

# Winning Profit in the Age of Continuous Innovation

## Enabling New Product Introduction while Ensuring High Quality

Daniel R. Matlis  
President  
Axendia Inc.



# Even if you're on the right track...

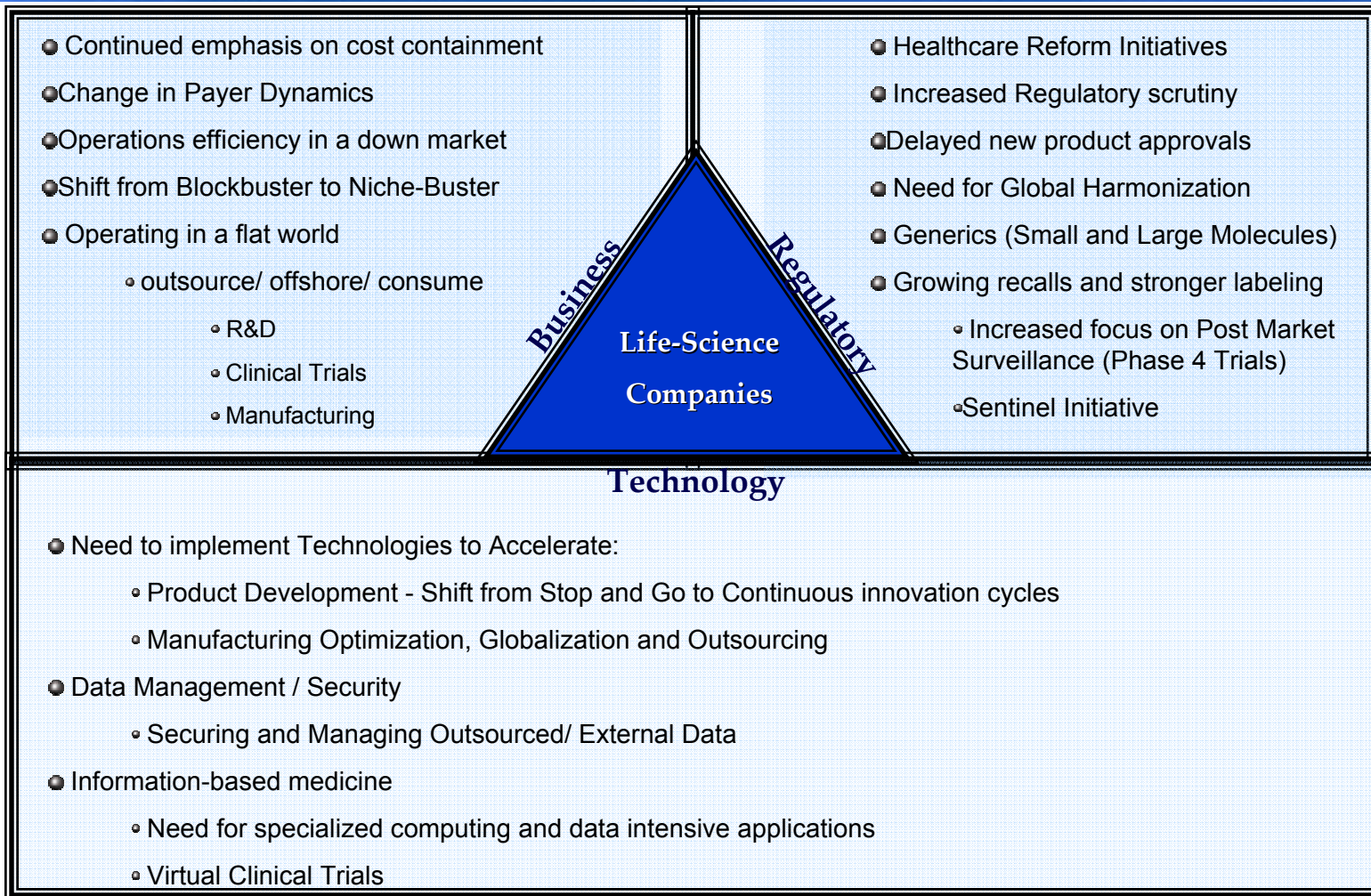


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# The Age of Continuous Innovation

- ▲ Transition from the “Information Age” to the age of “Continuous Innovation”.
- ▲ Shift away from “Incremental Innovation Cycles” supported by reactive, standalone and fragmented processes and systems.
- ▲ Embrace a proactive, cohesive and fully integrated approach to Manufacturing, Quality and Intelligence.

# Industry Challenges in The Age of Continuous Innovation



# The Current State of Quality

*“Despite the slogan ‘building quality in’, most quality assessment today relies on end-product testing. This is a problem in and of itself.*

*In addition, many of the test methods currently being used have severe limitations in the modern, mass production environment.”*

