

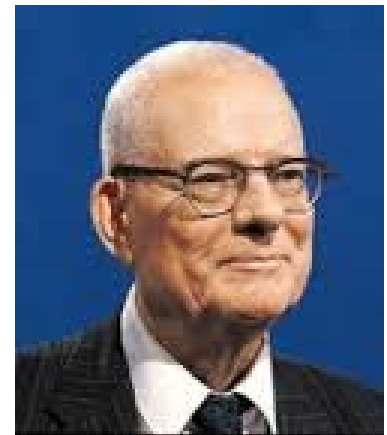
# Living the Future of Lab Testing Today: How Henry Ford Health's Clinical Labs and Pathology Department are Delivering More Value to Clinicians and Patients



Richard Zarbo, MD, DMD  
2016 Lab Quality Confab  
New Orleans, LA October 18, 2016

# The “Old Religion”

**“An important obstacle to continuous process improvement is the supposition that improvement of quality and productivity is accomplished suddenly by affirmation of faith”**



W. Edwards Deming

# The “New Religion”

**"Opportunity is missed by most people because it comes dressed in overalls and looks like work."**

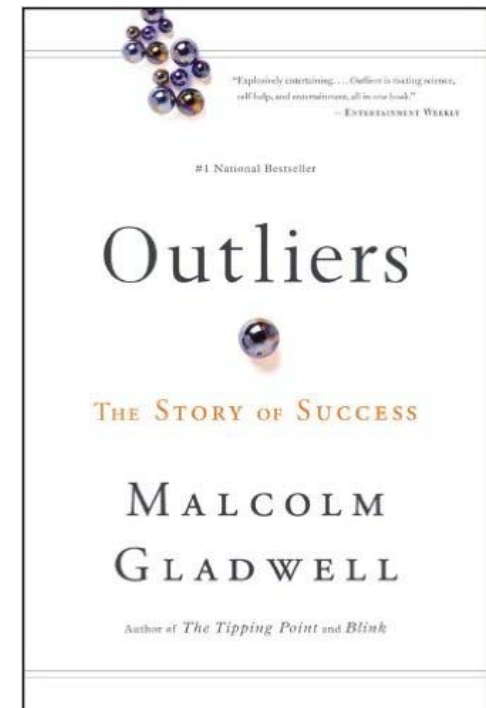
**“There are no rules around here- we are trying to accomplish something”**



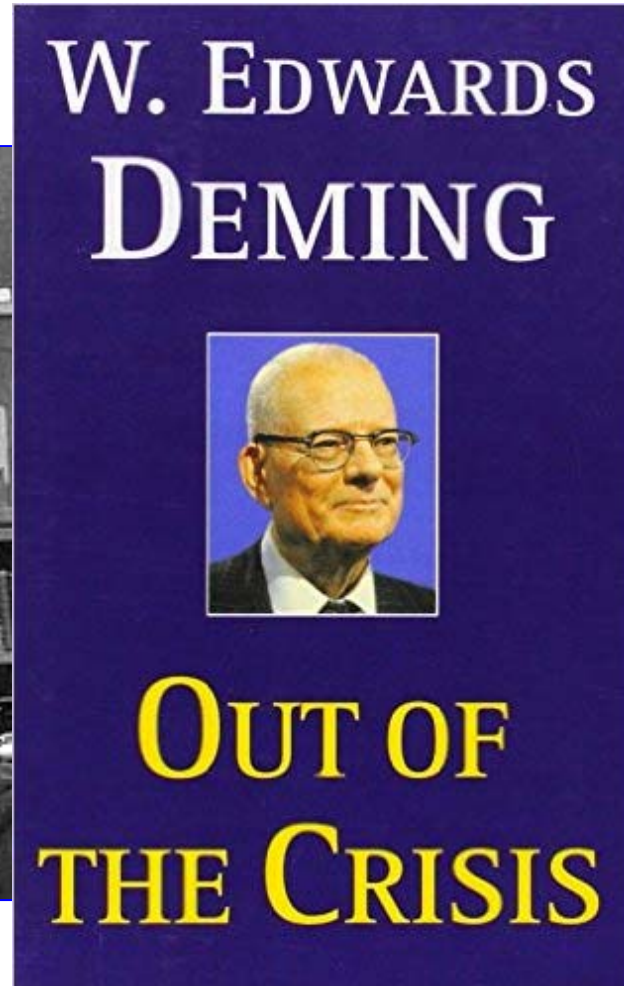
Thomas Edison

# The 10,000-Hour Rule

Key to achieving world class expertise-  
practicing a specific task the correct way,  
for a total of **10,000 hours**  
or 20 hours of work a week for **10 years**



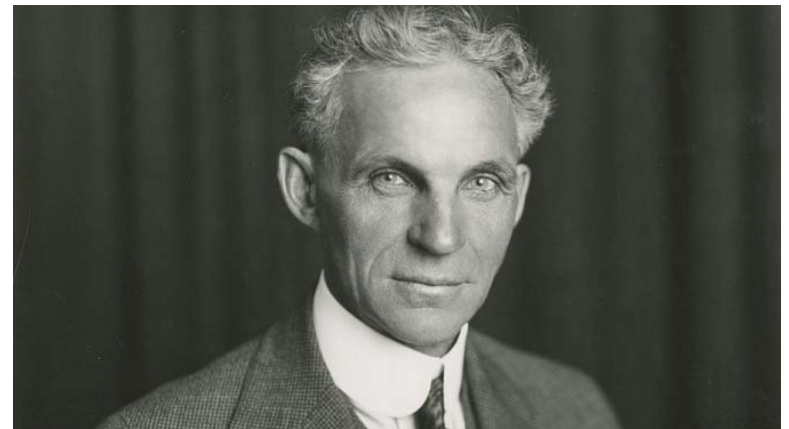
# Deming Influence



# Our Legacy

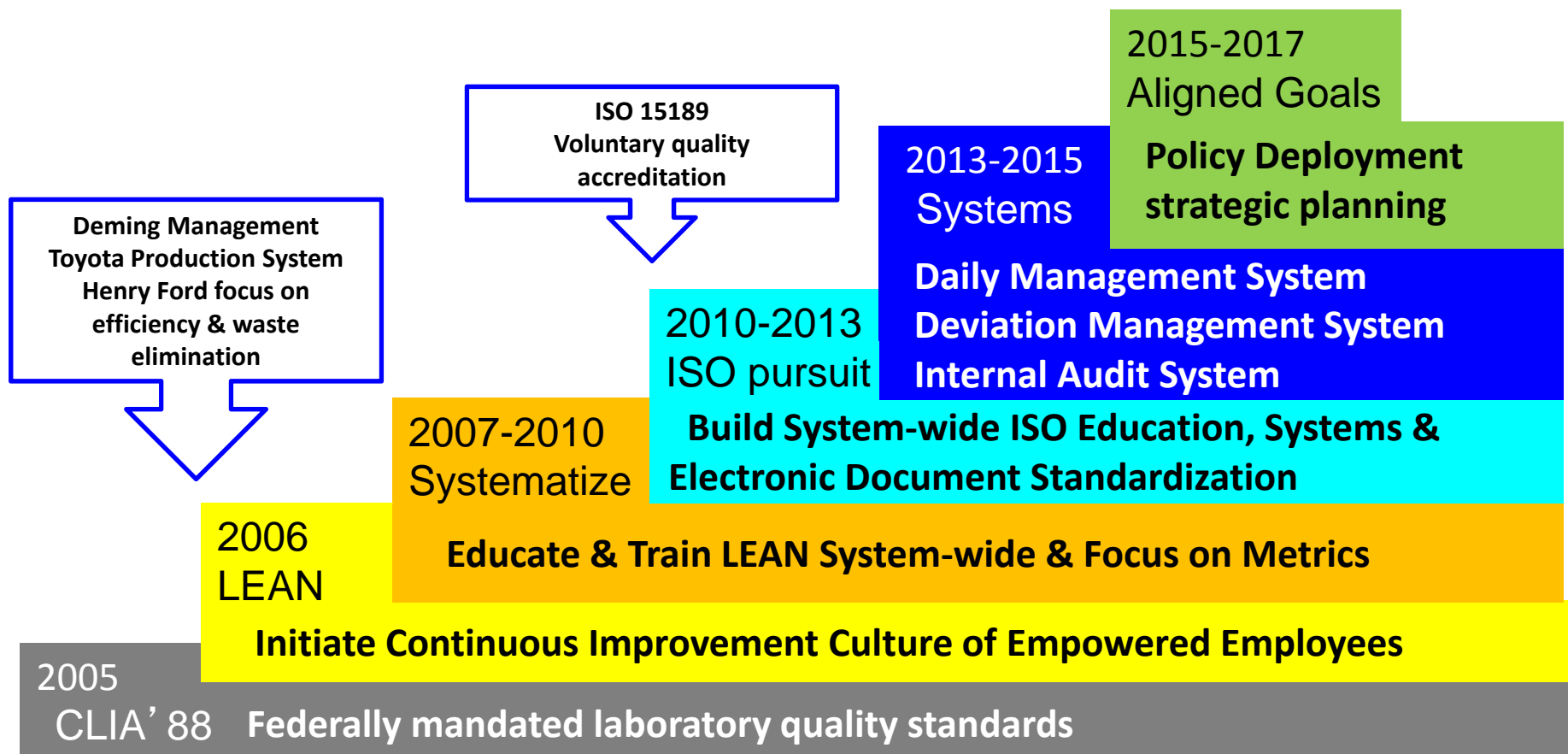
***"It's the work, not the man that manages."***

***"The business of management is to manage.  
The thing to be managed is the work."***



Henry Ford

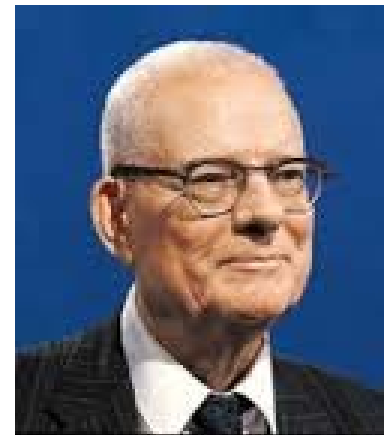
# Progression of Integrated Business Systems to Support Lean & ISO Quality Culture





# It's the System, Stupid 😊

**“A bad system will beat a good person every time.”**



W. Edwards Deming



# Focus on Quality Management System

Leadership defined organizational structure, procedures, processes and resources created to systematically implement quality management with intent to:

- Serve as the system to proactively achieve total quality management in all aspects of laboratory practice
- Manage and monitor activities to address quality standards
- Build quality into the laboratory's processes
- Provide ongoing assessment of laboratory performance
- Implement continuous quality improvements
- Consistently achieve organizational quality goals

# Basic Intent- Change Human Behavior

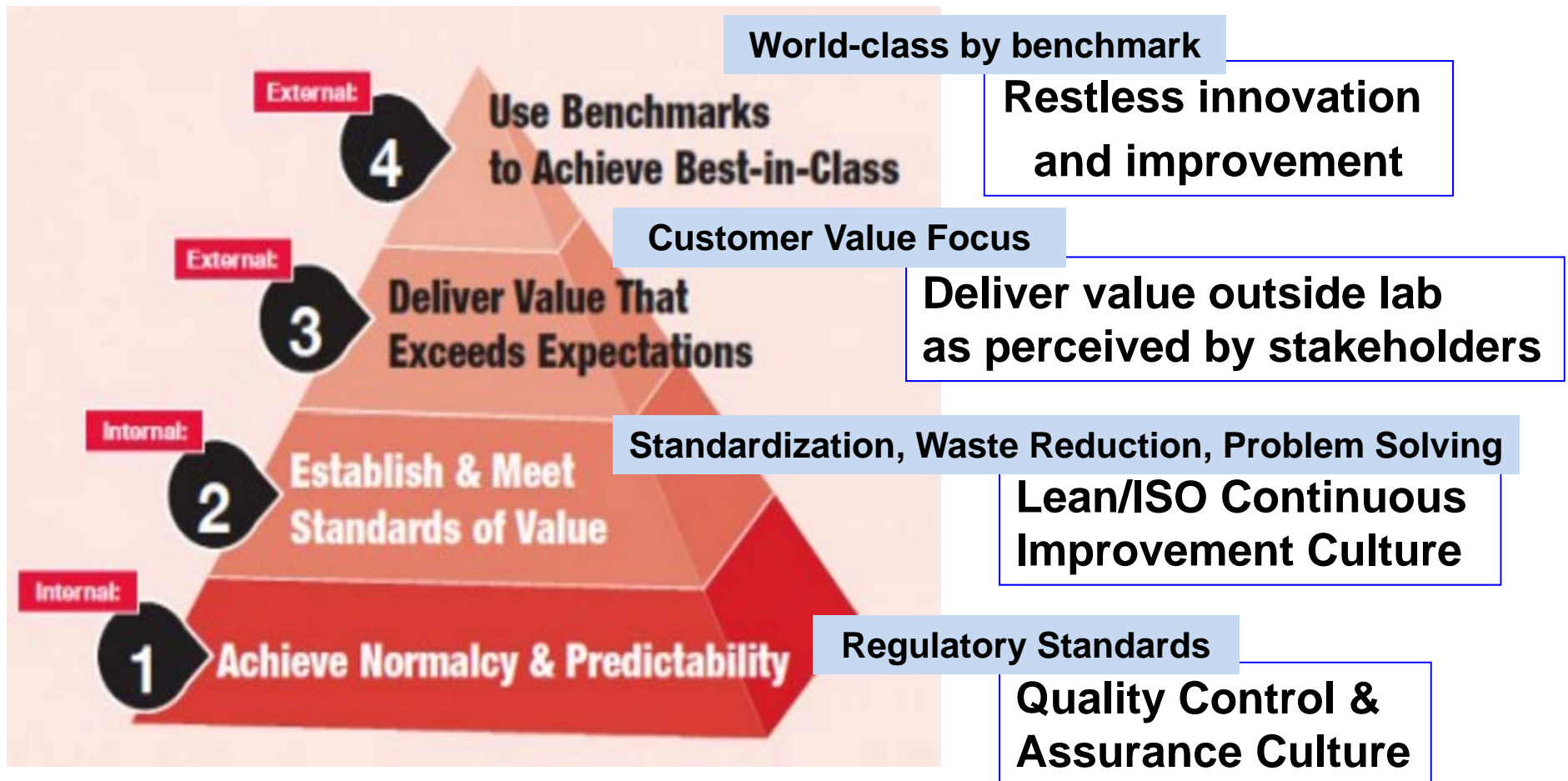
## **HIGH RELIABILITY**

**In short- a framework of processes and procedures structured to:**

**Ensure that people do the right and expected thing in performing tasks consistently**

- 1. Fulfill customer expectations**
- 2. Fulfill regulatory expectations**
- 3. Continually seek improvement**

