Clinic #1:
Six Sigma DMAIC - Control Phase

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American Society for Quality – Section 0701

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Learning Objectives

- Increase existing knowledge about the overall DMAIC process and its benefits
- Understand the differences between DMAIC, DFSS, and TQM
- Gain knowledge about the DMAIC Control phase
- Learn about the many tools used in the Control phase

What is Six Sigma?

"Six Sigma in its entirety is many things including a philosophy, a methodology, a goal, and a metric, and is certainly broad enough to work in pure manufacturing as well as wholly transactional and service industries, and anything in between"

Tennant (2002)

"…a comprehensive and flexible system for achieving, sustaining, and maximizing business success"

Pande, Neuman, and Cavanagh (2000)

Six Sigma as a Metric

Defects Per Million Opportunities (DPMO)

- Measure of process performance
- Calculated based on:

Sigma Level	DPMO	Yield (%)
1 s	690,000	31.000
2 s	308,537	69.146
3 s	66807	93.310
4 s	6210	99.379
5 s	233	99.977
6 s	3.4	99.999

When is good 'good enough' for your process?

Six Sigma as a Philosophy

Management philosophy focused on business process improvement:

- Proactive approach – designed to improve quality and performance by removing variation within an existing process or product
- Eliminate waste, rework, and mistakes
- Fact based, data driven, structured problem solving process
- Focused on the voice of the customer
- Increase profitability and competitiveness
- Implemented using project teams and collaboration

GOAL: Achieve Six Sigma quality levels!!!

Six Sigma: "TQM on Steroids"

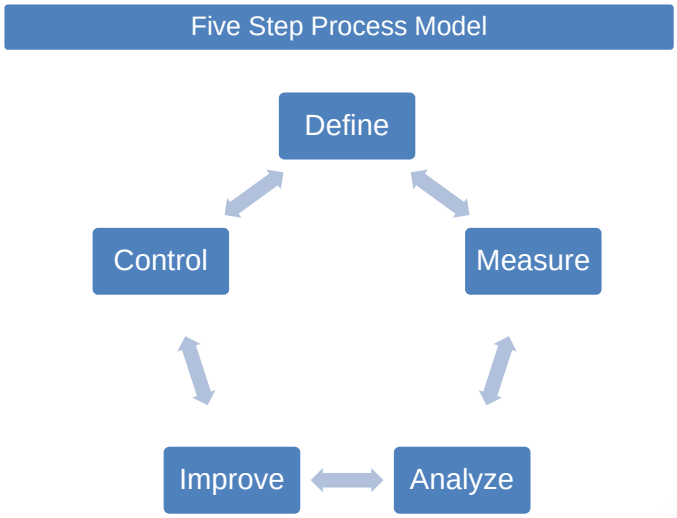
TQM

- Based largely on worker empowerment and teams
- Activities generally occur within a function, process, or individual workplace
- Training is generally limited to simple improvement tools and concepts
- Focused on improvement with little financial accountability

Six Sigma

- Owned by business leader champions
- Six Sigma projects are truly cross-functional
- Focuses on a more rigorous and advanced set of statistical methods and DMAIC methodology
- Requires a verifiable return on investment and focus on the bottom line

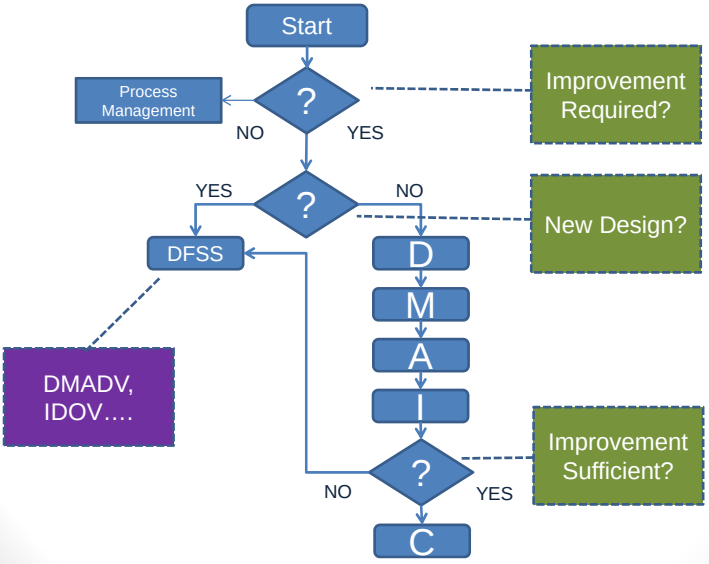
Six Sigma DMAIC Methodology



The Right Tool for the Job!