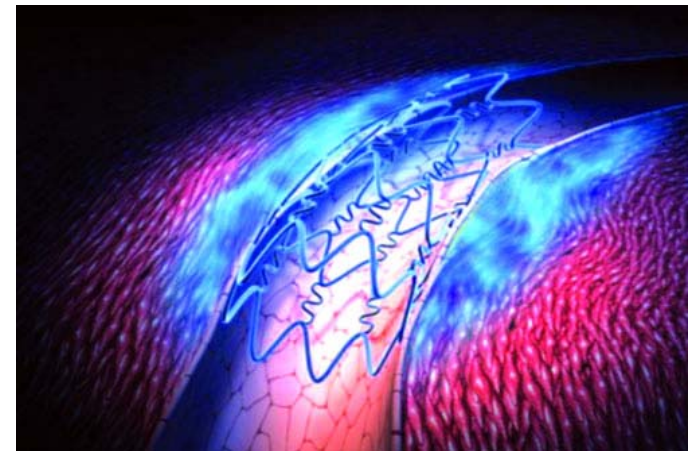
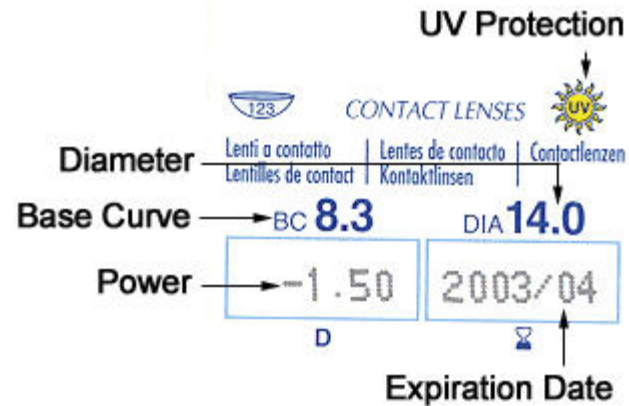
Dr. Janet Woodcock,

FDA’s Deputy Commissioner and Chief Medical Officer

Source: USFDA

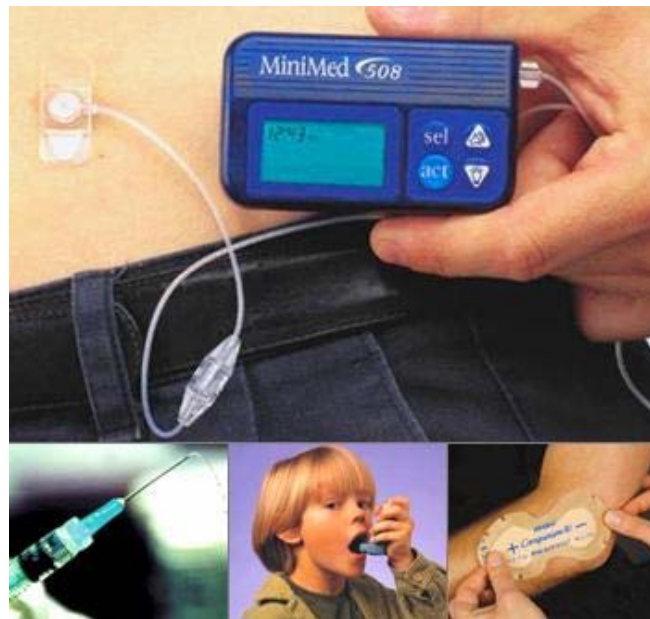
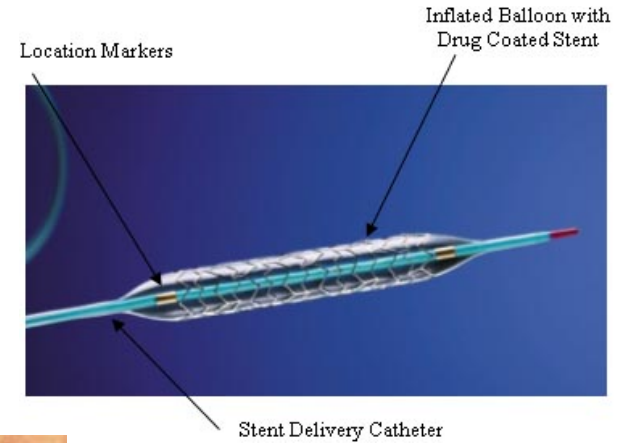


# Personalized Products: Increasing Complexity



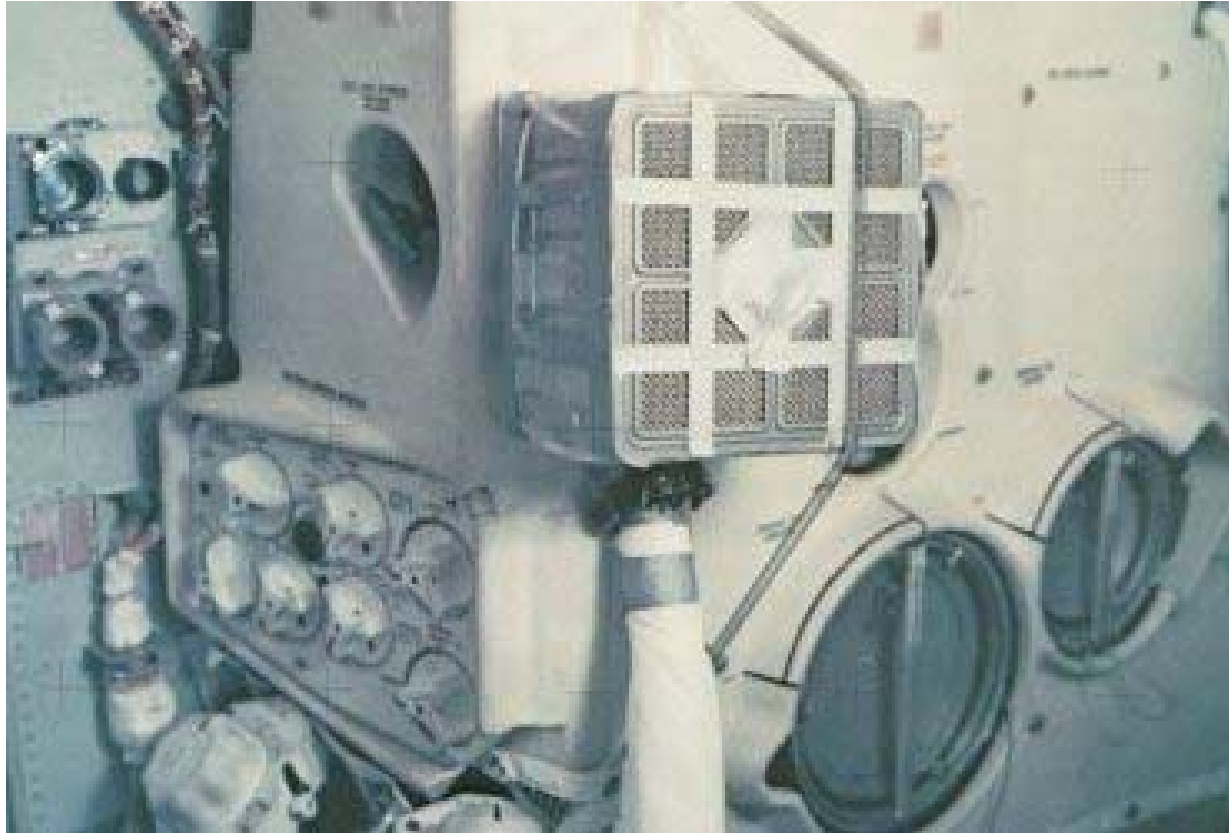
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# Combination Products