# Michel's Value Pyramid



# LEVEL

# 1

**Achieve normalcy  
& predicatability**

**Basic Accreditation**

**Regulatory Standards**

**Quality Control &  
Assurance Culture**

# Ground Floor View

**“The only things that evolve  
by themselves in an  
organization are disorder,  
friction and  
malperformance”**



Peter F. Drucker

# LEVEL 2

**Establish & meet  
standards of value**

**Lean/ISO**

**Standardization, Waste Reduction, Problem Solving**

**Lean/ISO Continuous  
Improvement Culture**

**Basic Accreditation**

# Transformation Begins Here

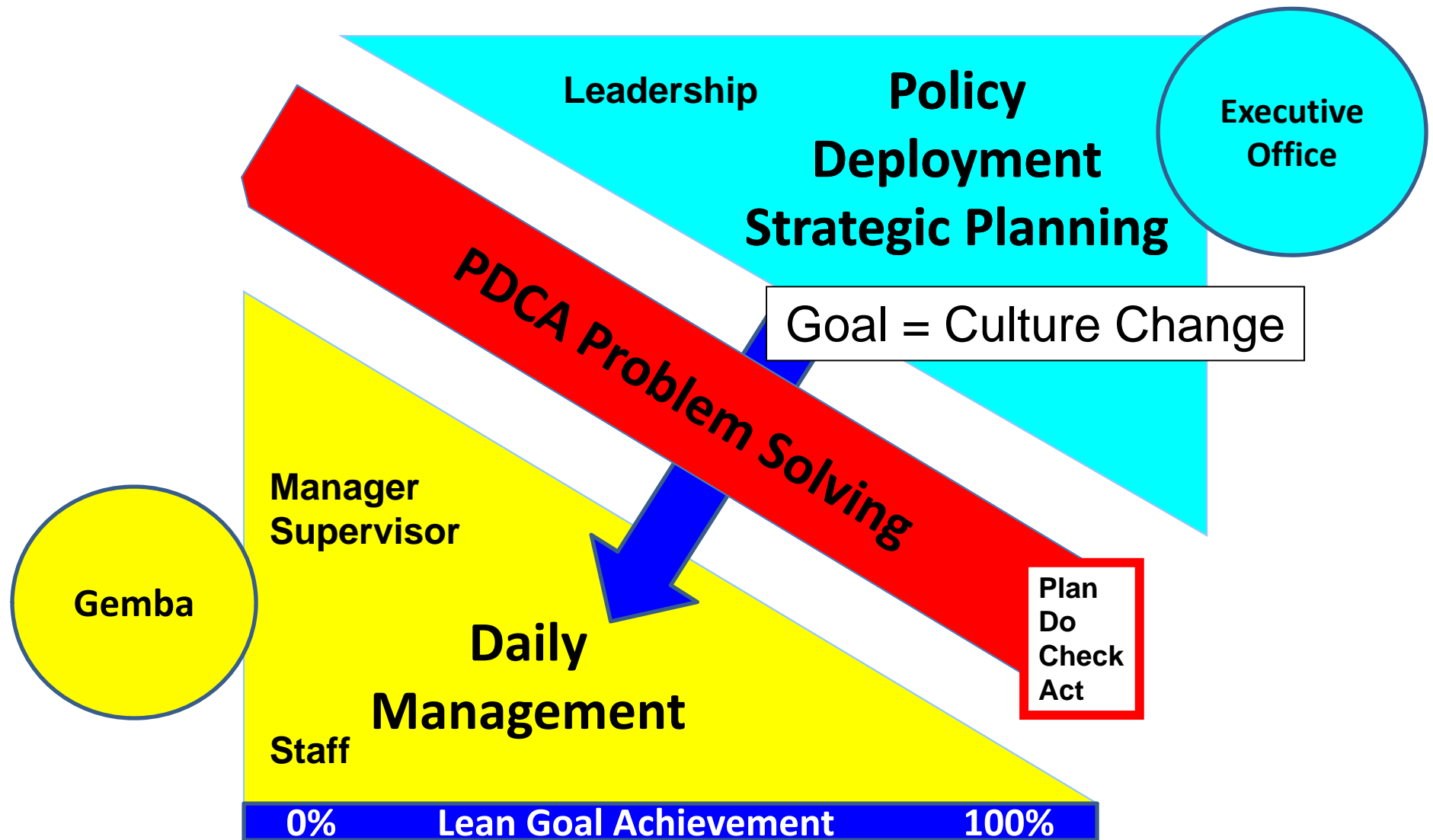
**“Quality starts in the  
Boardroom”**



W. Edwards Deming



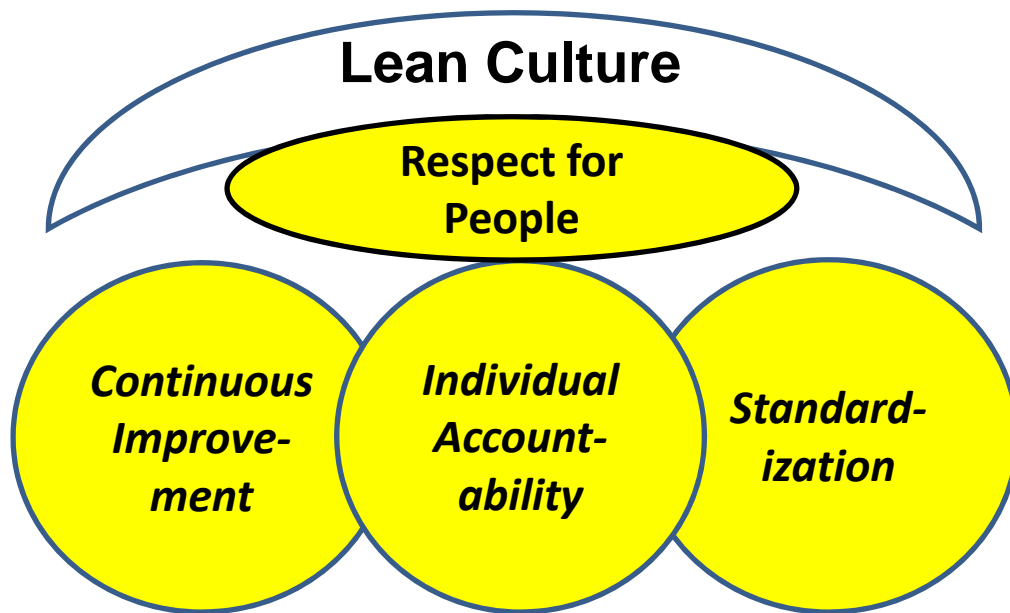
# Improvement by Strategic Plan



# Lean with ISO 15189

## Pathology and Laboratory Medicine Henry Ford Health System

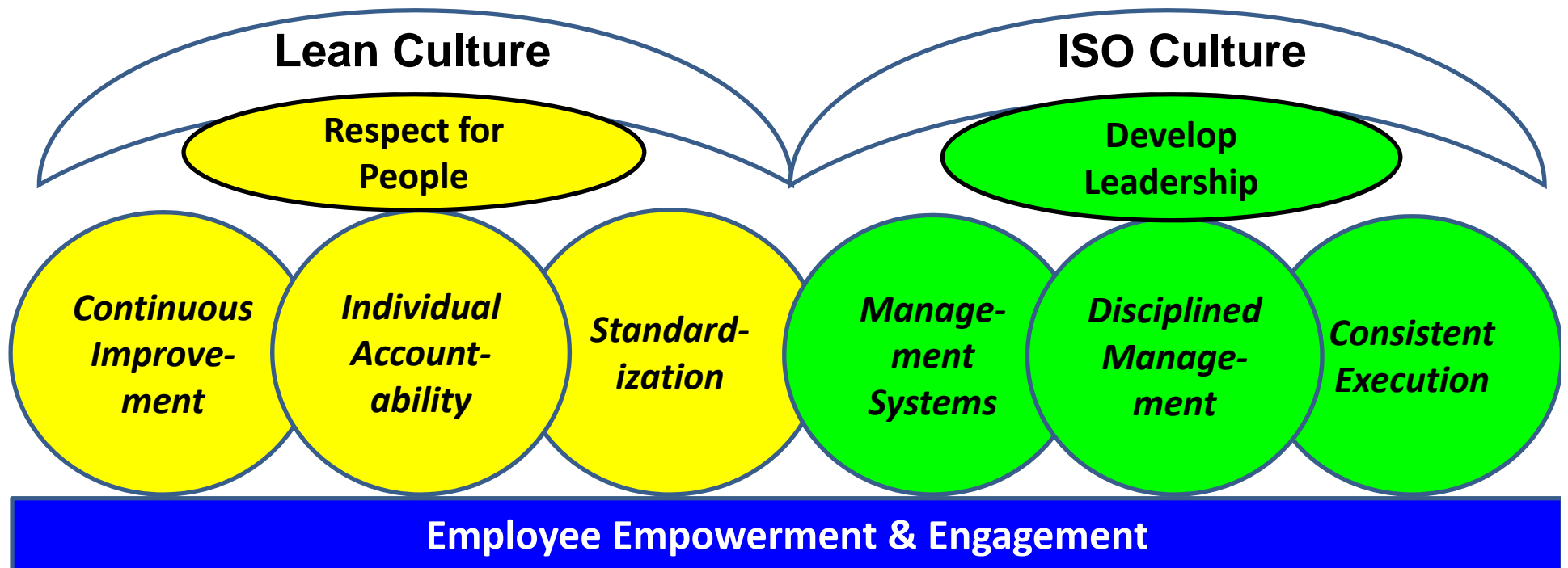
Henry Ford Production System



# Lean with ISO 15189

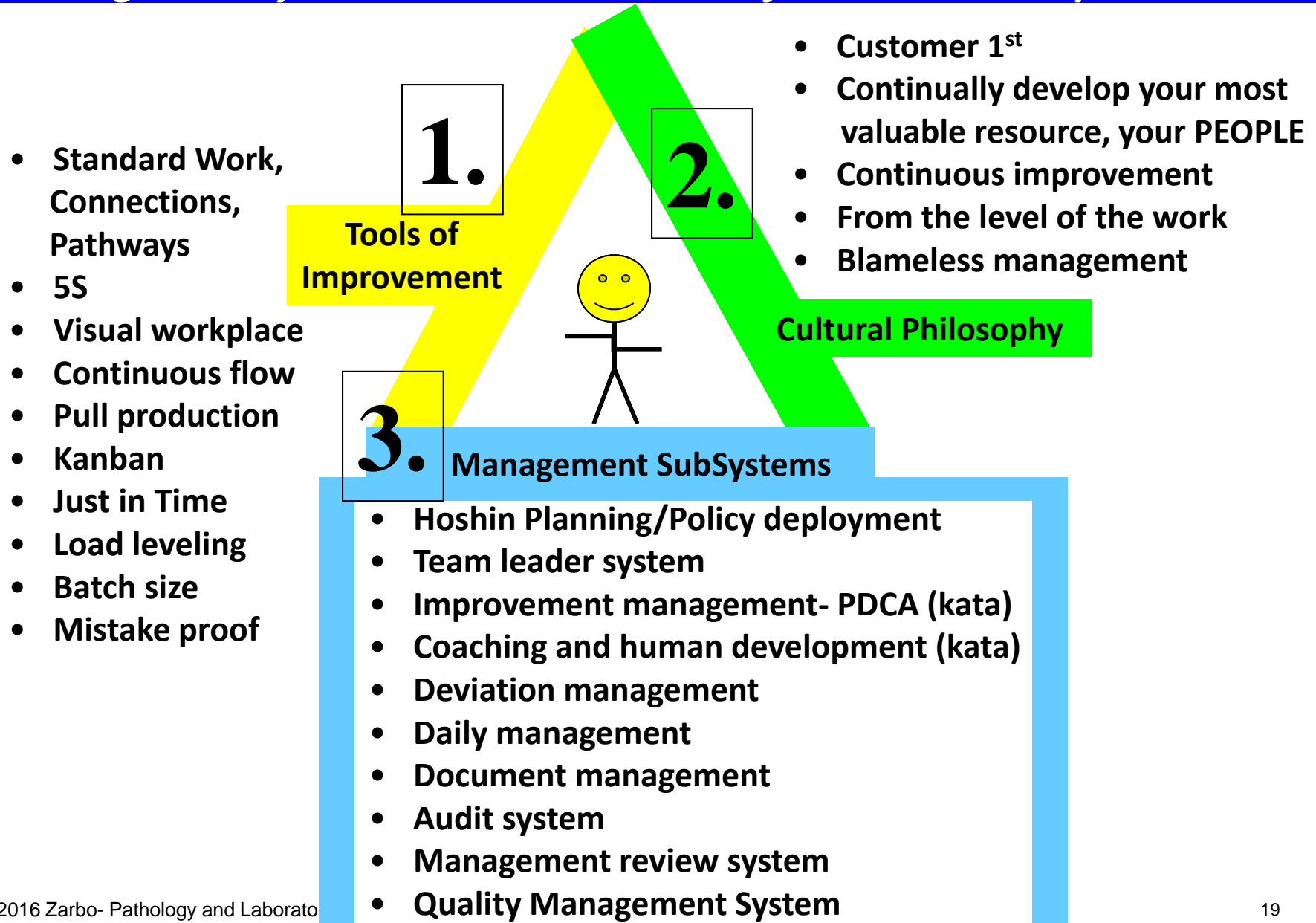
## Pathology and Laboratory Medicine Henry Ford Health System

### Henry Ford Production System



# Henry Ford Production System

## Integrated Systems Achieve Culture of Continuous Improvement



# Profound Knowledge

**“To successfully respond to the myriad of changes that shake the world, transformation into a new style of management is required.**

**The route to take is what I call *profound knowledge*- knowledge for leadership of transformation.”**



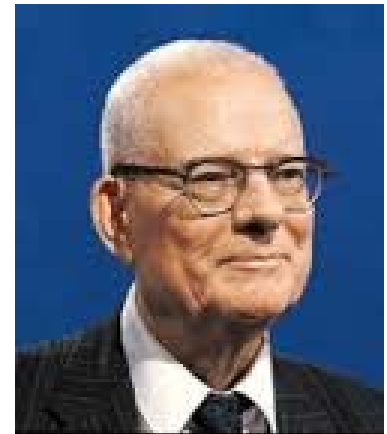
W. Edwards Deming

# HFPS Key Cultural Principles

- Lead with *Humility*
- Respect every individual
- Develop people to be proactive (action plans) and reactive (problem solving)
- Empower and engage everyone
- Integrate improvement with work in a blame-free culture
- Assure quality at the source - never accept, make or pass a defect
- Rely on data and facts and direct observation, not opinion
- Standardize and stabilize processes
- Assure a safe work environment
- Relentlessly seek perfection

