IT'S A MARATHON, NOT A SPRINT
HOW TO RUN YOUR BEST RACE
FRIDAY, SEPTEMBER 29, 2017
7:00 AM – 3:45 PM
BWI MARRIOTT

ONE-YEAR MEMBERSHIP INCLUDED IN FEE FOR FIRST-TIME MEMBERS.
Get the Skinny on Lean Six Sigma
Jennifer Ralston, CEO & Owner
Master Black Belt & Lean Sensei
Agenda

• 1hr 30mins
• Intro Lean Six Sigma
• How Regulations Can Fit In
• Examples of Problems
• Next steps

• SESSION 304 —Interested in learning about Lean Six Sigma? This introductory session will share the basics and examples of healthcare challenges that can be fixed by Lean Six Sigma. It will also provide an overview of regulatory requirements and how to begin implementing Lean Six Sigma methodology in your practice.
Meet Jennifer Ralston

Professional Summary – Jennifer Ralston

Jennifer Ralston is a Multifaceted Manager with unique blend of experience in quality, process improvement, process engineering, regulatory, pharmaceutical, quality auditing, software quality, project and program management, change management and lean six sigma.

Ralston has worked with American Red Cross Bio Medical Services Headquarters and Organ Transplant Team, Office of the Secretary of Defense (OSD), EJ Gallo Wines, Manulife, DALB, L-3, Rolls-Royce, Sysco, Aflac, Hollywood Casinos, The United States Department of Agriculture (USDA), United States Postal Service (USPS), the Naval Yard, Genentech part of the Roche Family, The Project Management Institute (PMI), Merck Pharmaceuticals, The Army, Reston Hospital, The National Security Agency (NSA), American Association of Blood Banks (AABB), Reston Hospital, Medical College of Virginia, University of Maryland Medical System, Georgetown University Cellular Engineering, Department of State Newborn Screening, and jetTravel Intelligence. She has presented Quality Concepts to places such as the University of Cairo in Egypt, conducting an International Audit of the Vascera, in Cairo, Egypt in 2001. This was a unique opportunity to teach regulatory concepts to a pharmaceutical company overseas. Ralston has also won the American Red Cross Spirit of Excellence Award, which is an award for individuals that achieve major results.

During her time working for American Red Cross, Jennifer was the Director of Process Improvement for Biomedical Services at American Red Cross National Headquarters. She is a certified Master Black Belt, Lean Sensei, and managed the Red Cross’ Lean Six Sigma Program and Computer Simulations. Ralston began her seven (7) year career at Red Cross in 2002, serving as Senior Change Engineer, Change Management, Senior Quality Design Engineer, and Systems Design Engineering. She was also the organization’s first Black Belt and Master Black Belt in the Six Sigma program. In this role, she introduced and implemented Six Sigma and Project Management tools in support of the continuous improvement program and in compliance with FDA regulations, applicable laws, cGMP, CLIA/CMS, as well as AABB, JCAHO and ISO Standards. Ralston is also an auditor for several organizations such as AABB, CAP and ISO. She has also trained with the American Society of Quality as a Certified Quality Auditor and Certified Quality Engineer. Ralston has also worked as a Clinical Technologist, Medical Technologist and Microbiologist when she first started her career in Health Care which later changed to a career in Quality and Process Improvement after she decided not to go to Medical School to be a Pediatrician.

Areas of Expertise
- Lean Enterprise & Standard Work Replication
- Lean Six Sigma & Design for Six Sigma
- Business & Strategic Planning
- Supplier Management & Procurement
- IT & Project Management
- Regulatory Compliance, FDA Experience
- Process and Product Design