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# Rockville, We've Had a Problem



*Emergency scrubbers built by Swigert and Haise. Consisted of a taped-over double canister holding one end of a suit nozzle. The canister was built of arched cardboard, which was covered by a plastic bag*

# Got CAPA?

- ▲ How many have a CAPA system?
  
- ▲ Why do you have a CAPA system?
  - ▲ FDA requires each manufacturer shall establish and maintain procedures for implementing *corrective and preventive action*.
  
- ▲ What is the key measurement for CAPA?
  - ▲ Time to Closure
  - ▲ Result: CACA
    - ▲ CA-CA-CA

# Stop Tracking CAPAs



## Start Preventing Them

# If we asked people in the industry,

- △ How do you know that a component or a manufacturing process or a device or a certain parameter of a device is acceptable?
  - △ We do a certain amount of testing and we test the components.
  - △ Most of the test methodology is standardized.
    - △ For example, shock and vibration testing, mechanical stability, electrical characteristics of parts, etc. - those test methodologies are pretty well established.
- △ How many devices or components do you test with that methodology?
  - △ We test 10 devices or 15 components and see if they work.
- △ What is driving that quantity?
  - △ That's engineering practice.
  - △ That's what we've done all along.
  - △ That's something that the whole industry has been doing for 40-plus years.
  - △ It's basically based on engineering know-how and experience over the years.

Fred Colen, President  
Boston Scientific Cardiac Rhythm Management division

Source "[The Gray Sheet](#)" - July 28, 2008



# Fred Colen's Answer

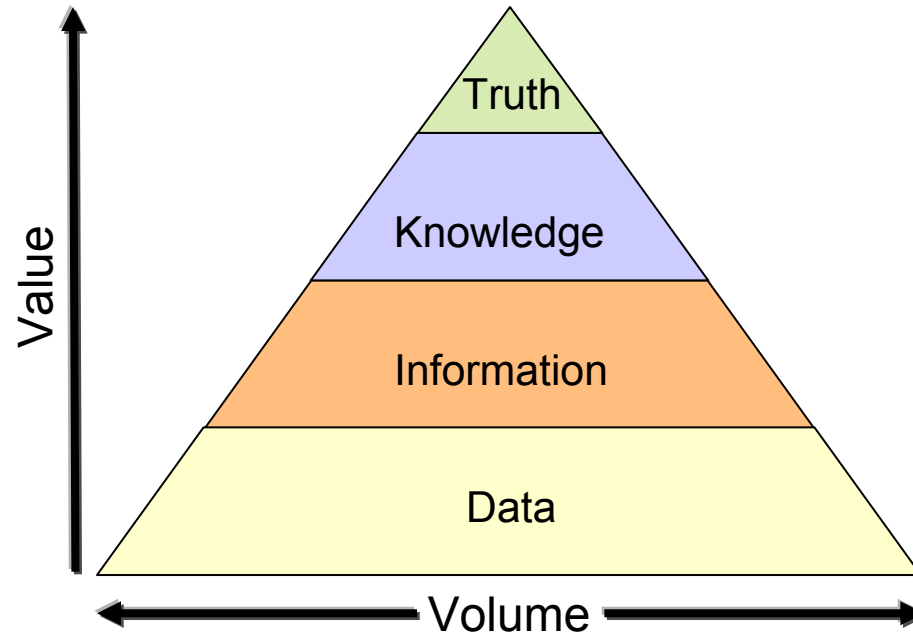
- △ That is the piece that we've changed.
  
- △ I compare this to a clinical trial where we say:
  - △ I have a hypothesis and I want to prove something.
  - △ If I want to prove or disprove the hypothesis with a certain confidence level, how many patients do I need to include in the clinical study?
    - △ It's a statistically-based approach and that is what we've now implemented in our organization.
  
- △ When we want to test a component or a device or a manufacturing process, we ask,
  - △ What is the statistically driven sample size that we need to use to say this with a certain level of confidence?'
  
  - △ And that determines the numbers.