# Define & Improve Processes Continually

**“If you can’t describe what you are doing as a process, you don’t know what you are doing.”**



W. Edwards Deming

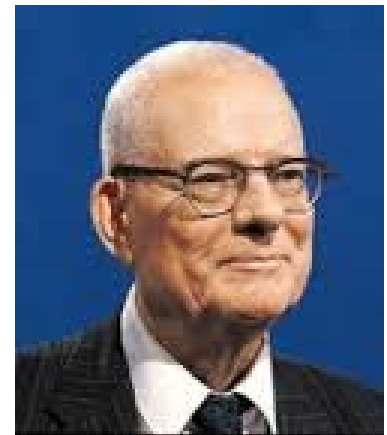


# The HFPS Way Forward

- **Lean continuous improvement begins with leadership and is owned by managers**
- **Engage and empower your people to solve problems at the level of the work**
- **Reduce work variation & waste by standardizing activities, connections and pathways**
- **Rely on organizational structure and management subsystems to drive continuous change**
- **Form core teams with strong team leaders and members along the path of workflow**
- **Break down barriers between silos of control so improvements can occur horizontally**
- **Foster regular customer-supplier communications within and between work cells**
- **Integrate people, process, tools, and technology that support the new manner of work**
- **Implement visual management, with posted daily metrics of value for each work unit reflecting opportunities for change or stability of the process**
- **Leverage PDCA way of thinking as the operational engine of continual improvement**

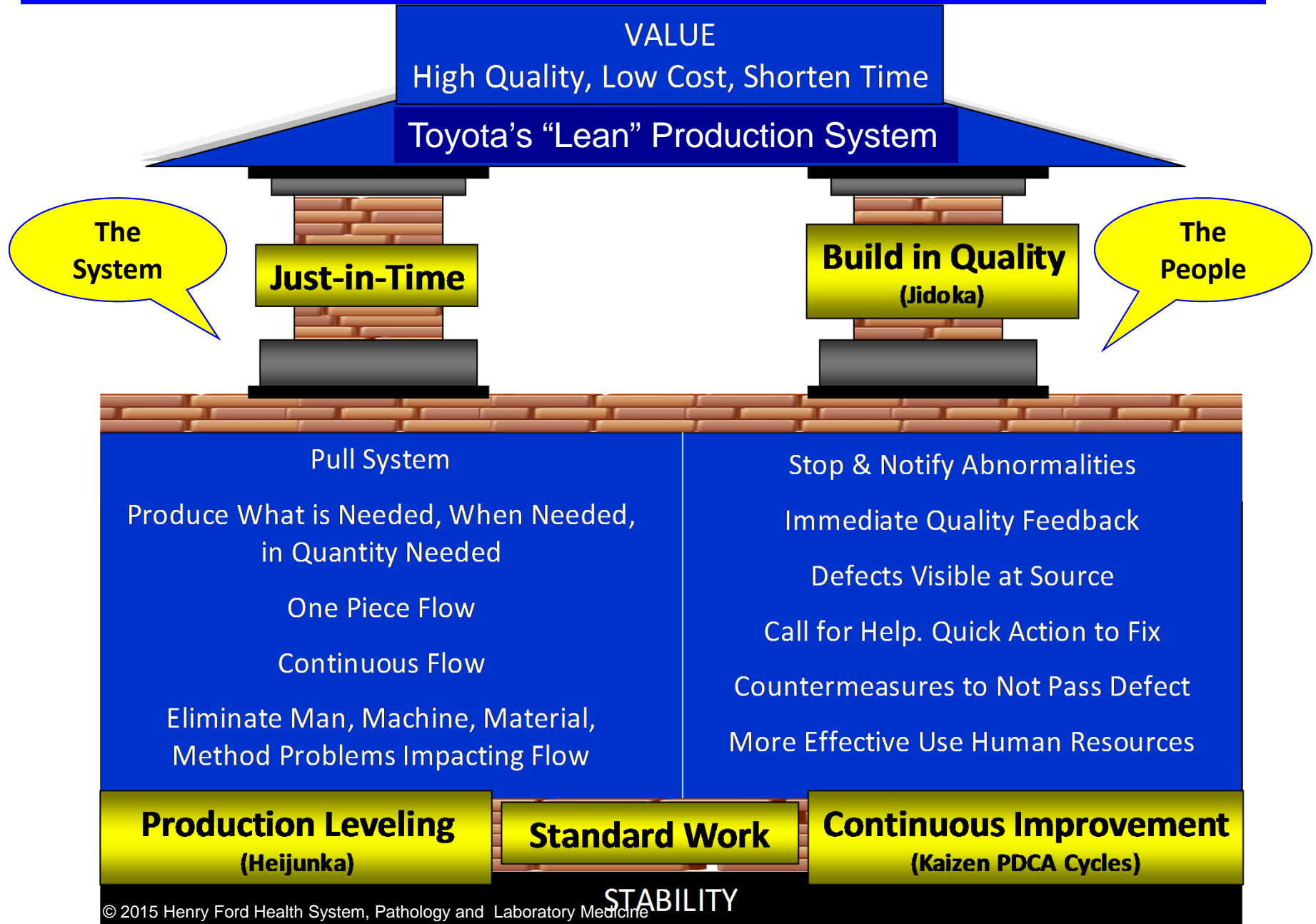
# People Waste

**“The greatest waste in America is failure to use the abilities of people.”**



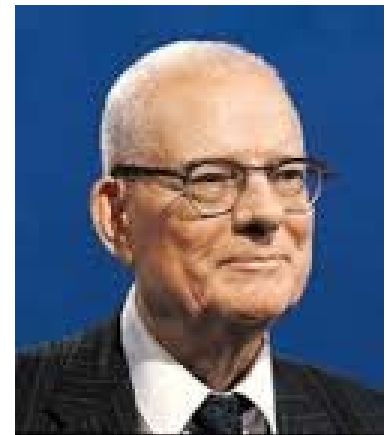
W. Edwards Deming

# Foundations of Lean Production



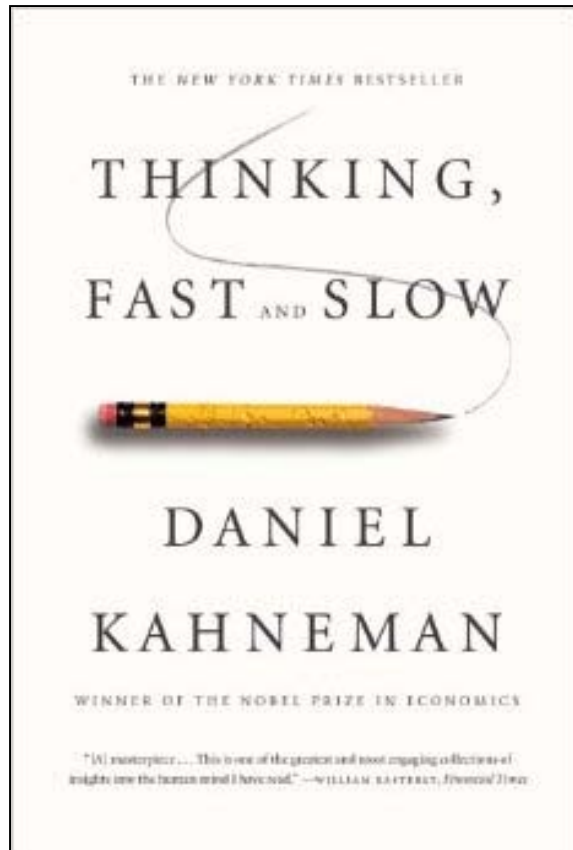
# Data Rules

**“In God we trust.  
All others bring data.”**



W. Edwards Deming

# PDCA Problem Solving

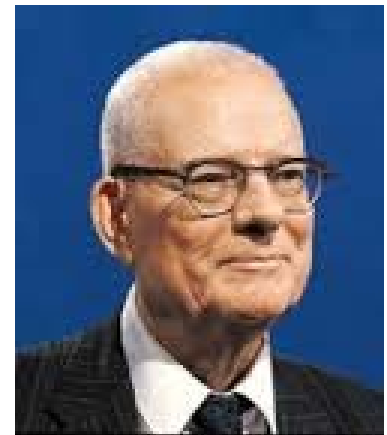


Why so difficult?

| <b>FAST</b><br>System 1 | <b>SLOW</b><br>System 2 |
|-------------------------|-------------------------|
| Fast                    | Slow                    |
| Parallel                | Serial                  |
| Automatic               | Controlled              |
| Effortless              | Effortful               |
| Associative             | Rule-governed           |
| Slow Learning           | Flexible                |
| Emotional               | Neutral                 |