Problem Type	Problem Description	Solution
Conformance	Unsatisfactory performance within a well-specified system	SS DMAIC
Efficiency	Unsatisfactory performance from the standpoint of internal stakeholders	Lean Tools
Unstructured performance	Unsatisfactory performance by a poorly specified system	Creative Thinking
Product design	Designing new products that better satisfy customer needs	DFSS/ Special Tools
Process design	Designing new processes or substantially revising existing processes	Combined Approaches

When to Use SS DMAIC

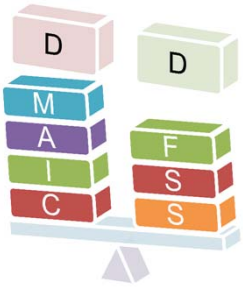


DMAIC vs. DFSS Projects

Product or Process Improvement

- Shorter timeline
- Lower risk
- Narrow focus addressing few CTQs
- Even distribution of resources

Project Objective: Incremental Improvement



New Product or Process Design

- Longer timeline
- Higher risk
- Broad approach addressing many CTQs
- Front loaded resources

Project Objective: Huge Leap in Performance

Corporations that Embrace Six Sigma

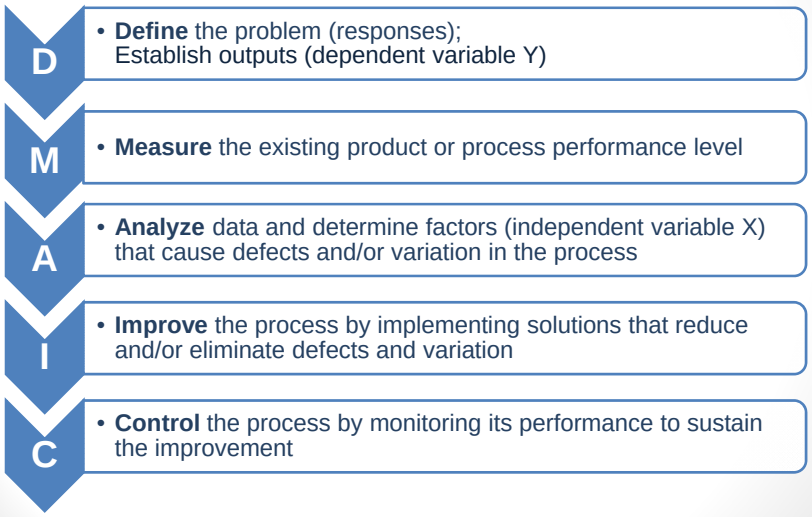
- Motorola
- General Electric
- Allied Signal
- Sony
- Ford Motor

"The most important initiative GE has ever undertaken"

"Six Sigma has changed the DNA of GE - it is now the way we work - in everything we do and in every product we design"

- Jack Welch, CEO General Electric -

Six Sigma - DMAIC Process



DMAIC - Define Phase

- **Define** the problem and develop a project charter
  - Scope - Project definition and objective(s)
  - Establish the project team and sponsor
  - Determine the customers, CTQs, and KPOVs on which the project focuses
  - Define existing measures and performance benchmarks
  - Project expected benefits and financial justification
  - Establish a project timeline and needed resources to execute the project

DMAIC - Define Phase Tools

- Activities and Resource Planning
- Benchmarking
- Budget and Cost Planning
- Communication Planning
- Change Management
- Cost of Quality Analysis
- Cross Functional Team Formation
- Gantt Chart
- Multi-Generation, Strategic Plan
- Project Charter
- Project Scope, Framework
- Project Business Case
- Project Management
- Project Mapping
- QFD

DMAIC - Measure Phase

- **Measure** the existing product or process performance level
  - Process map / flow chart
  - Determine current performance
  - Estimate capability of the process (Cpk, Ppk…)
  - Define key process input variables KPIV – X's
  - Define key process output variables KPOV – Y's
  - Understand cause and effect relationships
  - Determine key metrics
  - Conduct measurement system analysis (MSA)
  - Use selective control charting (diagnostic tool)

DMAIC – Measure Phase

- Focus on understanding process performance and collecting the data necessary for analysis
  - Key data collection questions
    - What questions are we trying to answer?
    - What type of data will we need to answer the question?
    - Where can we find the data?
    - Who can provide the data?
    - How can we collect the data with minimum effort ($) and with minimum chance of error?