Industry Experience
- Pharmaceutical
- Healthcare
- Government

Education and Certificates
- Certified Six Sigma Master Black Belt & Lean Sensei
- American Society of Quality Certified Quality Engineer
- American Society of Quality Certified Quality Auditor
- Certified Kepner Tregoe Problem Solving & Decision Making
- Assessor for American Association of Blood Banks
- ISO Auditor
- Inspector for the College of American Pathologist
- Senior Member of Society of Manufacturing Engineers
- Member of International Society for Six Sigma Professionals Master Black Belt Circle
- Senior Member of American Society of Quality
- Bachelors Degree, Biology & Chemistry Longwood University
<table>
<thead>
<tr>
<th></th>
<th>Six Sigma</th>
<th>Lean</th>
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<tbody>
<tr>
<td><strong>Goal</strong></td>
<td>Improve performance</td>
<td>Reduce waste, increase process speed, and Standard Work</td>
</tr>
<tr>
<td><strong>Focus</strong></td>
<td>DMAIC with Total Quality Management tools to eliminate variation</td>
<td>Identify non-value added steps and cause for delay</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>Management engagement, dedicated Champions and Black Belts</td>
<td>Kaizen events, Value Stream Maps</td>
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DMAIC Methodology

How do we guarantee performance?
What needs to be done?
What is wrong?
How are we doing?
What is important?

DEFINE

MEASURE

ANALYZE

IMPROVE

CONTROL

What is important?
How are we doing?
What is wrong?
What needs to be done?
How do we guarantee performance?
The Focus of Six Sigma:

If we can...

1. Establish a relationship between inputs and outputs, and
2. We can control the inputs, then
3. We can predict the outputs!

\[ Y = f(x) \]

\[ \text{Outputs} = f(\text{Inputs}) \]

\[ \text{KPOVs} = f(\text{KPIVs}) \]
Our Focus

KPOV  KPOV  KPOV

CTx (CTQ)

Critical to Quality

Process Output Ys

KPIV  KPIV  KPIV  KPIV

Process Inputs Xs

Process
Is Your Organization “On Target”

- Dr. Deming would often say: What is your aim? Why are you in Business?
- Discussion: What do these questions really mean to your organization?
  - What’s your organization’s purpose?
  - Who are your customers?
  - What do they want?
  - Are you delivering what they want?
  - If not, what is it costing your organization?
- Question: How can we adequately meet the needs of our customer?
Most successful organizations are built on the following:

- **Continual Improvement**: A focus on continual improvement of operations with input from all associates to innovate and achieve quality at reduced costs.
- **Differentiation**: Differentiate yourself from the competition.
- **Responsiveness**: Responsiveness to understand what is desired and to provide it quickly.
- **Customer Focus**: True focus and commitment to satisfying both internal and external customers.
- **Vision and Commitment**: Vision and commitment from top management are key to achieving success.
Six Sigma is: A rigorous management discipline that systematically eliminates "defects" and improves the economics of business processes to improve customer satisfaction and increase customer loyalty.

Uncontrolled variation is the enemy of quality.

— W. Edwards Deming —
Lean Definition

**Lean** is all about **streamlining processes** and **promoting efficiency** by **eliminating waste** and **non-value adding activities**.

Value Add Activities =

1) Something the Customer will pay for
2) Contributes to Transformation of the product or service
3) Contributes to First Time Right
Industry typically reports:

- 80% improvement in quality
- 75% improvement in use of space
- 80% reduction of work-in-process inventory
- 90% reduction in lead time (or cycle time)
- 50% increase in productivity.
Fold a Piece of Paper
Fold a Piece of Paper

How to Make an Envelope

1. Fold the paper in half
2. Open the fold
3. Fold the other half
4. Open it up
5. Fold the left corner to meet at the center
6. Repeat with the right corner
7. Fold the bottom corner up to the dotted line
8. Fold the bottom left corner
9. Repeat with the bottom right corner
10. Put glue and fold
11. Fold the triangular top
12. The envelope is complete

COOL28KIDS.COM
Why do we care about Lean Six Sigma?