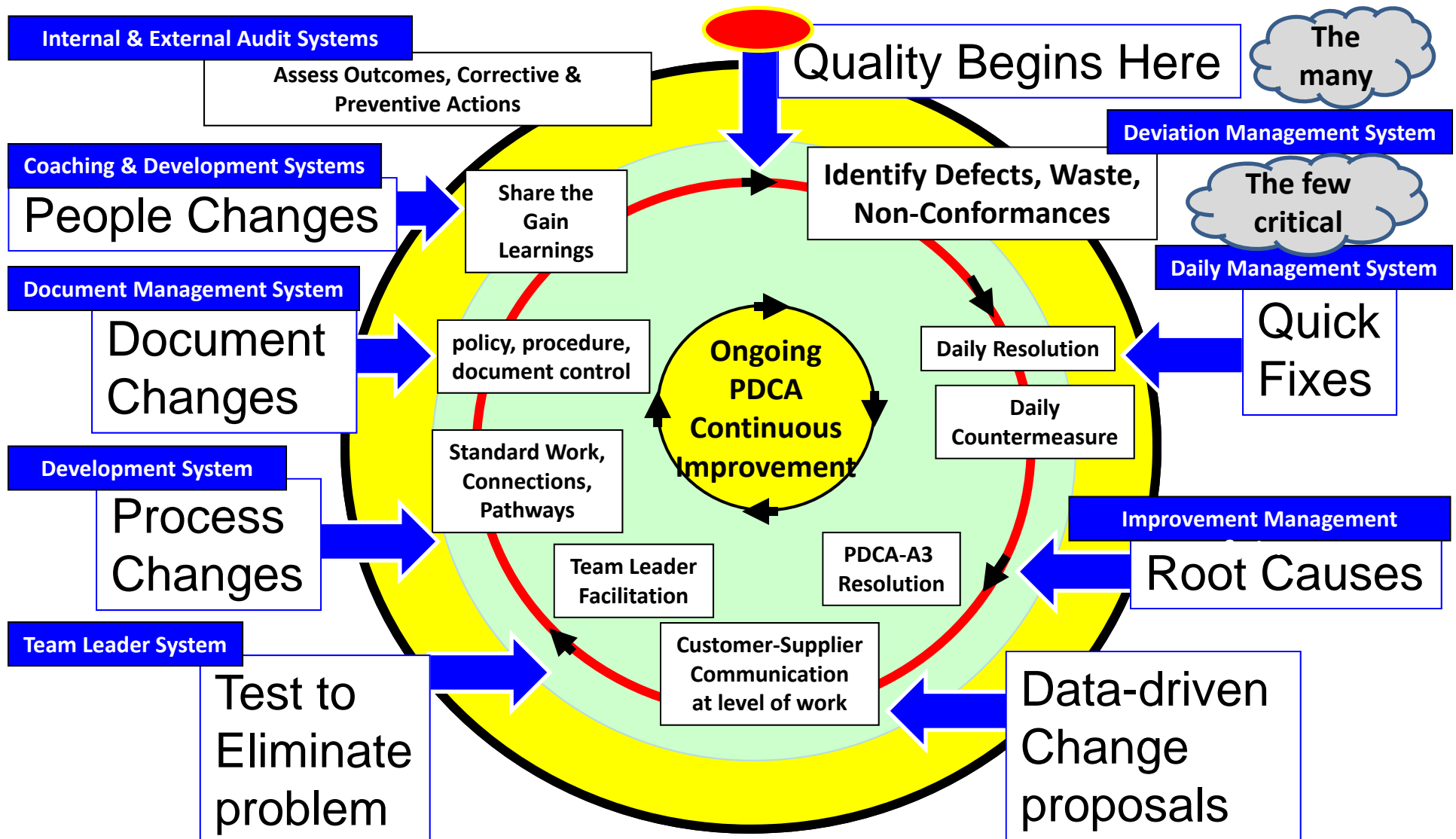
# Ownership

**“Quality is everyone’s responsibility.”**



W. Edwards Deming

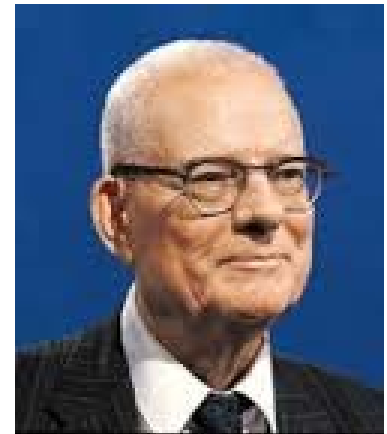
# Systems Facilitate Continuous Improvements from Level of the Bench Work





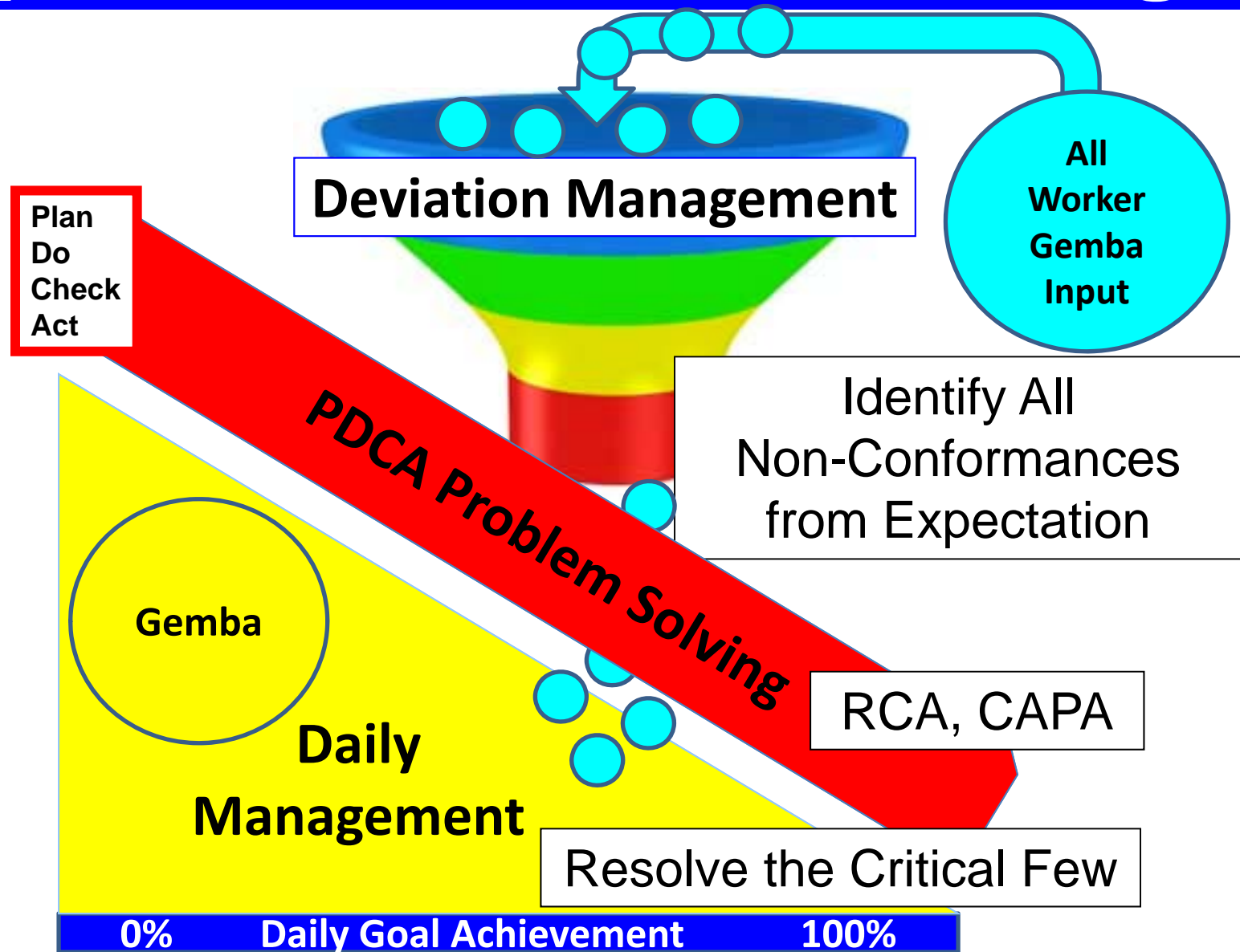
# Knowledge is Powerful

**“Information is not knowledge.  
Let’s not confuse the two.”**



W. Edwards Deming

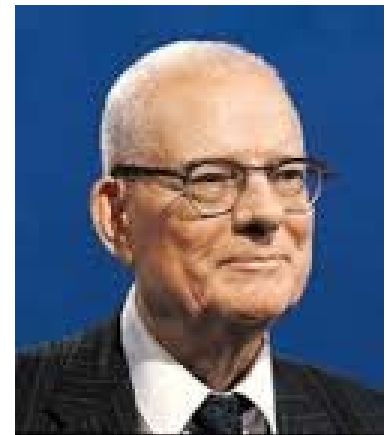
# Improvement from Knowledge



# DEVIATION MANAGEMENT

# Manage by Measure

**“You can’t manage  
what you don’t measure.”**



W. Edwards Deming

Answer = 50,000 per year

Q: What is 0.125%  
of 40 million lab tests performed?

Does that mean 99.875%  
of the work is without  
defect

**NO**

# Deviation Management

process => human or machine => product or service

**-Deviation from standard**

**-Defective work product**

Anything having to do with a process that can be described as-

- defective, in non-ideal or perfect form,
- not right the first time, or
- not following policy or procedure (root cause



# A Structured Management System

- Created by user consensus, System wide quality technical team
- Manager-Supervisor owned process
- Key aspect of managers' standard work, weekly, monthly
- Paper based input documented at Gemba by all 720 employees
- Excel spreadsheet with logic-pivot tables, located on shared drive
- System wide standardization of:
  - ISO compliant process for defect identification, documentation, tracking and trending
  - Classification of defects (taxonomy of 260 types)
  - Documentation of root causes, corrective and preventive actions
  - Elimination by PDCA based resolution, documentation attached to spreadsheet
- System wide analysis by Quality Specialists
- Priority defects reviewed by System Lab Quality Management Committee
- Platform for System-wide standardized resolution of common deviations

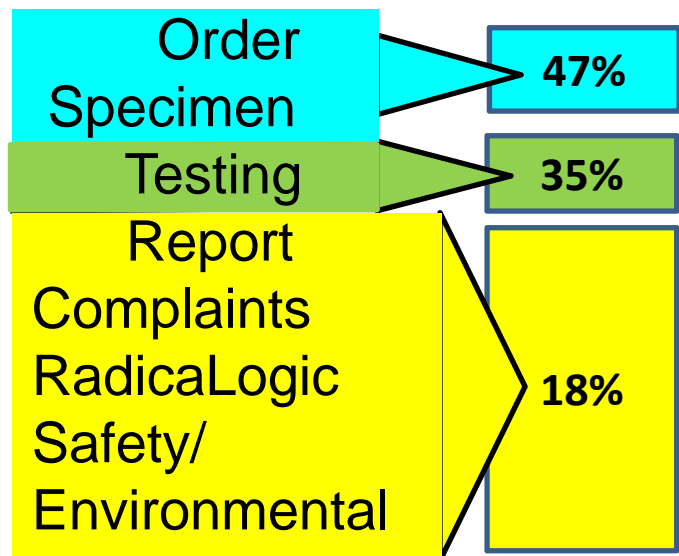


# Pick List of Deviations

#125 types in 2014

#260 in 2016

*and growing*



Pre-analytic

Analytic

Post-analytic

OCC-PALM-8.1-pro-stw1: DEFECT NUMBER SUBCLASS LIST

Pathology & Laboratory Medicine  
OCC-PALM-8.1-pro-stw1: DEFECT NUMBER SUBCLASS LIST

