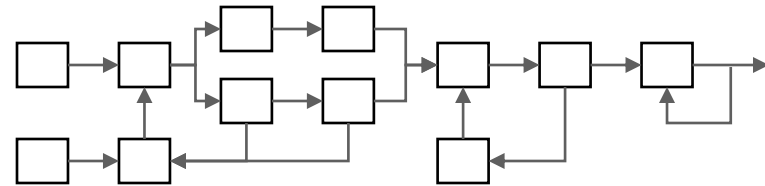
# Framework (cont'd)

- Implementation
  - Process mapping is a visual method used to describe sequential flow of work activities in a process that will help implementation.

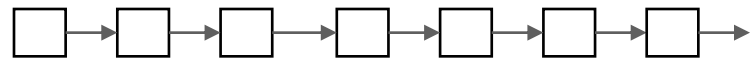
What you think it is



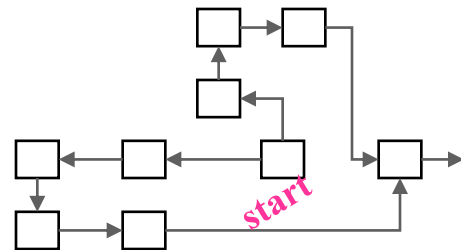
What it really is



What it should be



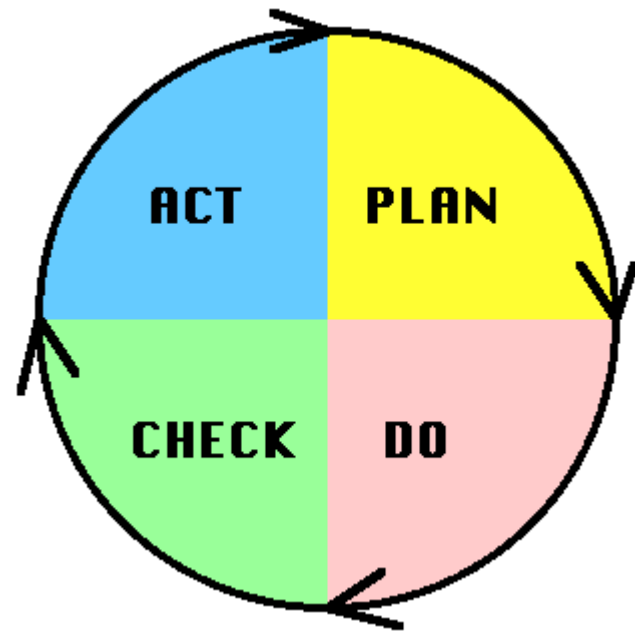
What it could be



Confidential

## Framework (cont'd)

- ▶ Risk Based Approach
  - The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating, and reviewing risk.
- ▶ Agency expectations around risks
- ▶ Promotes continuous Improvements



# Challenges

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- ▶ Inconsistencies in understanding of regulations and processes
- ▶ Changing requirements by agencies for data collection
- ▶ World economy tightening the belts on resources-intellectual property management
- ▶ Speed of change in systems
- ▶ Need of speed from discovery to commercialization due to competition

# Case Study

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- ▶ Coca-cola is famous drink world-wide. Why is that?