DMAIC - Measure Phase Tools

- Benchmarking
- Cause/Effect Matrix
- Descriptive Statistics
- Design Score Card
- Detailed Process Mapping
- FMEA
- Gage R & R
- Ishikawa Diagrams
- Measurement System Analysis
- Process Capability Analysis
- QFD
- Run Charts
- SPC

DMAIC - Analyze Phase

Analyze data and determine factors (independent variable X) that cause defects and/or variation in the process

- Conduct DOE Screening
  - Identify significant inputs (X's = KPIV's)
    - Strong relationship with outputs (Y's= KPOV's)
    - Critical inputs are the drivers of performance
- Determine components of variation (Multi-Vari)
  - Piece to piece, lot to lot, time to time
- Review previous FMEAs to focus on important X's
- Use regression analysis to understand Y = f(X) relationships
  - Generate a regression formula
- Determine potential improvement actions
  - Outline DOE designs to be conducted in the Improve phase

DMAIC - Analyze Phase Tools

- Cause and Effect Analysis
- DOE Screening
- FMEA
- Functional Analysis
- Hypothesis Testing
- Multi-Vari Analysis
- QFD
- Regression Analysis
- Root Cause Analysis
- Scatter Diagrams
- SPC
- Statistical Inference

DMAIC - Improve Phase

Improve the process by implementing solutions that reduce and/or eliminate defects and variation

- Conduct DOE
  - Determine the significant process inputs (X's = KPIV's)
  - Optimize the process outputs (Y's= KPOV's)
- Evaluation and Selection
  - Use a scoring model to assess possible solutions against established criteria:
    - Cost, time, quality, resources required, and barriers to implementation, etc.
- Conduct a confirmation run or pilot run
- Develop a plan to implement the new process

DMAIC - Improve Phase Tools

- Design Score Card
- DOE, Statistical Testing
- Deming Cycle
- Facility Layout Planning
- Fishbone Diagram
- Flow Charting
- FMEA
- LEAN Tools
- Mistake Proofing
- Pilot Run
- Process Capability
- Prototyping/Pilot Run
- Pugh Matrix
- QFD
- Tolerance Design
- Value Stream Mapping

DMAIC - Control Phase

"…the Control Phase is the forgotten C in DMAIC"
Rybarczyk (2005)

- Control is needed to sustain the SS project gains
- Effective quality control systems include:
  - Methods for monitoring and controlling critical quality characteristics
    - Applied to incoming materials, key processes, and final products/services
    - Checklists, status reviews, SPC, etc.
  - Documentation of new standards and procedures
  - Training the workforce
  - Control plans are established with reaction plans
    - Ownership and control is transitioned to the process owner
  - Lessons learned are documented
  - Teams are recognized; Project is closed

DMAIC - Control Phase Tools

- Configuration Control/Documentation
- FMEA
- LEAN Manufacturing Tools
- Lessons Learned
- Mistake Proofing
- MS Re-Analysis
- Process Control Plan
- Process Management
- Statistics Process Control
- Total Productive Maintenance
- Training Plan Deployment
- Visual Factory

DMAIC - Control Phase

- **Control** is “the activity of ensuring conformance to requirements and taking corrective action when necessary to correct problems and maintain stable performance”

Evans & Lindsay (2015)

DMAIC - Control Phase

- Elements of control system:
  - A standard or goal
  - A means of measuring the process
  - A comparison of results with the standard to provide feedback
  - The ability to make corrections as appropriate
- Control should be the basis for organizational learning and lead to improvement and prevention of defects and errors

DMAIC - Control Phase

Statistical Process Control (SPC)

- Technique for applying statistical analysis to processes
  - Measure
  - Monitor
  - Control
- Major component - Various forms of control charting
- Originated by Walter Shewart (1931)

DMAIC - Control Phase

Statistical Process Control (SPC)

- Fundamental Assumption: All processes have variation
  - Common Cause
    - Random or Chance Cause
  - Special Cause
    - Assignable Causes specific to 5M-E
- Process is said to be 'In Statistical Control' when:
  - Sources of Special Cause are eliminated
  - Characterized by plot points that do not exceed the UCL and LCL

DMAIC - Control Phase

Statistical Process Control (SPC)

- Benefits
  - Ability to monitor a stable process and determine if changes occur
    - Average level of a quality characteristic
    - Variability level of a quality characteristic
    - Consistency of performance

DMAIC - Control Phase

Statistical Process Control (SPC)

- Selection of variables (KPIV/KPOV) for charting is based on:
  - Items with high defect rates
  - Major sources of customer complaints/RMAs
  - Items that affect human safety or environment
  - Items that show adherence to applicable standards
  - Items that cause high internal quality costs
  - Variables that help control the process