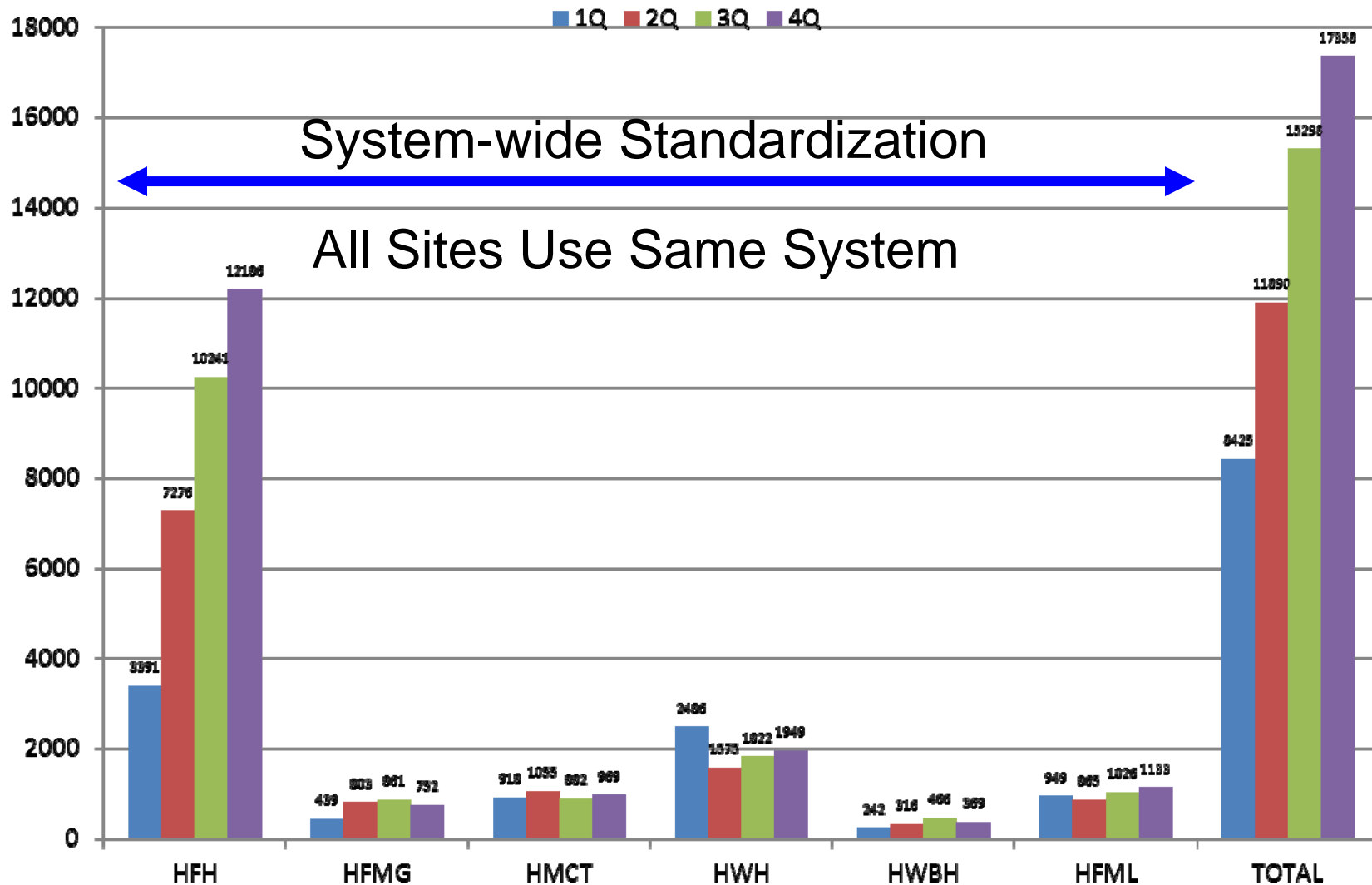
| Order Defects (O)   | Specimen Defect (S)  | Testing Defects (T)   | Report Defects (R)  |
|---|--|---|---|
| <b>O1- Patient Name/MRN mismatch</b><br><b>O2- Other Identifier issues (Date of Birth)</b><br><b>O3- Test name</b><br><b>O4- Test Code</b><br><b>O5- Diagnosis</b><br><b>O6- Diagnostic code/ICD code</b><br><b>O7- Practitioner Name</b><br><b>O8- Practitioner Code</b><br><b>O9- Wrong part type</b><br><b>O10- Part type not accessioned</b><br><b>O11- Laterality switched</b><br><b>O12- Case assigned to incorrect pathologist</b><br><b>O13- Incorrect specimen class type</b><br><b>O14- Wrong number of cassettes</b><br><b>O15- Missing specimen</b> | <b>S1- No spec ID/ unlabeled</b><br><b>S2- Inadequate sample ID</b><br><b>S3- No sample</b><br><b>S4- Quantity not sufficient (QNS)</b><br><b>S5- Wrong container</b><br><b>S6- Clotted sample</b><br><b>S7- Hemolyzed sample</b><br><b>S8- Inappropriately timed sample</b><br><b>S9- Specimen initially NOT fixed</b><br><b>S10- Other</b><br><b>S11- Improper handling/transport/storage</b><br><b>S12- Contaminate (e.g. LV TPN)</b><br><b>S13- Improper specimen collection</b><br><b>S14- Improper tube type drawn for test request</b><br><b>S15- Mislabelled specimen container</b><br><b>S16- Suspect Anti coagulate contamination</b><br><b>S17- Poor Quality Specimen</b><br><b>S18- No Date/Time on specimen container</b> | <b>T1- Quality control failure (QC)</b><br><b>T2- Test condition defect (temp., etc.)</b><br><b>T3- Kit failure</b><br><b>T4- Reagent defect</b><br><b>T5- Instrument failure</b><br><b>T6- Procedure (SOP) deviation</b><br><b>T7- Quality Assurance failure (e.g. No action for out of control result)</b><br><b>T8- Insufficient triage of specimen Submitted</b><br><b>T9- Frozen section measurements missing</b><br><b>T10- Inadequate blocks</b><br><b>T11- Missing or extra blocks</b><br><b>T12- Slides/Blocks do not match</b><br><b>T13- Tissue too thick</b><br><b>T14- Not sectioned enough to get tumor/block not adequately cut</b><br><b>T15- Specimen not fixed properly</b> | <b>R1- Post-verification delay in manual results entry</b><br><b>R2- Failure of results to cross computer interface</b><br><b>R3- Failure to initiate critical value/action alert results call</b><br><b>R4- Difficult, delayed, failed attempted critical value/action alert call</b><br><b>R5- Absent or incomplete documentation of critical value/action alert call</b><br><b>R6- Intervention required to correct reported</b> |

Page 1 of 1

Revision Number: 4; Revision Date: 16 Feb 2015

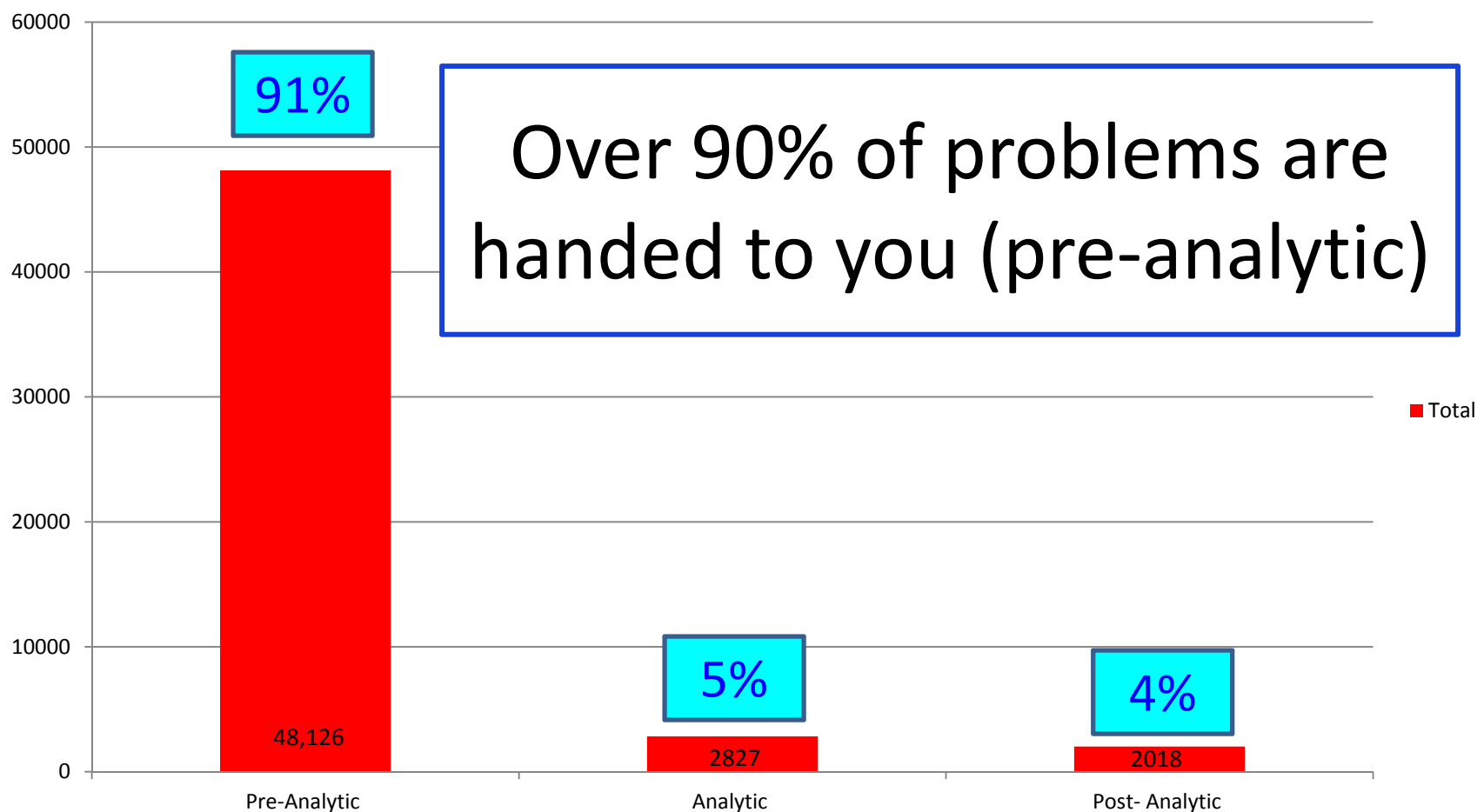
# PALM 2015 Deviation Management

## 52,971 Deviations



# Deviations Classified by Test Cycle Phases

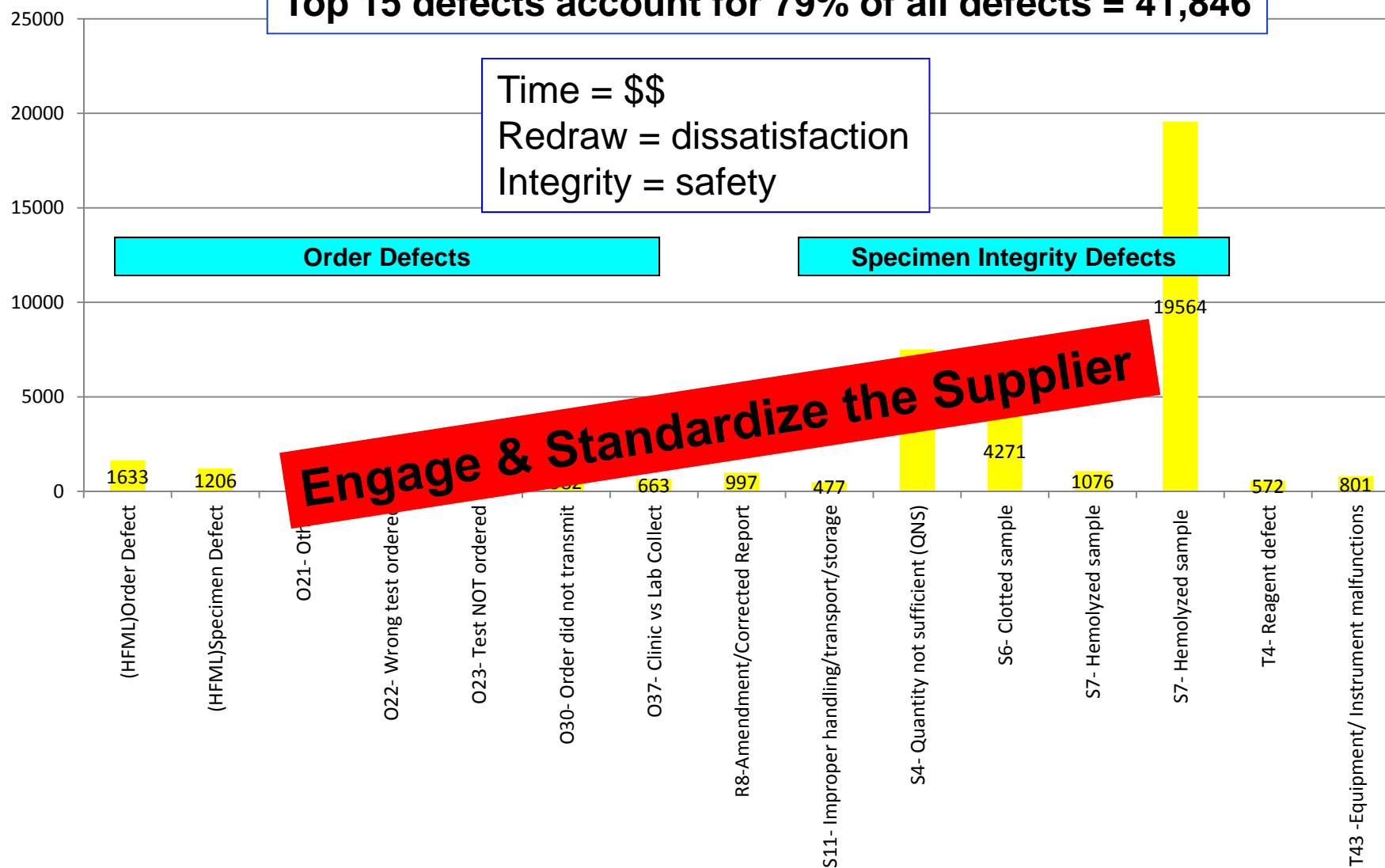
2015 Total Deviations = 52,971



# Deviation Management Surveillance Trending

**Total Defects for 2015 = 52,971**

**Top 15 defects account for 79% of all defects = 41,846**



# LEVEL

**Deliver value that  
Exceeds expectations**

**3**

**Customer Value Focus**

**Deliver value outside lab  
as perceived by stakeholders**

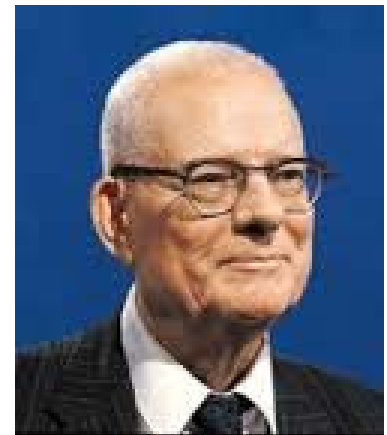
**Lean/ISO**

**Basic Accreditation**

# Cost of Failures

**“No one knows the cost of a defective product – don’t tell me you do.**

**You know the cost of replacing it, but not the cost of a dissatisfied customer. ”**



W. Edwards Deming

# Pathology & Laboratory Medicine- All for You

**80%**

## Faster OPD Lab Test Result Times since 2008

- 98% of Same Day Tests by 6AM
- 90% of Same Day Tests by Midnight vs. 50%
- Epic MyChart test results to patient within 4 hours of OPD visit
- Faster Critical Value notification and timely clinical intervention