Fred Colen, President  
Boston Scientific Cardiac Rhythm Management division

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# The Pyramid Truth™



- ▲ Transform Wisdom to Truth or Facts
- ▲ Transform Knowledge to Wisdom
- ▲ Transform Information to Knowledge
- ▲ Transform Data to Information

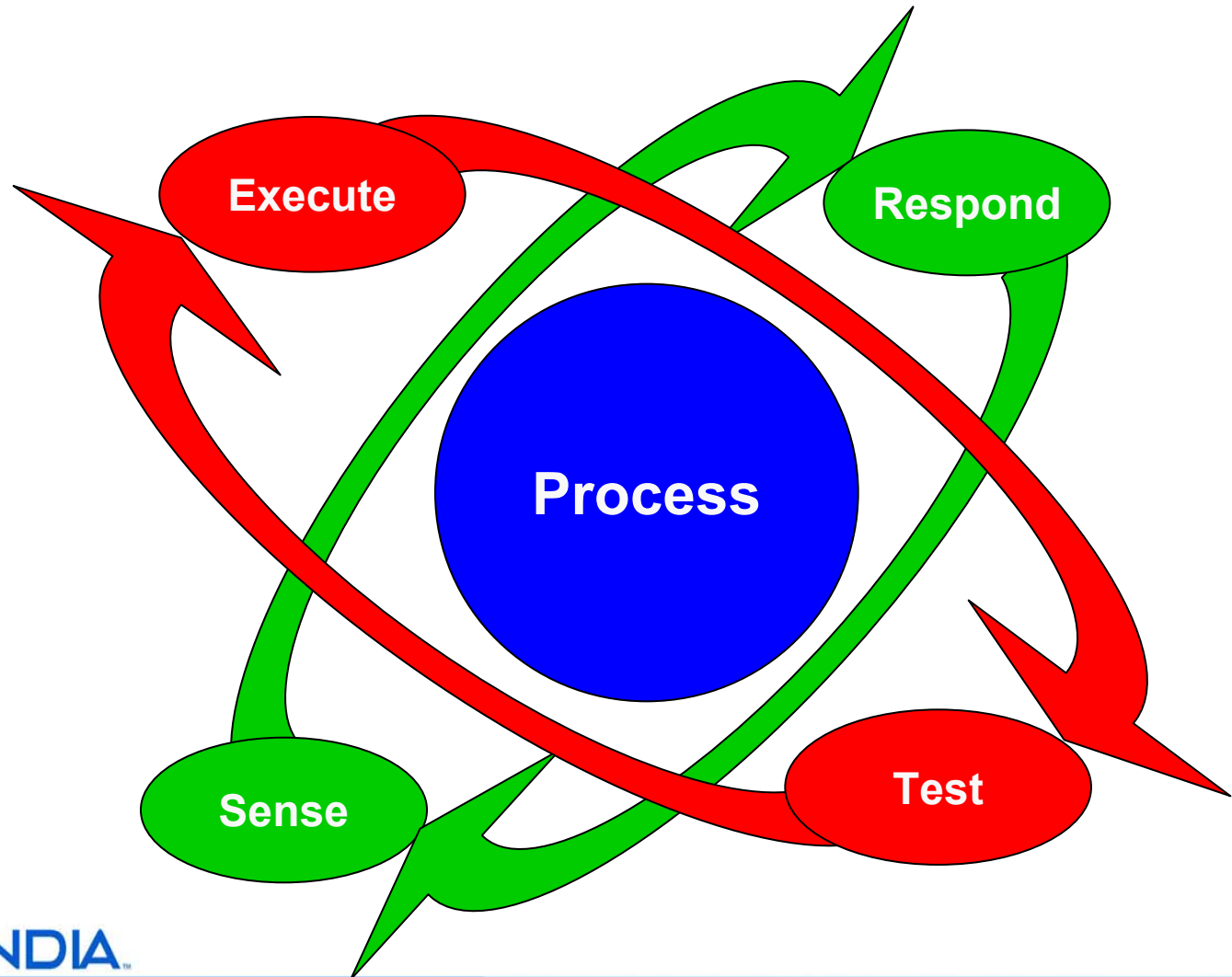
# The Desired State

- ▲ Product quality and performance achieved and assured by design of effective and efficient manufacturing processes
- ▲ Product specifications based on mechanistic understanding of how formulation and process factors impact product performance
- ▲ An ability to effect Continuous Improvement and Continuous "real time" assurance of quality