<table>
<thead>
<tr>
<th><strong>3.8 Sigma</strong></th>
<th><strong>6 Sigma</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(99% Good)</td>
<td>(99.99966% Good)</td>
</tr>
<tr>
<td>2 short or long landings at most airports each day</td>
<td>1 short or long landing every 5 years</td>
</tr>
<tr>
<td>15 minutes of unsafe drinking water each day</td>
<td>1 minute of unsafe drinking water every 7 mo.</td>
</tr>
<tr>
<td>750 dropped babies in the US each week</td>
<td>13 dropped babies a year</td>
</tr>
<tr>
<td>200,000 wrong drug prescriptions each year</td>
<td>68 wrong prescriptions per year</td>
</tr>
</tbody>
</table>
Where are Companies Today

(with ± 1.5 σ shift)

- IRS - Tax Advice (phone-in) (140,000 PPM)
- Restaurant Bills
- Doctor Prescription Writing
- Payroll Processing
- Order Write-up
- Journal Vouchers
- Wire Transfers
- Airline Baggage Handling
- Purchased Material Lot Reject Rate

Best-in-Class
Average Company

Sigma Scale of Measure

DPMO

PPM
What Is Six Sigma look like?

<table>
<thead>
<tr>
<th>$\sigma$</th>
<th>DPMO</th>
<th>Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>690,000</td>
<td>30.9%</td>
</tr>
<tr>
<td>2</td>
<td>308,537</td>
<td>69.2%</td>
</tr>
<tr>
<td>3</td>
<td>66,807</td>
<td>93.3%</td>
</tr>
<tr>
<td>4</td>
<td>6,210</td>
<td>99.4%</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
<td>99.98%</td>
</tr>
<tr>
<td>6</td>
<td>3.4</td>
<td>99.99966%</td>
</tr>
</tbody>
</table>
The Strategy

Know What is Important to the Customer

Reduce Variation

Center Around Target

Reduce Defects
Roles and Responsibilities

• Champion
• Master Black Belt
• Black Belt
• Green Belt
• Yellow Belt
Champion:

1. Select projects for the teams to validate
2. Review improvement projects using the DMAIC methodology
3. Review weekly achievements, obstacles, key deliverables
4. Remove obstacles and barriers as necessary
The Belts

Master Black Belt
- The Vanguards of the DMAIC Methodology
- Full time dedicated position.
- Drives transformational change leading large, complex projects.
- Accountable for Implementing Improvement solutions & sustaining results.
- Provides technical leadership, training, coaching & mentoring of other belts in the understanding of LSS tools and methods.
- High Performers! Future Leaders!

Black Belt
- Full-time / can be embedded.
- Coordinates the efforts of problem-solving teams.
- Accountable for Data Based Improvements.
- Manages complex projects & Kaizen events.
- Must have Analytical & People Skills

Green Belt
- Operates within their own organization.
- Working knowledge of Lean Six Sigma theory & problem solving tools.
- Leads mid-sized projects.

Lean Practitioner
- Operates within their own organization.
- Familiar with Lean Six Sigma theory & problem solving tools.
- Performs smaller-scale projects & participates on project teams.
1. This is a level that has been added to provide additional resources for the team.
2. Part-time team members who have other full time responsibilities.
3. Training is typically limited to awareness training.
4. Potential Green belt candidates.
DMAIC Methodology

DEFINE

MEASURE

ANALYZE

IMPROVE

CONTROL

What is important?

What is wrong?

What needs to be done?

How do we guarantee performance?

How are we doing?
# Five Phases and Key Tools

<table>
<thead>
<tr>
<th>Define</th>
<th>Measure</th>
<th>Analyze</th>
<th>Improve</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine Customer</td>
<td>Metrics</td>
<td>Graphs</td>
<td>DOE</td>
<td>Control Plan</td>
</tr>
<tr>
<td>Select Project</td>
<td>Process Map</td>
<td>Hypothesis Tests</td>
<td>Brainstorming</td>
<td>SPC</td>
</tr>
<tr>
<td>Determine Scope</td>
<td>C&amp;E Matrix</td>
<td>ANOVA</td>
<td>Benchmarking</td>
<td>Error Proofing</td>
</tr>
<tr>
<td>Estimate Savings</td>
<td>FMEA</td>
<td>DOE Plan</td>
<td>Root Cause Analysis</td>
<td>Automated Control</td>
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<tr>
<td></td>
<td>Gage Study</td>
<td>Root Cause Analysis</td>
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<td></td>
<td>Capability Analysis</td>
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## Project Charter