**55%**

## Lean Outreach Revenue Growth, last 24 months

- >\$2M in new Net Revenue

**50%**

## Faster IPD Lab Test Result Times since 2008

- 90% of ER Tests now 30-35 min vs. 90 minutes
- 95% of ER Troponins now in 35 min vs. 70 minutes
- 90% Stats in now 45 min vs. 90 minutes

**97%**

## Pathology O.R. Order Accuracy Post Epic in 2014

- Error reduction in 1<sup>st</sup> 6 months

**64%**

## Increased Phlebotomy Patient Satisfaction since 2015

- 16 draw sites
- Satisfaction rating overall mean 4.8 out of 5
- 10 of 16 sites scoring 5.0
- >600,000 annual phlebotomies

**33%**

## Reduced Phlebotomy Wait Times Since 2014

- Mean wait time = 7 minutes
- Best performer mean time = 3 minutes
- Worst performer mean time = 14 minutes

**Quality Focus is Great**

**But in the end,  
value boils down to  
\$\$**





# Pathology & Laboratory Medicine- All for You

## Faster Micro-organism Identification Melding New Technologies with Lean Process

Advances in HFHS Microbiology testing using new technologies to identify micro-organisms

- Bacteria & Yeast- Laser Desorption Ionization-Time of Flight (MALDI-TOF)
- Candida sepsis- PCR, nanoparticle hybridization and T2 magnetic resonance signaling

Stakeholder value (**V-metrics**)

- **Faster for caregivers**
  - Decision making while in ER
  - Reduced use of inpatient and ICU beds to isolate while waiting for test results
- **Safer for patients**
  - Lower mortality
  - More immediate and appropriate interventions
- **Cost effective for hospitals and payers**
  - ICU length of stay
  - Appropriate use, overuse and under use of therapies

## Pathology & Laboratory Medicine- All for You

### Faster Micro-organism Identification Maldi-TOF

- Bacterial results improved to 1 day from 2.2 days **55%**
- Yeast results improved to 1.4 days from 4 days **65%**
- Decrease LOS for IPD Sepsis

#### • Annual LOS

**\$5,783,287**

Yeast & Gram Pos. bacterial sepsis

**\$3,230,437**

Gram Neg. sepsis

**\$2,552,850**

## Pathology & Laboratory Medicine- All for You

### Facilitate Appropriate Therapy Maldi-TOF

Rapid differentiation of pathogenic *Staphylococcus aureus* (coagulase positive) from blood culture contaminant coagulase negative Staphylococci may decrease hospital costs \$4000-\$6,100/patient (Forrest et al. AAC, 2008, Clin Perform Qual Health Care, 1998)

Approx. 924 patients/year with coagulase negative positive blood cultures at HFH

Reduced **unnecessary antibiotic usage** and **reduced length of stay** in a significant number of patients with coagulase negative positive blood cultures

**Annual projected \$\$ savings**



**\$610,000**

## Pathology & Laboratory Medicine- All for You

### MALDI Summary

- Rapid ID ICU LOS reductions= \$5,783,287 per year
- Reagent savings per year = \$11,212
- Rapid ID of *S. aureus* from contaminants in blood = \$610,000.

**Annual overall \$\$ savings**

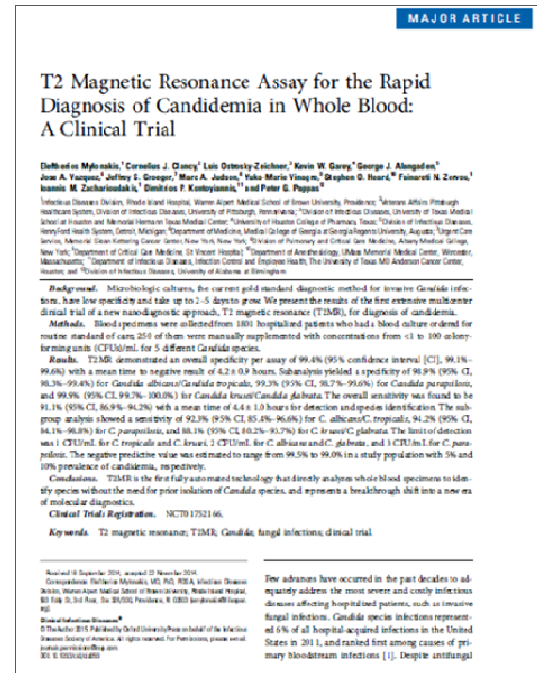
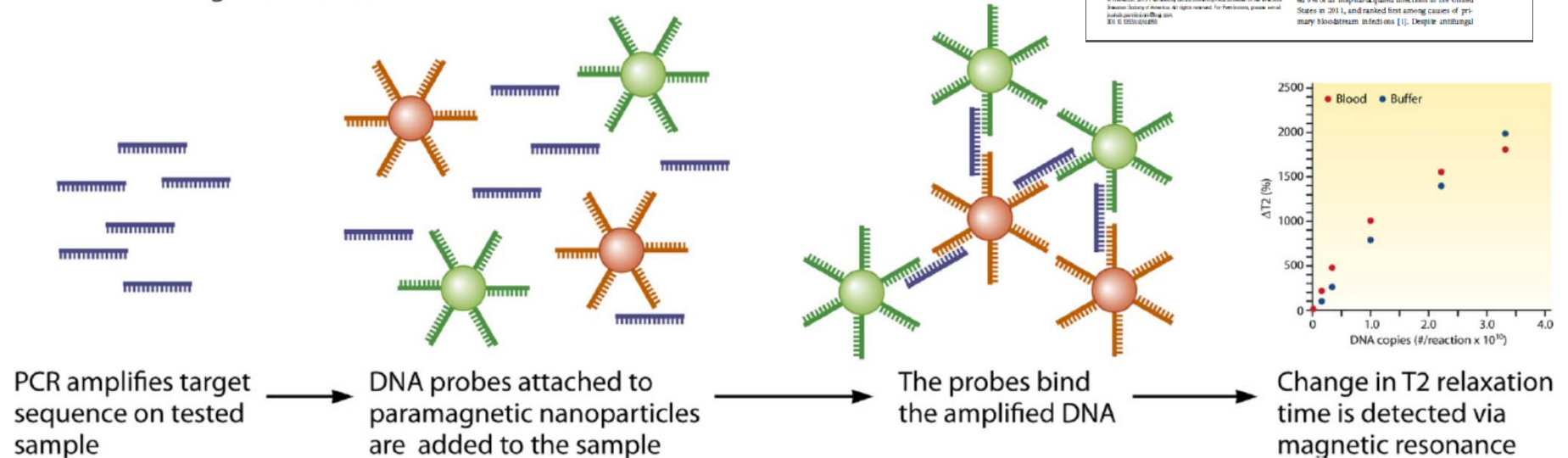


**\$6,404,499**

# T2 Candida: Direct from Whole Blood

- Type of Specimen: Whole Blood
- DNA extraction: No
- Sensitivity: 91.1%
- Specificity: 99.4%
- Time to Result: 3-5 hours
- Number of *Candida* Species Detected: 5

## D T2 nuclear magnetic resonance



## Pathology & Laboratory Medicine- All for You

### Rapid Whole Blood ID Candida Sepsis

- Candidemia mortality 40% despite antifungal therapy
- Mortality triples after 12 hours delay
- Blood culture gold standard takes 1-3 days ☹️ T2 detection & speciation = 3-5 hours
- HFH annual send-out cost fungal antigen testing = \$244,000, eliminated
- Candida sepsis episode (1997) = \$44,536 per patient
- ICU LOS reduced from 15 to 8 days when rapid identification methods are combined with antimicrobial stewardship (Huang et al. 2013)
- Reduce 1 day ICU LOS + reduced antifungal usage = **\$564,000** annual savings
- Minus cost T2 testing \$480,000

**Overall annual \$\$ savings**



**\$328,000**

# LEVEL

# 4

**Use benchmarks to  
Achieve Best-in-Class**

**World-class by benchmark**

**Restless innovation  
and improvement**

1

Value

Lean/ISO

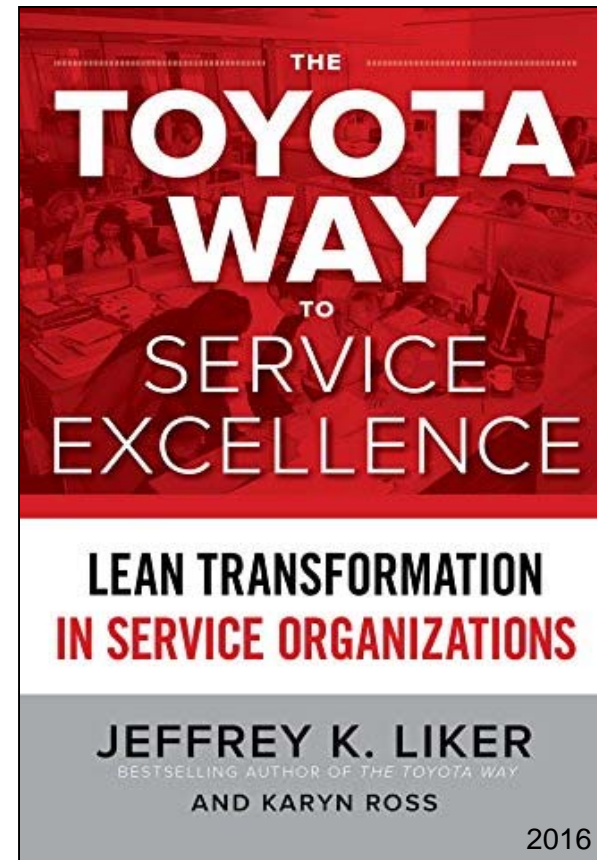
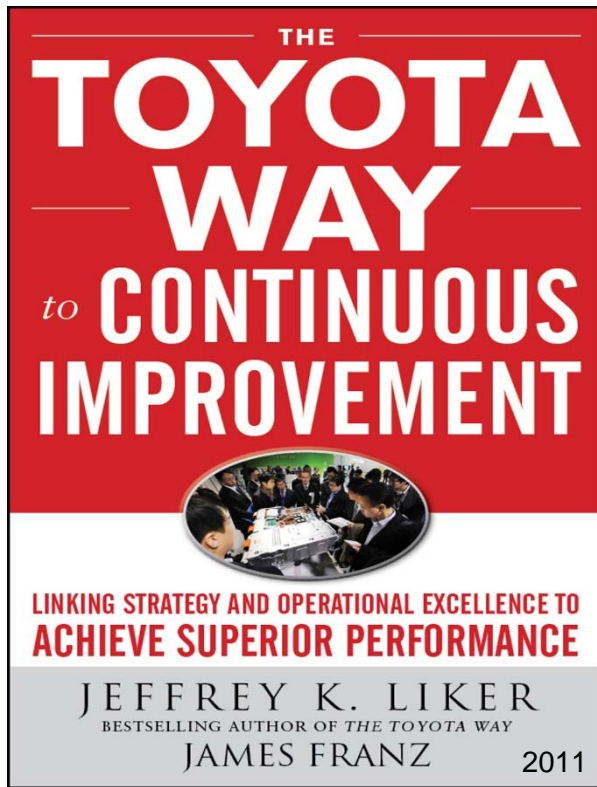
Basic Accreditation



# Recognition of Culture

***“We know from the changes that have already been brought about that far greater changes are to come, and that therefore we are not performing a single operation as well as it ought to be performed.”***