DMAIC - Control Phase

Types of SPC Charts

Variables (measured)	Attributes (counted)
• Xbar - R	• p (faction defective)
• Run	• np (defectives)
• MXbar - MR	• c (defects)
• X - MR	• u (defects per unit)
• Xbar - S	
• Median	
• Cumulative Sum	
• Moving Average	

Control - Training Plan Deployment

"When a new methodology or process change is introduced in an area, training is the most critical aspect in the successful implementation of that change"

Gupta (2004)

- Employee Training
  - The process aimed at improving the skills and expanding the knowledge of employees
  - Goal: Close the gap between current and desired abilities
- Employee Development
  - The learning of basic principles for future application

Training and development are catalysts for change in employees!

Control - Training Plan Deployment

"Quality control starts and ends with training"

Ishikawa (1985)

- Training, Development, and Deployment Program
  - Fully supported by all levels of management
  - Deployed for all new or revised processes
  - Continuous, progressive, interactive, validated, tested, and robust
  - Requires the proper identification of individuals
    - Need to understand the benefits of the change
    - Need to understand their roles and responsibilities
  - Structured to attain the goals of the organization

Control - Documentation

An effective 'Control System' is accomplished by formal documentation

- It is important to create or revise process documents to incorporate the changes that contributed to the DMAIC improvement
- To maintain consistency in the process and sustain the improvements
- Hierarchy of Documentation
  - Manuals
    - Procedures
      - Standard Operating Procedures
        - Work Instructions
          - Process Control Plans
            - Records

Control - Documentation

- Control System - Documentation Guidelines
  - Established to define the controls needed:
    - Reviewed and approved by appropriate levels of authority/responsibility (prior to issuance)
    - Configured - Revision status of documents are identified
    - Available at points of use
    - Legible and readily identifiable as to its purpose
    - Controlled distribution
    - Prevent the unintended use of obsolete documents
  - Simple, clear, and brief
  - Properly understood by employees
  - Meaningful and appropriately developed

Source: ISO9001 QMS/Documentation Requirements/Control of Documents

Process Control Plan (PCP)

- Used to sustain a continuous improvement effort
- Control critical characteristics (X's/Y's) of a process
- Sources of KPIV's and KPOV's:
  - FMEAs
  - Process flow charts
  - C-E Analysis
  - Historical and statistical data
  - Lessons learned
  - Team process knowledge
  - Regression analysis
  - Multi-vari studies
  - QFD
  - DOE

Process Control Plan

Affected Part Number(s):									Date:		Rev	A
Control Plan Number:				Division/Unit:					Type:			
Process Owner:					Line				ECN #:			
Process Name	Sub-Process	KPIV	KPOV	Special Note	Spec	Meas Gage	Sample Size	Freq	Cpk	Resp Person	Control Method	Reaction Plan
1	2	3	4	5	6	7	8	9	10	11	13	14
A	-											
B	-											
C	-											
D	-											

Example: Blank Process Control Plan

Automotive Sector -
ISO/TS 16949 Quality Management Systems
Advanced Product Quality Planning and Control Plan (APQP)

Process Control Plan (PCP)

- Maintains conformity of a process or product
- Supplements WI's and SOP's
- Addresses all processes
- Best managed by the process owner
- Created by a team of individuals (cross functional)
- 'Living document' - continually updated

Process Control Plan (PCP)

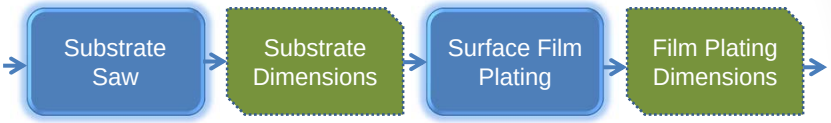
- Contents of a Process Control Plan
  - Define the product and process steps
  - Which quality characteristic (KPIV/KPOV) to control
  - Which specification or tolerances to maintain
  - Which instruments and analysis methods to use
  - Which sample sizes to take
  - The frequency of inspection
  - Identify responsible person
  - Instructions on what to do if defects are detected

Process Control Plan (PCP)

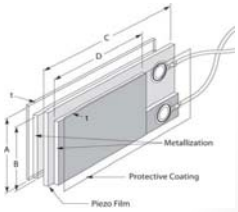
- Three types of Process Control Plans (APQP)
  - Prototype
    - Used in early development stage
  - Pre-Production (Pilot Run)
    - Used after Prototype phase
    - Much more detailed than the Prototype phase
  - Production
    - Used during Full Scale Production
    - Most comprehensive content