Source: USFDA



# Shift from Reactive to Proactive



# Tilting at Silos



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# The Catapult effect



# Looking For Truth In All The Wrong Places



# We Need Situational Awareness



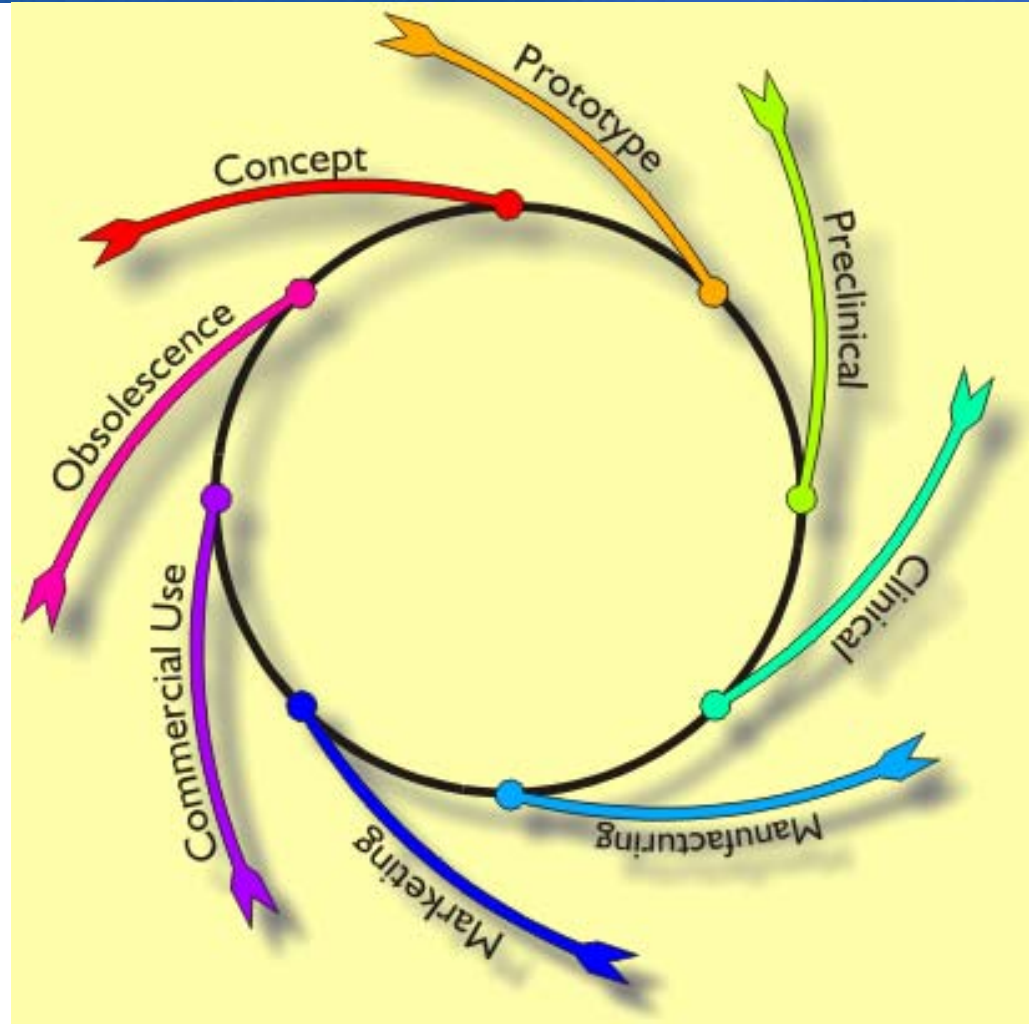
# CDRH Vision:

Ensuring the health of the public  
throughout the Total Product Life Cycle  
(TPLC)