– Henry Ford





DanaHER Business System

*International Center of Excellence*

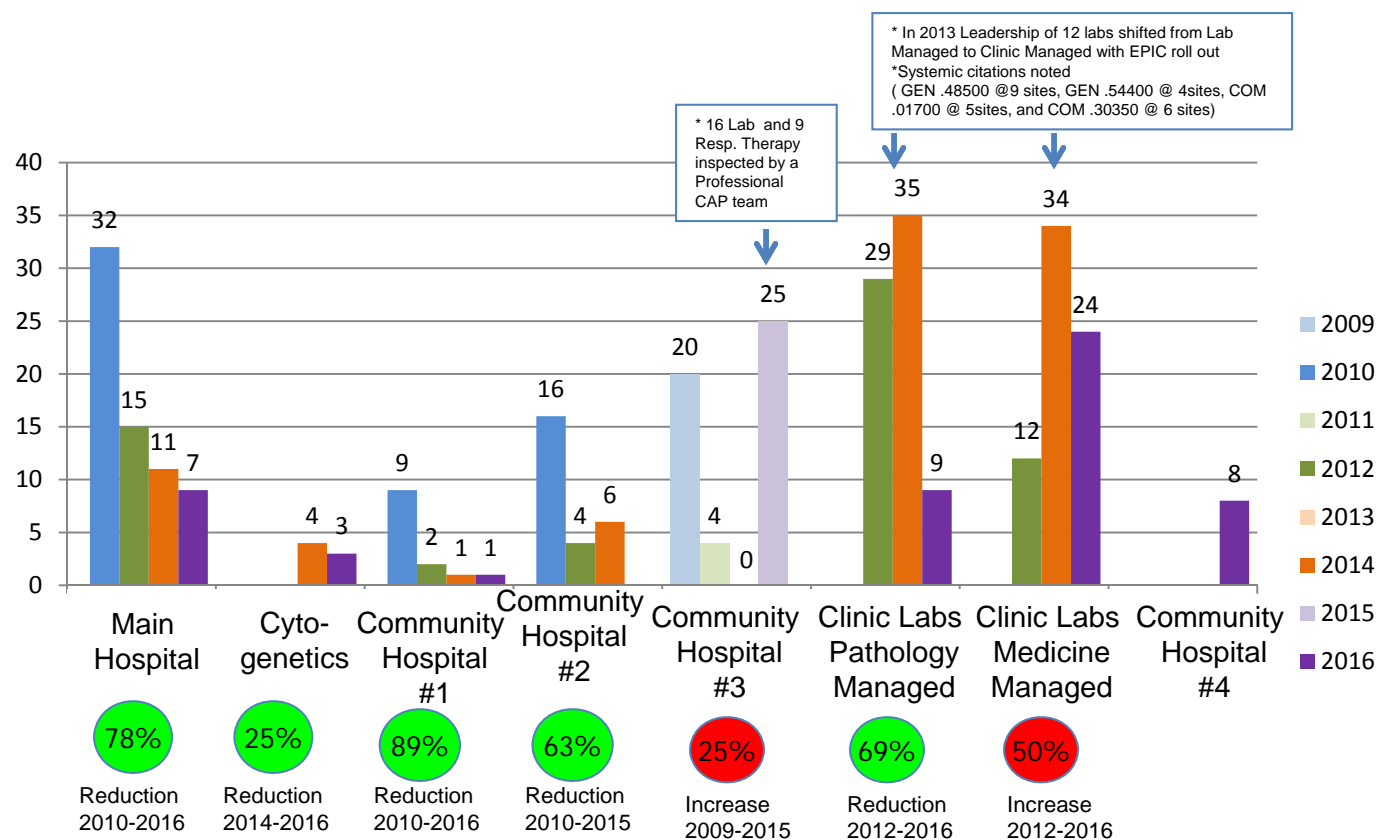


Pathology and Laboratory Medicine

CAP ISO 15189 Center of Excellence and Learning

# CAP LAP Citation Trends for PALM

2009-2016



# That's All Well and Good

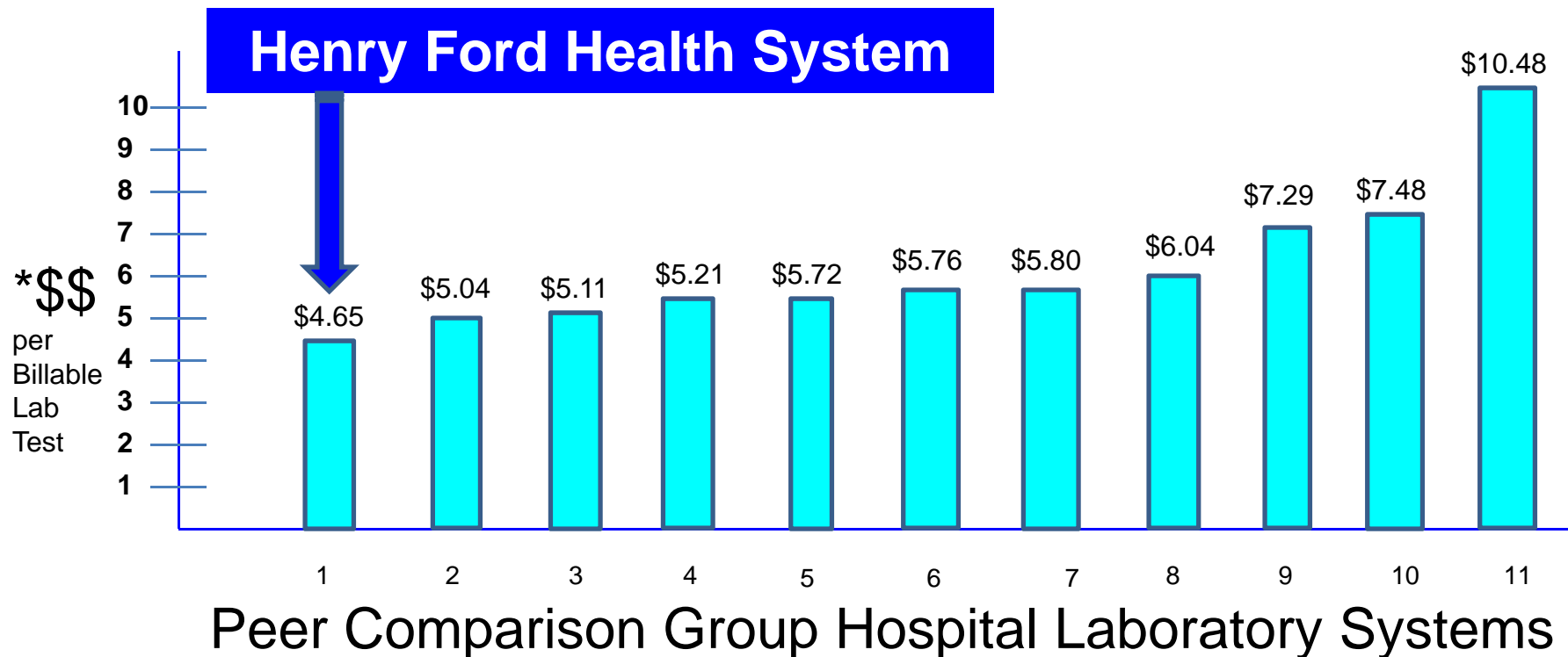
**Self praise is No Praise.**

**Because in the final analysis,  
to those who control your fate,  
you are a COST CENTER.**



# Lab Cost per Unit of Service

## 2016 National Peer Laboratory Benchmarking



\* Cost = Labor + Agency Labor + Non Labor + Corporate

**Someone Will Always Be...**

**Prettier**



**Someone Will Always Be...**

**Smarter**





# Someone Will Always Be...

# Faster





# Someone Will Always Be...

## Cheaper



**Someone Will Always Be That...**

**But not  
High  
Value to  
Stakeholders**

Dissatisfied with status quo

Anticipating customer needs

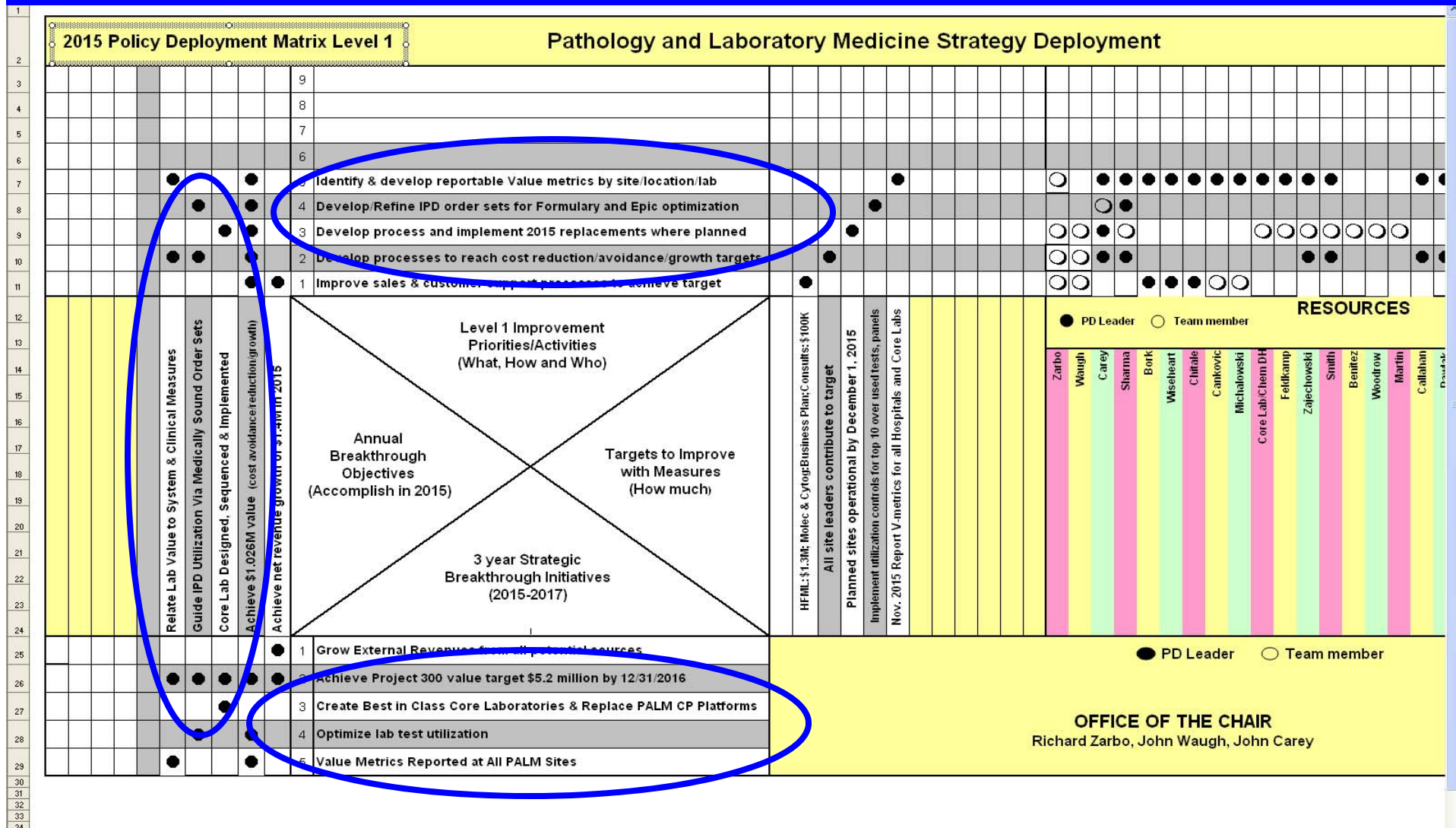
Creative in problem solving

Can do and will do mentality

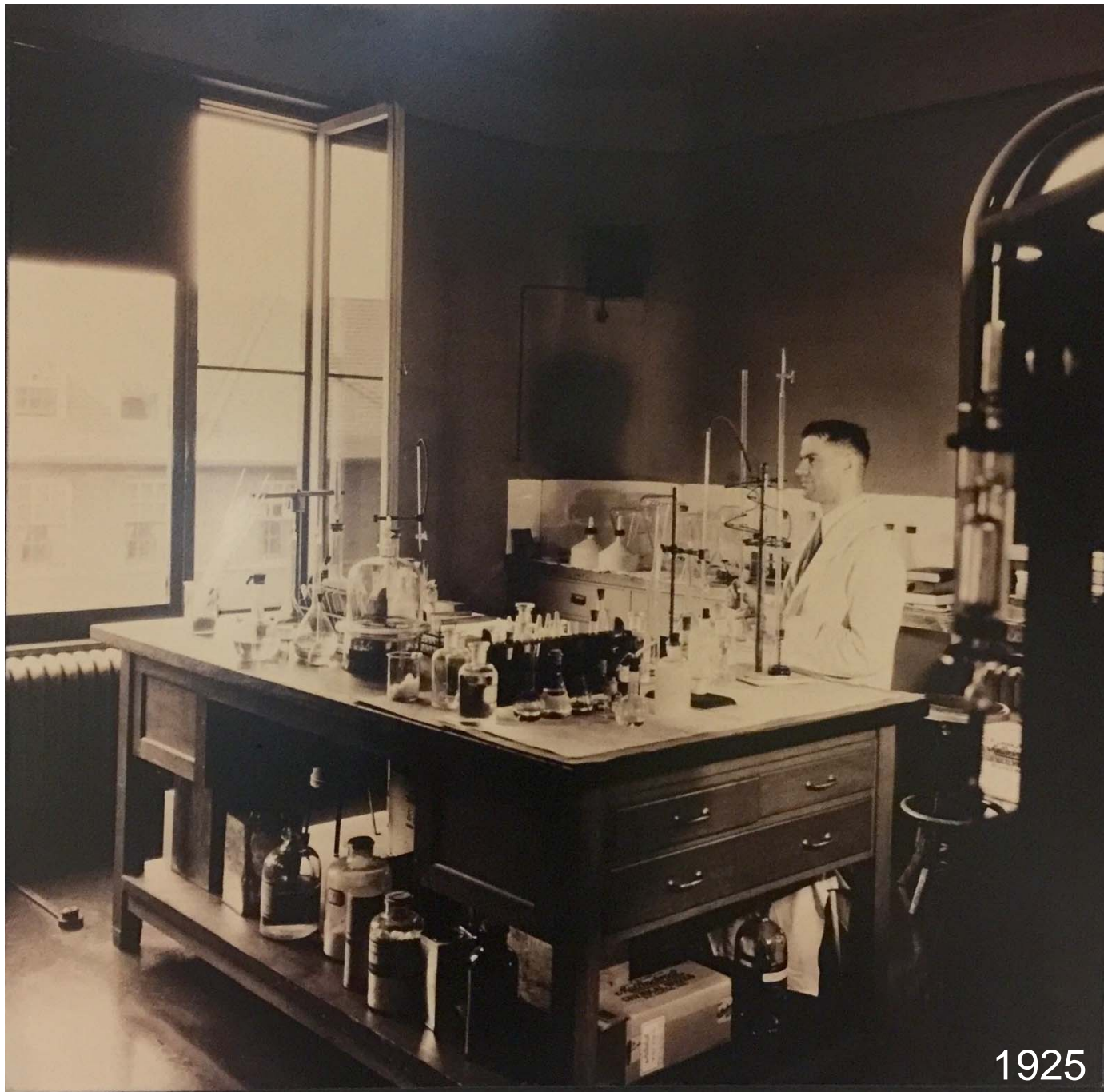
Team-based successes

Because this is what we do!