### Business Case:

### Project Leader:

#### Team Members:

#### Key Contacts:

### Problem Statement:

### Goal Statement:

### Primary Measure:

### Secondary Measure:

### Cost of Poor Quality:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Start Date</th>
<th>End Date</th>
<th>% Complete</th>
<th>Health</th>
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<tbody>
<tr>
<td>Start Date</td>
<td></td>
<td></td>
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<tr>
<td>Define</td>
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<td>Measure</td>
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<td>Control</td>
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<tr>
<td>Completion Date</td>
<td></td>
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### Project Scope:
Blood Services FY09 Strategy Map

Overarching Objective

With a commitment to quality, ensure availability of blood products and services that consistently meet or exceed all expectations

Mission Results

M1: Achieve sustained compliance
M2: Become recognized leader in transfusion medicine
M3: Achieve margin growth
M4: Grow market share

Constituencies/Stakeholders

S1: Develop strong local and national relationships with new and committed sponsors
S2: Improve donor experience & relationship to increase repeat donations
S3: Identify and fulfill hospital and patient needs for safe and effective blood products and services
S4: Develop win-win relationships with new & existing hospital customers & become 'preferred provider'

Internal Processes

P1: Simplify and standardize our work processes
P2: Optimize demand-driven hospital to donor supply chain
P3: Enhance donor & sponsor recruitment, management and retention process
P4: Improve blood & blood component collection in alignment with donor expectations
P5: Identify and provide valued services

Organizational Capital

O1: Leverage capacity and infrastructure
O2: Establish a culture of compliance
O3: Improve alignment, engagement, and personal accountability
O4: Attract, select, develop, and retain a high performing workforce
O5: Improve staff performance
**What Matters To Customers?**

<table>
<thead>
<tr>
<th>Quality</th>
<th>Delivery</th>
<th>Cost</th>
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<tbody>
<tr>
<td>♦ Reliability ♦ Capability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Durability ♦ Functionality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Usability ♦ Fast response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ 24-hour hot line ♦ Positive interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Accessibility ♦ Politeness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Knowledgeable ♦ Friendliness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Reasonable price ♦ Extended warranty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Good value ♦ Discounts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>♦ Easy terms ♦ Free shipping</td>
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</table>

Competitive battles are being fought in many arenas; specific factors may be different.
Determining the voice-of-the-customer involves continuously “listening”, then developing a systematically driven set of activities centered on establishing a learning relationship between suppliers and customers that drives business objectives.
KANO Analysis

- Delighters!
- Performance (Satisfier)
- Must Be (Dissatisfier)
- World Class

Customer Satisfaction:
- Delight
- Neutral
- Dissatisfaction

Presence of the Characteristic:
- Absent
- Fulfilled

World Class
Best in Class

Fulfilled
Absent
A collection of activities that takes one or more inputs and transforms them into outputs that are of value to the customer.
High Level Process Map

Detailed Process Map
The Hidden Factory
Focus on Value Streams
avoid “suboptimization”
Cause and Effect Diagram
Let’s Talk about Regulations
Count the Eggs
Simple Visual Management
What are the 8 Wastes?

- Transportation
- Inventory
- Motion
- Waiting
- Over-production
- Over-processing
- Defects
- Skills - Creativity
Simple Examples of Success
Problem Challenges with Tubes

- Attaching 6 tubes to each bag requires time and agility - possible repetitive motion injuries
- Tubes on bags hard to scan and fill.
- Tubes missed during scan (Regulatory Problem)

Solution Create Reusable Holder
Kaizen Idea Tube Holder

- Easy to scan each tube
- Allows sample tubes to be drawn easily and quickly
- Keeps the bag and tubing together
- Can be “loaded” with tubes ahead of time

Tube holder keeps tubes in-place for easy scan and fill
Problem with Health History

- Health historians can't see if histories are occupied.
- Staff walk the length of all the histories looking for a vacant booth.
- Staff can’t tell when donors are done with Self Administered Health History and waiting.
- Donors had to stand and wait for staff to finish health histories.