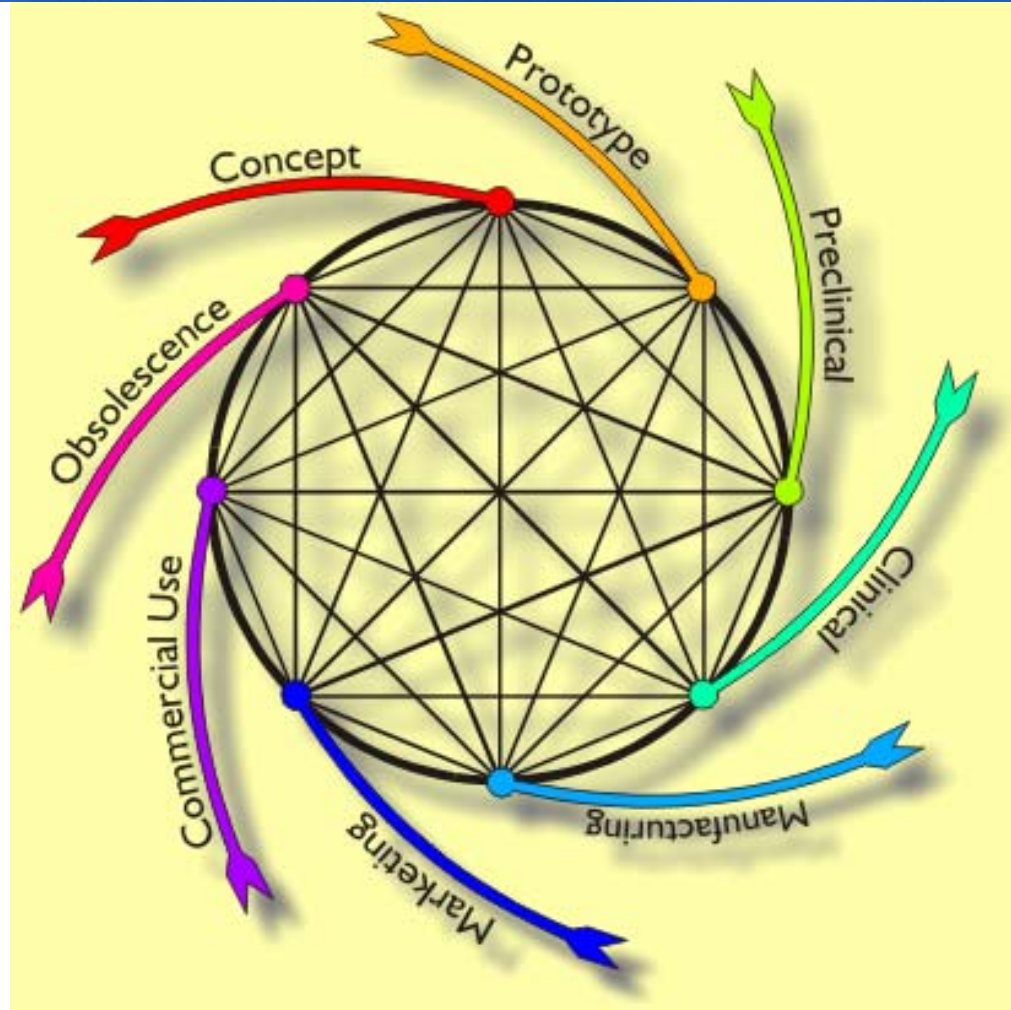
— *it's everybody's business*



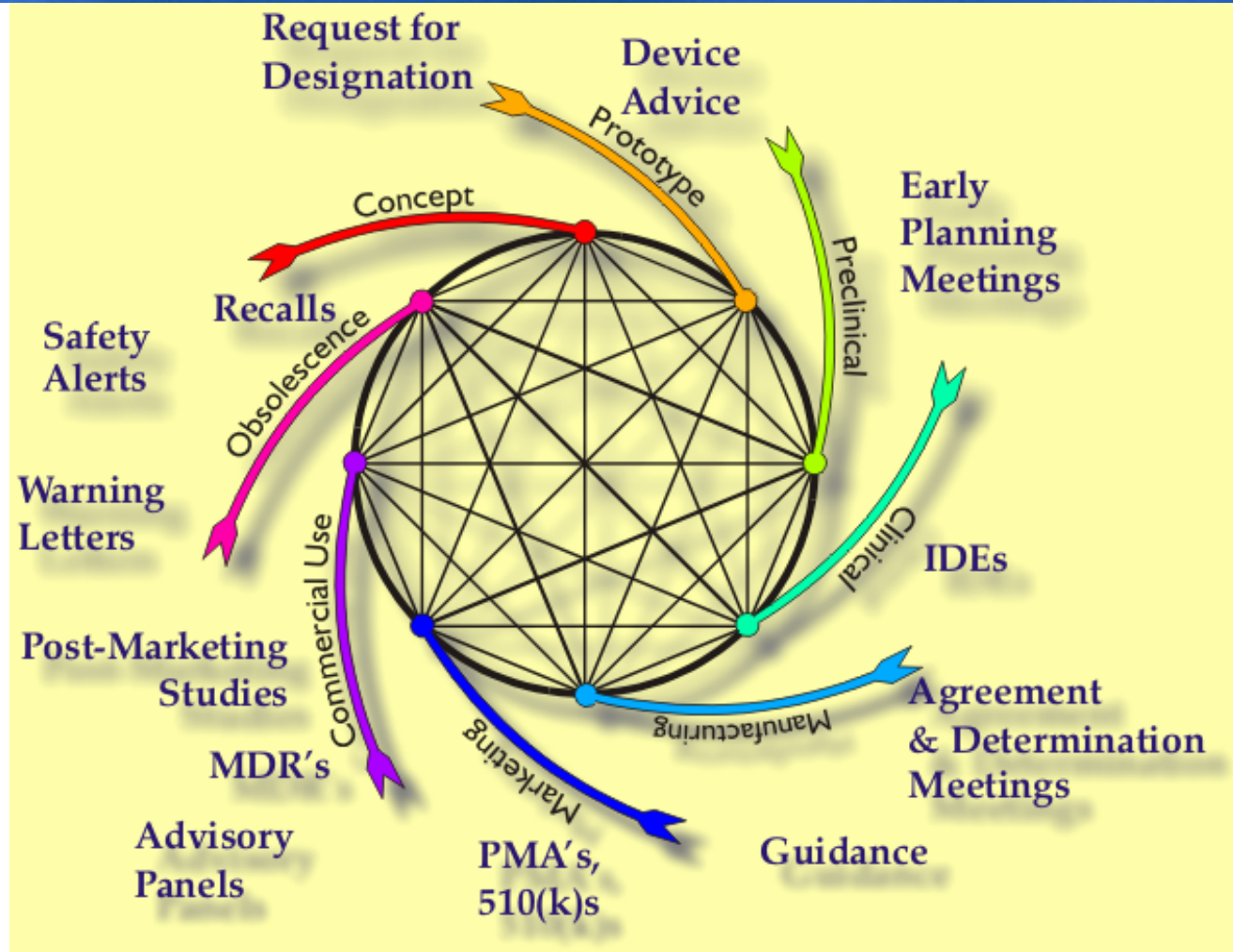
# The Total Product Life Cycle (ideal)



