



# Back to School

## Quality 101

ASQRS Quality Conference September 2016



**Thank Goodness for Problems! If  
it's "No Problem", it's "No Fun"!**

**Quality Professionals - Solving and  
Preventing Problems – It's What  
We are all About!**

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# Solving and Preventing Problems – It's What We are all About!

Problems Range from: “My Product Won't Sell, Won't Work!, or Cost are Too High” to “Safety Issues that can Cause Harm.”

Being Effective at Problem Solving Requires Experience with the Tools outlined in Body of Knowledge of Quality Professionals.

Problems to Consider:

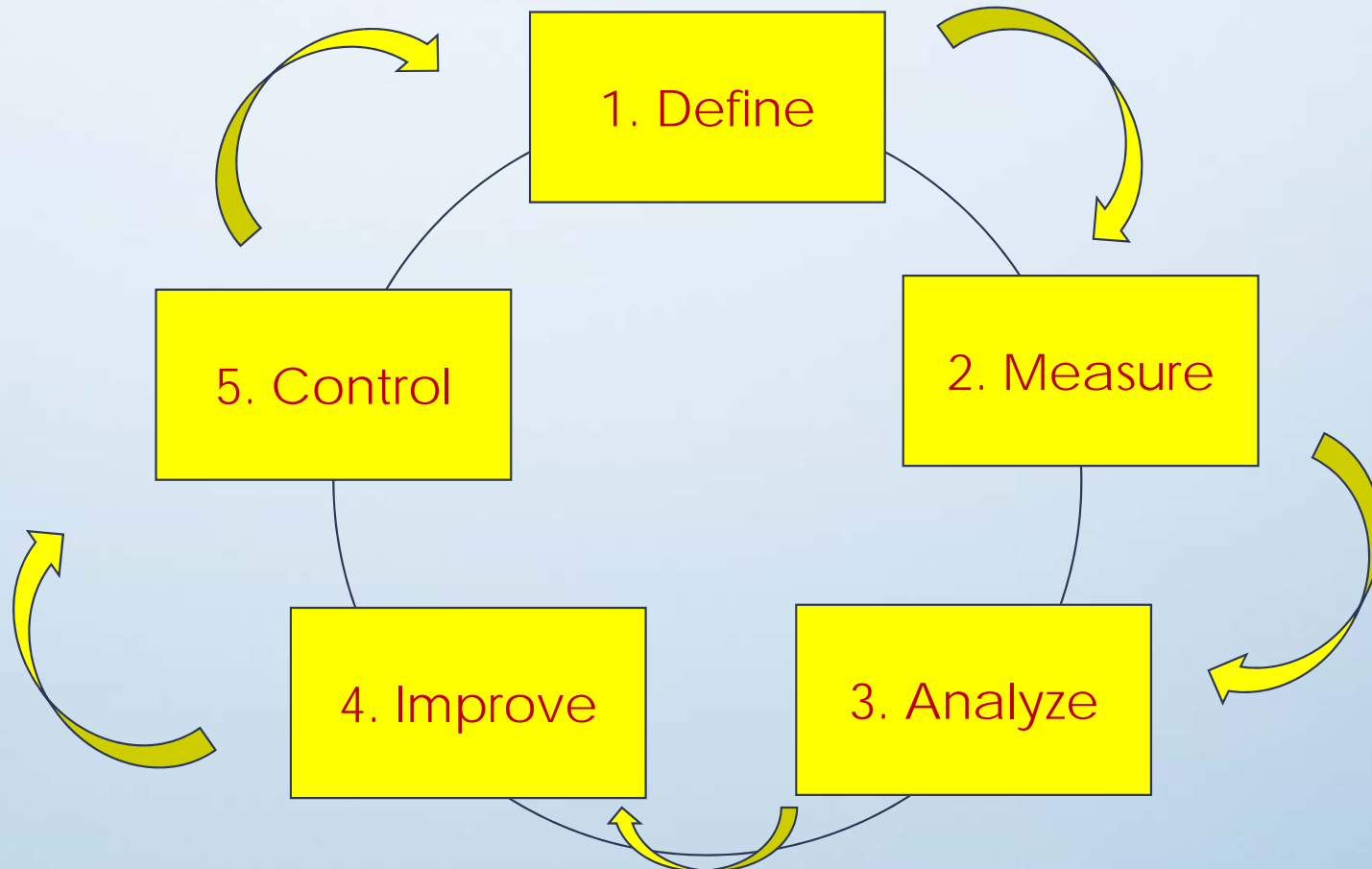


# Solving and Preventing Problems

Problems Range from: “My Product Won’t Sell, Won’t Work!, or Cost are Too High” to “Safety Issues that can Cause Harm.”

- DMAIC Structure for Problem Solving
- Personal Case Studies
  - Food Packaging Sales
  - Ophthalmic Anti-Reflective Coatings
  - New Product Ink Jet
- Serious Case Studies involving Harm
  - Un Anticipated Acceleration
  - Fungus in Pharmaceuticals
  - Airline Flight 173

All of the tools involve data, and methods such as PDCA and DMAIC can help focus the team of subject matter experts that are required for today's complexity.



# 1. DEFINE:

## Problem Statement

### Clear Definition of the Problem

Accountable Person: \_\_\_\_\_

Problem Solving Lead: \_\_\_\_\_

- Where / When is it?
- Where / Where is it not?
- What Resources are required to start the Problem Solving Process?
- What are the Key Milestones for Communication?

## 2. MEASURE:

### Map the Process

#### SIPOC

Supplier  
Input Process Output  
Customer

- Voice of Customer
- Data Collection
- MSA / Process Capability
- Value Stream Maps
- Walk / Be the Process
- Baseline Capture

## 3. ANALYZE:

### Root Cause Determination

- Brainstorming
- FMEA – Failure Mode Effect Analysis
- Design of Experiments
- 5 Whys?
- Physics of Failure
- If – Then Relationship



## 4. IMPROVE:

### Product Design

- Materials
- Form – Function
- Operability
- Error Proofing
- Automation

### Process Design

- Documentation
- Training / Procedures
- Process Controls
- Error Proofing
- Check Lists

# 5. CONTROL

- Control Charts
- Published Reports
- Dashboard Trend Charts
- Visual Signage
- Industrial Standards
  - GMP – FDA Regulations
- Internal / External Audits
- Legislation and Enforcement
- Presentations to Quality Boards
- Celebrations of Success!

# Personal Case Studies

- **Food Packaging – Product Sales  
(Mobil Chemical)**
- **Ophthalmic Anti-Reflective Coating  
(Bausch and Lomb)**
- **Ink Jet Printer – New Product Launch  
(Xerox)**

# Case Studies

## Serious Problems Causing Harm

- **Un-Anticipated Acceleration  
(Toyota)**
- **Fungus in Pharmaceuticals  
(Bausch and Lomb)  
(Johnson and Johnson)**
- **Airline Flight 173  
(United Airlines)**

# Summary Discussion

## Quality Professionals: Solving and Preventing Problems – It's What We are all About!

Problems Range from: “My Product Won’t Sell, Won’t Work!, or Cost are Too High” to “Safety Issues that can Cause Harm.”

Being Effective at Problem Solving Requires Experience with the Tools outlined in Body of Knowledge of Quality Professionals.

**DMAIC Process can be very Effective!!!**



# Thank YOU!!!!!!

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