No way for staff to tell which booths are occupied.
Kaizen Idea Flip Signs

- Create flip signs for visual cues of Health History Status.
  - Ready – Pink
  - In-Use – Orange
  - Re-check - Yellow
  - 2RBC – green
- Quality Improvement- Improved donor confidentiality.

Improved donor confidentiality & Visual Management
Walking distance decreased from 257ft to 114 ft
(approx 48 secs per staff per history)
Simple Solutions then Replicate
High School: 12 Health Histories and 15 Beds - 3 DRC with a Health History Conceptual Drawing

- Printer dedicated to a unit and located for easy access to the health histories
- Health Histories (4) dedicated to a 5 bed VP unit
- Pack table near VP units
- MUA table near VP units
- Dedicated 2RBC health history

Notes:
- 15 bed drive utilizes three 5 bed VP units.
- Health Histories dedicated to VP units to reduce walking.
- Extra health histories and VP beds should be set up at high school and college drives to accommodate 1st time donors and reactions in the VP unit.
- 2RBC unit
- VP units are duplicate 5 bed VP units. Very effective use of floor space.
### Standard Work Guidance - Reception

**Version #:** CO-02-12102008

**Scope of Operations**
- From: Donor arrives at site
- To: Staff takes donor to Health History

**Display at Reception**
- Reception Area Set-up Example
  - Set up area according to space availability at drive location

**Process Flow (Refer to Regulated Procedures for Tasks)**

**When Donor Arrives:**
- Greet the donor and mark arrival time on Donor Survey Card if needed
- Instruct donor to read Stop Sign
- If donors has questions refer to Supervisor or Staff
- If donor can not donate based on information provided politely thank them for coming.

**Donor can donate:**
- Ask for American Red Cross donor card or proper identification
- Refer donors without identification to available member of the collection staff.
- Ask donors if they would do a Double Red Blood Cell (DRC) donation.
- If Yes, provide information and apply DRC identification
- Provide the donor reading materials.
- Instruct the donor to sit in the Reading Area and read all the pre-donation materials and then bring the book back to the reception desk when done.

**Materials**
- Appointment Schedule
- Pens and Donor Sign-In sheet
- Name tags: **Green:** New Donors **Red:** Repeat Donors

**Equipment**
- Stop Sign and Holder
- Reading materials
- What You Must Know Before Giving Blood
- CJD Information Sheet
- Medication Deferral List
- What You Must Know About NAT
- Chairs for Health History Queue
- Chairs for Reading Area Table
- Volunteer identification
- Standard Work Guidance

**After donor completes Reading Material:**
- Refer donors with health or donation questions to Staff
- If donor has no questions ask the donor to to Sign-In on sheet
- If donor has appointment mark them off the Schedule
- Select a **Green** name tag for new donors, or a **Red** name tag for repeat donors. Ask donor how they would like to be addressed and fill in donor name tag with Name, Sign-In number, and a "W" if a walk-in
- Thank the donor for coming
- Ask them to sit in the Health History Waiting Queue
Donor Name Tag

New Donor

Repeat Donor
Phlebotomy Kits Before
Phlebotomy Kits After
Before Lab Storage Room
After Lab Storage Room
Cost of Errors and Mistakes

Cost vs Time of Identification
Join us in December

LEAN SIX SIGMA – GREEN BELT CERTIFICATION

December 11, 2017
8:30am

MD MEP
8894 Stanford Blvd. Suite 304, Columbia, MD 21045 (map)

$3,500
Training Reimbursement Funds Available!

http://www.mdmep.org/event/lean-six-sigma-green-belt-certification/
Thank you!