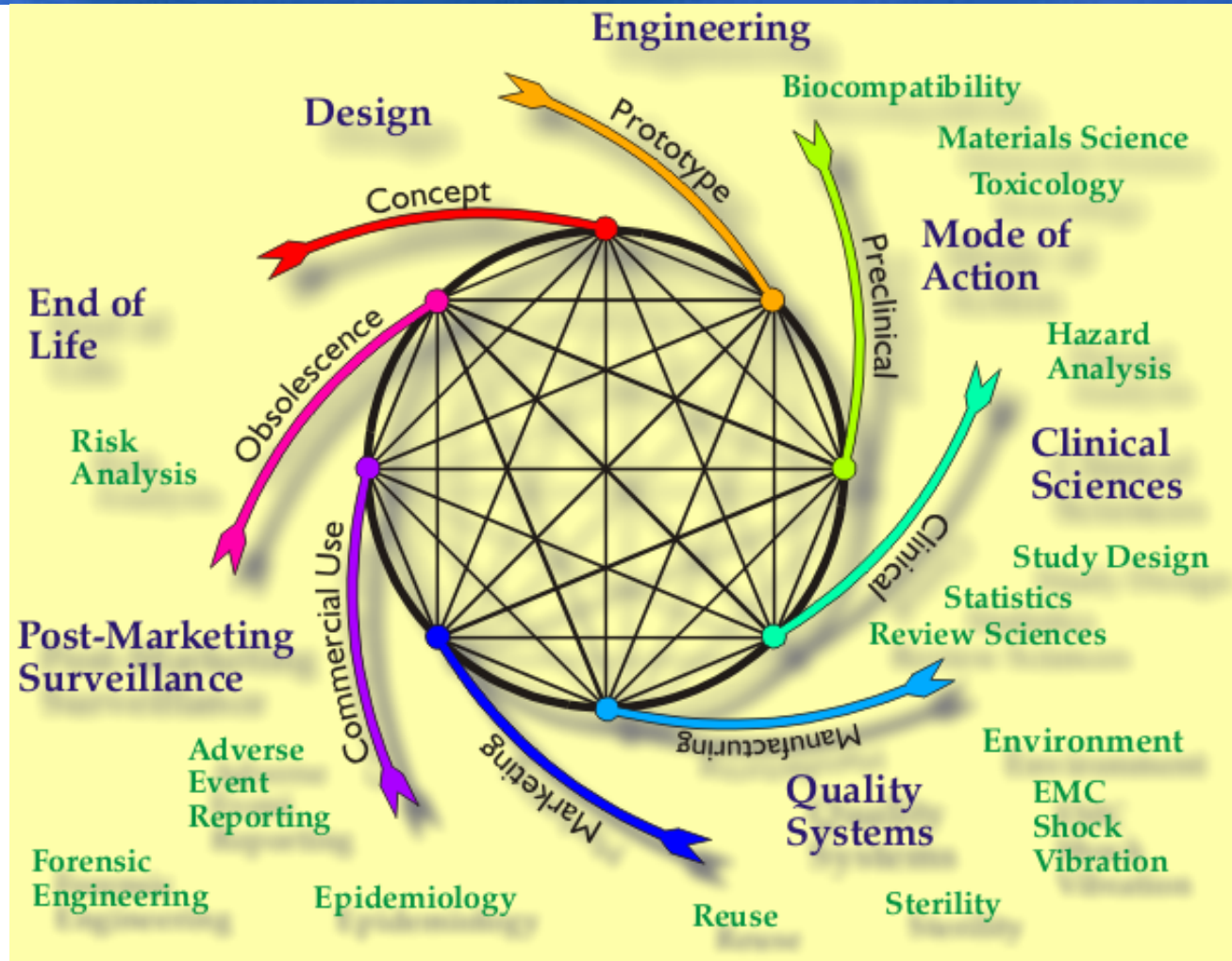
# The Total Product Life Cycle (Real)