PCP Example: Process Flow Chart

An Example: Piezoelectric Sensor



- An excerpt of the overall process
- Rectangular elements of piezo film
- Screen printed Silver ink electrodes



Voltage proportional to mechanical stress or strain
Film and electrode dimensions are critical

Process Control Plan (PCP)

Affected Part Number(s): PS-100-627S									Date: 07-12-2016	Revision:		C
Control Plan Number: 43312-100					Division/Unit: South Building				Type: Production			
Process Owner: John Smith						Line B1				ECN #: 8774		
Process Name	Sub-Process	KPIV	KPOV	Special Note	Specification	Measurement Gage	Sample Size	Sample Frequency	Initial Cpk	Responsible Person	Control Method	Reaction Plan
1	2	3	4	5	6	7	8	9	10	11	13	14
Substrate Dimensions	A	NA	Length	B WI# 1002	20.0mm +/- 0.05mm	XZ-500 Micrometer	5 pcs	Each Lot	1.7	Process Owner	Control Chart Xbar-R	Notify Engineering
	B	NA	Width	C WI# 1002	8.0mm +/- 0.05mm	XZ-500 Micrometer	5 pcs	Each Lot	1,65	Process Owner	Control Chart Xbar-R	Notify Engineering
	C	NA	Thickness	T WI# 1002	0.8mm +/- 0.02mm	XZ-500 Micrometer	5 pcs	Each Lot	1,65	Process Owner	Control Chart Xbar-R	Notify Engineering
Surface Film Plating	A	NA	Film Thickness	T1 WI# 1010	1200A +/- 100A	Profilo-meter E-349	30pcs	Start of each shift	1.5	Process Owner	Check Sheet	Prod Stop - Notify Production Manager

Used to sustain a continuous improvement effort and control critical characteristics (X's/Y's) of a process

Control - Measurement System Re-Analysis

- Originally completed in Measure Phase
  - Determine the measurement system requirements
  - Evaluate measurement system capability
- As process capability improves:
  - Measurement system needs to be re-evaluated
  - Determine if requirements or measurement capability also need to be improved to achieve the desire level of control

MSA: Determine variation/uncertainty of measuring a system
- Bias, linearity, stability, repeatability and reproducibility -

Control - TPM

- Total Productive Maintenance (TPM)
  - An activity that promotes the coordination of group activities to optimize equipment effectiveness
- Features of TPM:
  - Maximize equipment effectiveness
  - Total system maintenance
  - Implementation by engineering, manufacturing, QA
  - Involvement of all employees
  - Company led small work groups

Overall Equipment Effectiveness:
Operating Rate x Performance Efficiency x Equipment Availability

Control - Visual Factory

- Visual display of information on what is happening on the shop floor:
  - Kanban (billboard) cards
  - Production boards
  - Maintenance boards
  - Schedule boards

- Purpose
  - Makes problems visible
  - Helps workers focus on the workplace (gemba)
  - Communicates targets for improvement

Control - Visual Factory

Commonly Displayed Items

- Order status
- Training records
- Delivery issues
- Throughput
- Productivity charts
- Shipment performance
- Quality levels
- 5S activities
- TPM status
- Tool/machine downtime
- Safety trends
- Production goals

Control - Lessons Learned

- 'Postmortem Analysis' or 'Post Project Appraisal'
  - Formal documented review and critique
  - Covers all SS DMAIC phases
  - Review process established by management
  - Conducted by a committee of qualified company personnel
    - Management, Black Belts and Master Black Belts, Manufacturing, Engineering, Purchasing, and QA
  - Review Project Criteria (Success or Failure)
    - Goals and objectives (achieved)
    - Schedule (meet or exceed target dates)
    - Cost (at or below budgets)
  - Project review and other project documentation should be archived for future reference

Control - Team Recognition

- Employees who feel appreciated when they are recognized for their accomplishments:
  - Often go above and beyond what is expected of them
  - Are more productive, motivated, and loyal
  - Are more likely to stay with the organization
  - Can help build a supportive work environment
  - Have a sense of workplace ownership
  - Know that their work is valued and appreciated

Control - Team Recognition

- SS Group Project Recognition
  - Formal program/policy: rewards and recognition
  - Given to the SS project team as a whole
  - An open, company-wide acknowledgement of the SS team contributions
  - Provides an example of success for future project groups
  - Supported by the HR department and SS executive management
  - Can include awards, certificates, or gifts
  - Project closure

Questions?

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DMAIC Speakers:

D - Upen Patel

M - Mark Lindsey

A - Larry Bartkus

I - Ned Schneider

C - Tom Culhane

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