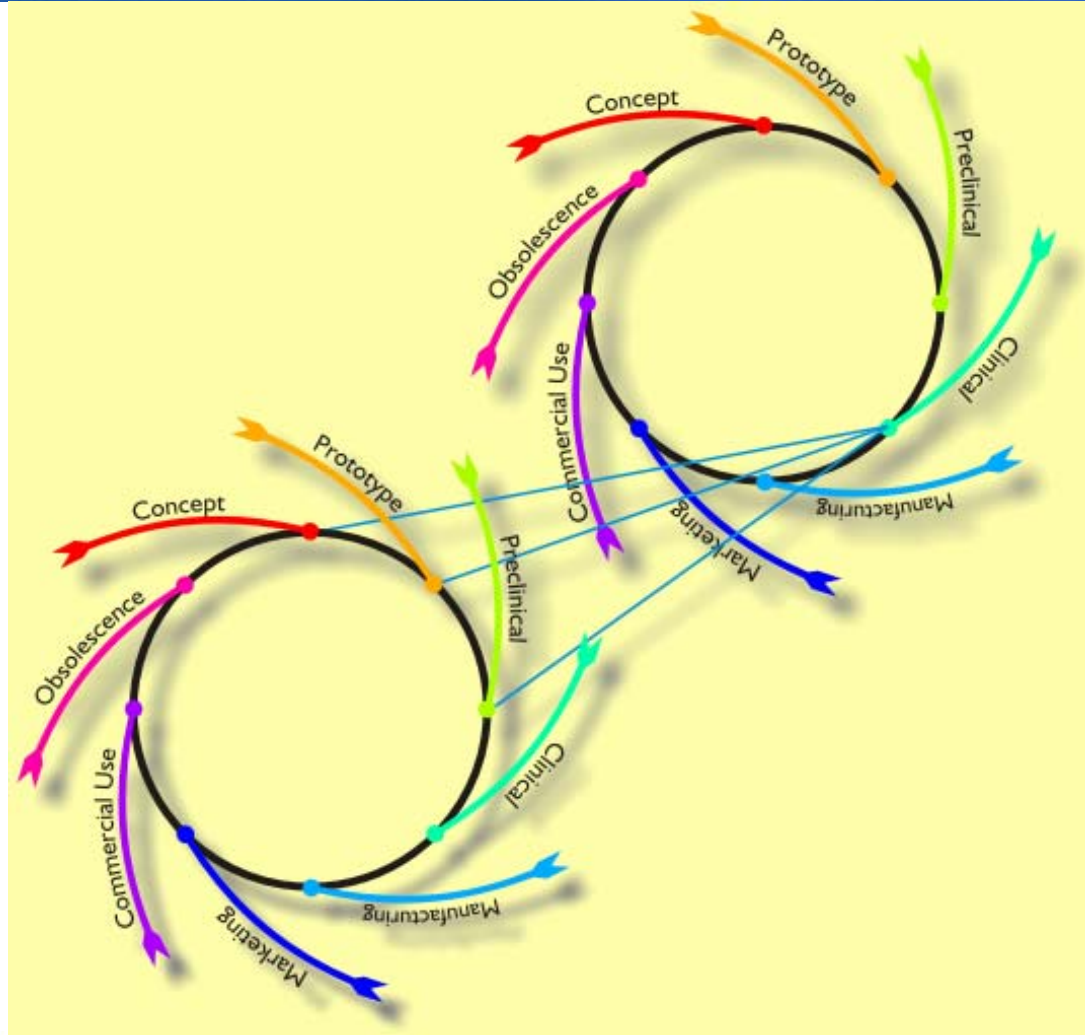
# The TPLC Regulatory Cycle



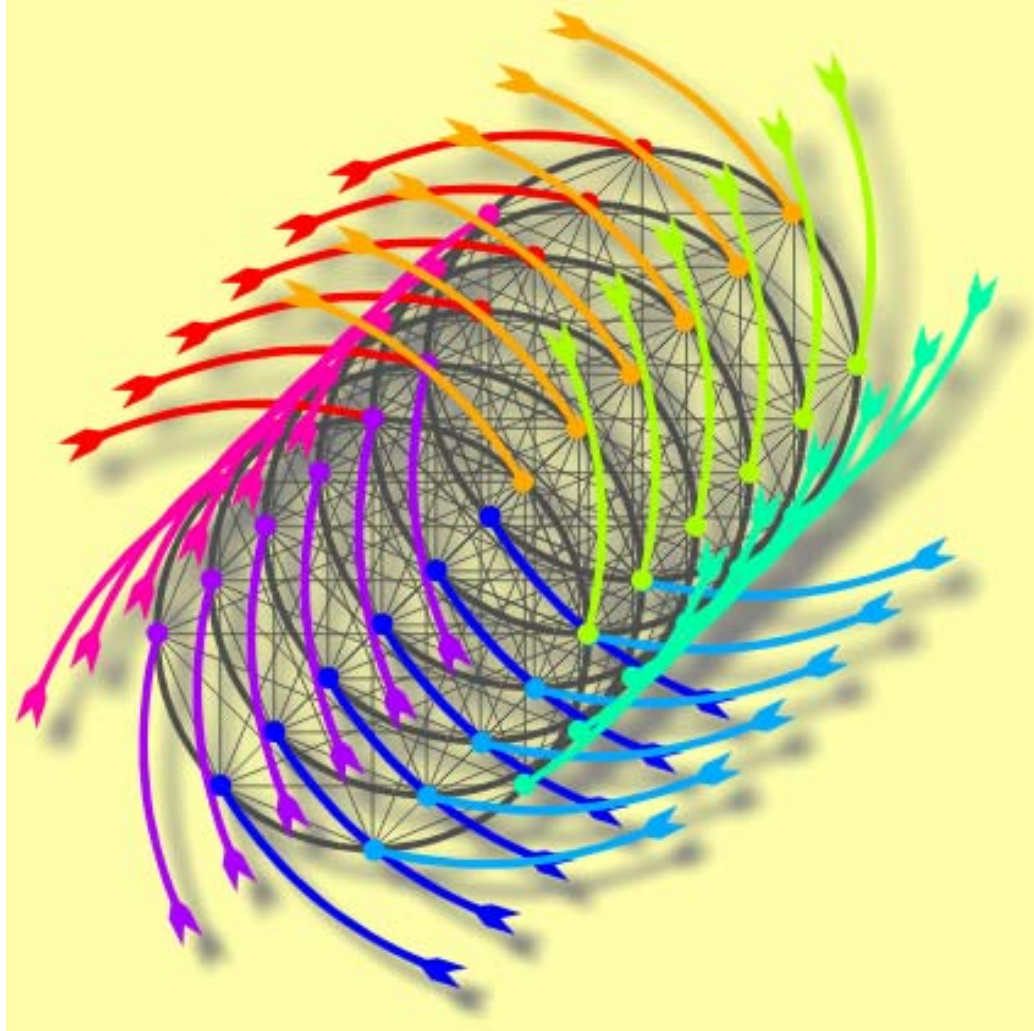
# The TPLC Science Cycle



# TPLC Across Generations



# TPLC and the Pipeline



# How Do We Get There?

- ▲ Drive to 0 CAs by increasing PAs
- ▲ Shift from silos to an integrated approach
- ▲ True Root Cause Analysis
  - ▲ based on real-time manufacturing data
- ▲ Deep understanding of critical to quality parameters
- ▲ Tightly controlled manufacturing process
- ▲ Shifting to building quality in, not testing it out
- ▲ Close the loop between
  - ▲ Design
  - ▲ Manufacturing
  - ▲ Suppliers
  - ▲ Quality



# Winning Profit in the Age of Continuous Innovation

- ▲ Business Impact vs. Regulatory Mandate
- ▲ Build on Foundational Standards
- ▲ Stop Tilting at Silos
- ▲ Shift from Reactive to Proactive and Predictive
- ▲ Total Product Lifecycle Management
- ▲ Concurrent Development
- ▲ Intelligent Root Cause Analysis
- ▲ Global Visibility Across ALL Stakeholders
- ▲ Situational Awareness
- ▲ Total Visibility & Control



# Thank You

## Contact Information

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