# Value by Design – Policy Deployment



# LEAN AUTOMATION



1925

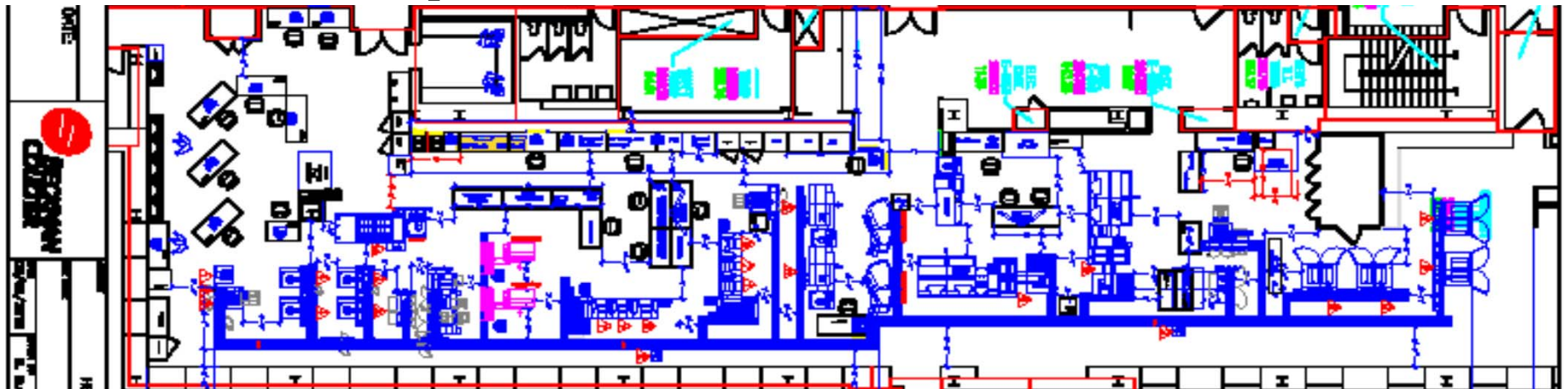


# Automation at Henry Ford

Just how **BIG** is it?

159 feet long

**Most comprehensive automation in US**



53 yard field goal

8 feet taller than Statue of Liberty

# Automation with the “Human Touch”

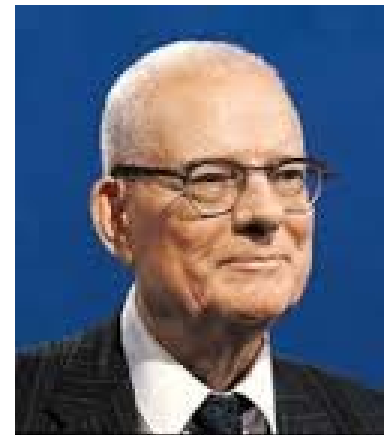
Technology infused with what humans do better through our Lean problem solving culture is improved !



# Man & Machine

**“If you don’t understand how to run an efficient operation, new machinery will just give you new problems of operation and maintenance.**

**The sure way to increase productivity is to better administrate man and machine.”**



W. Edwards Deming



# Our Approach to Automation

**Process Automation** - Machines doing work at the Gemba previously done by people

**The Advantage** - Machines increase standardization, capacity, productivity and economics of the process

**Lean** - Engaged people continuously solving work problems from the level of the Gemba

**The Advantage** – Constantly learning from problems, parsing unique differences and improving the process

# 3P - Production Preparation Process

An event-driven process for developing a new product  
concurrently with the operation (process)  
that will produce it,  
by the people who will interact with it



**"The thing is to keep everything in motion and take the work to the man  
and not the man to the work."  
- Henry Ford**





# 51 Days of Kaizens Over 2 Years

|      |   |
|------|---|
| 2014 | <p><b>October 28, 2014 (1 day)</b><br/>3P modeling and design of automation layout, sample delivery, metrics (current vs future process steps, load leveling strategies, staffing vs. volume)</p>   |
| 2015 | <p><b>January 12-15, 2015 (4 days)</b><br/>Revise automated instrument locations &amp; outlets Chem vs. Heme/Coag to optimize manual stations, cross coverage, upfront processing, sendout testing</p>  |
|      | <p><b>January 28-29, 2015 (2 days)</b><br/>External site visit OSU</p>  |
|      | <p><b>March 10-13, 2015 (4 days)</b><br/>Redesign manual workstations to reduce motion, specimen transport, touch points, lead and cycle times in the flow of specimens from receipt to testing area</p>  |
|      | <p><b>April 28- May 1, 2015 (4 days)</b><br/>Reduce touches points to line for cooler specimens, redesign handoff &amp; tracking from Specimen Receipt to Cytology and Serology, reduce specimen hold time after testing and devise validation plan for new UA and Heme analyzers</p> |
|      | <p><b>July 14-17, 2015 (4 days)</b><br/>Design just-in-time reagent inventory &amp; storage requirements for Instruments &amp; manual testing, reduce specimen touches from Specimen Receipt to Micro/ Serology</p>   |
| 2016 | <p><b>August 19-21, 2015 (3 days)</b><br/>Develop and try-storm Lean designs for Specimen Receipt and Delivery area</p>   |
|      | <p><b>October 6-8, 2015 (3 days)</b><br/>Finalize Lean design for Specimen Receipt and Delivery area</p>  |
|      | <p><b>January 13-15, 2016 (3 days)</b><br/>Design processes to support installation of automated line and achieve continuous flow of specimens from delivery to Core Lab to respective testing sites</p>  |
| 2016 | <p><b>April 26-29, 2016 (4 days)</b><br/>Design processes to support the outlets -aliquots, sendouts, manual testing in Heme/Coag, Chem, Wets, UA and specimens sent to Micro/Serology/HLA</p>  |
|      | <p><b>June 14-16, 2016 (3 days)</b><br/>Design reporting by Client Services rather than bench techs to Medical Centers for defective/inadequate samples by 12 noon next business day, Design notification of Core Lab critical values by Client Services.</p>                         |
|      | <p><b>August 16-19, 2016 4 days)</b><br/>Design processes to support downtime of Power Express and Automate to continue to achieve ER TAT of &lt;30min for Heme, Coag, UA, Lyt7 and CTNI</p>  |
|      | <p><b>September 13-16, 2016 (4 days)</b><br/>Standardize and optimize Remisol for Chemistry, Heme and Coag. Design specimen delivery rolling band conveyer to inlet.</p>  |
| 2016 | <p><b>November 7-18, 2016 (8 days)</b><br/>Line Go-Live</p>   |
|      |   |

# Kaizen Fueled Change

## Action Items

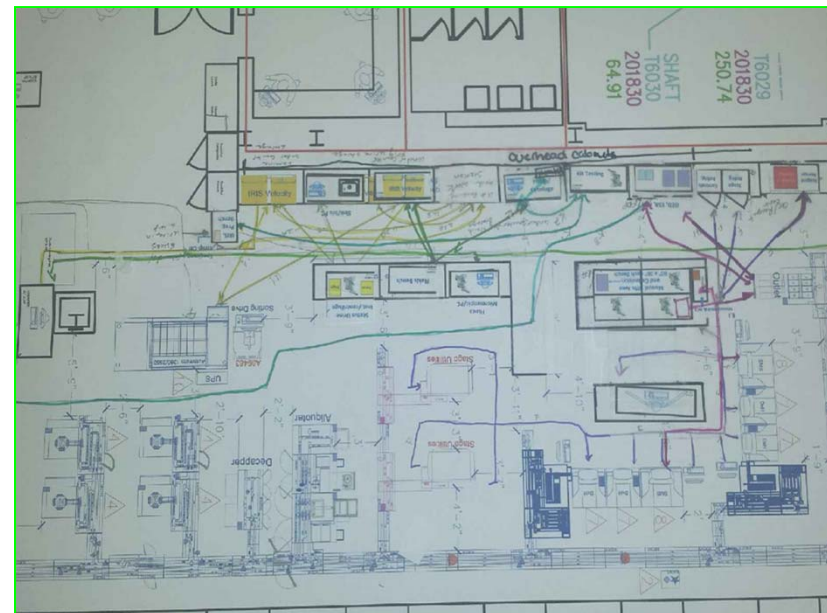
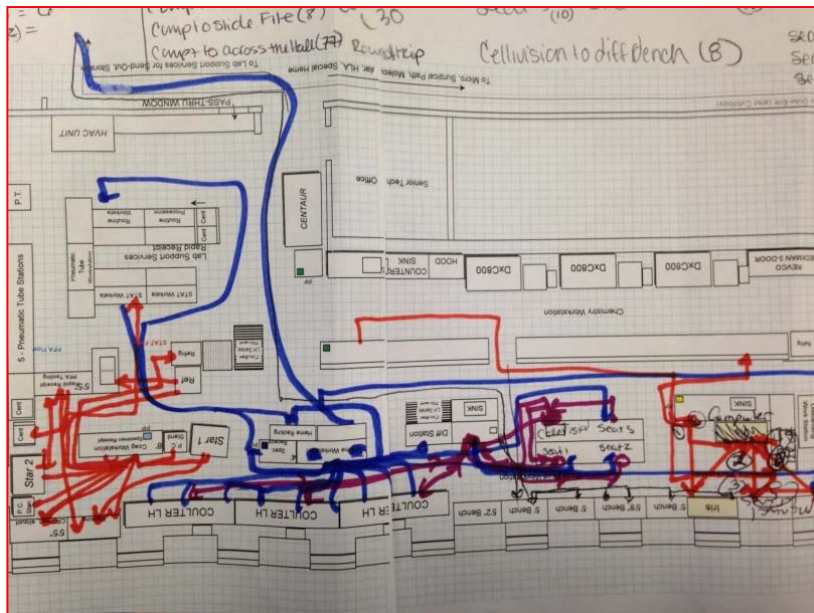
Oct 2014 – Aug 2016

- 141 action items
- 101 complete (72%)
- 40 open
  - 7: open (past due)
  - 11: upcoming due date
  - 22: new as of August 19th

# Motion Reduction Kaizen

69 FTE's throughout 24 hours

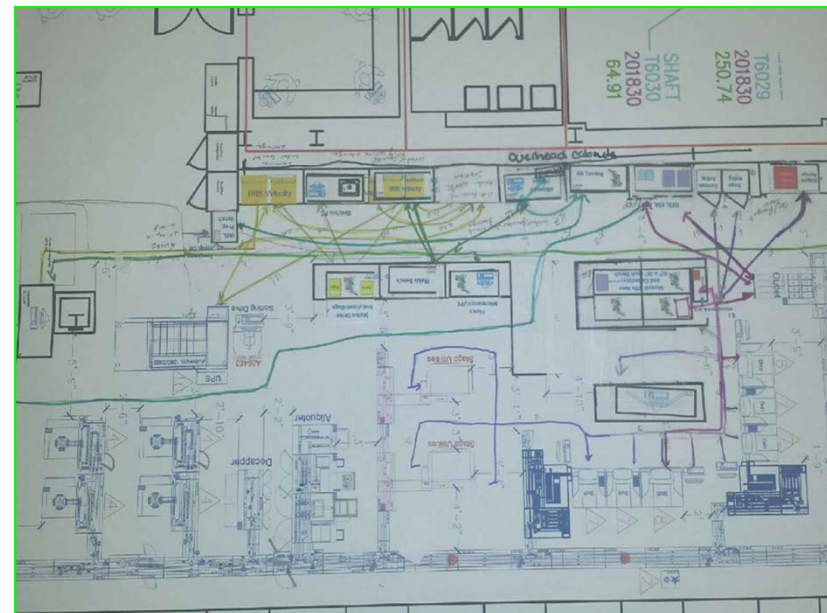
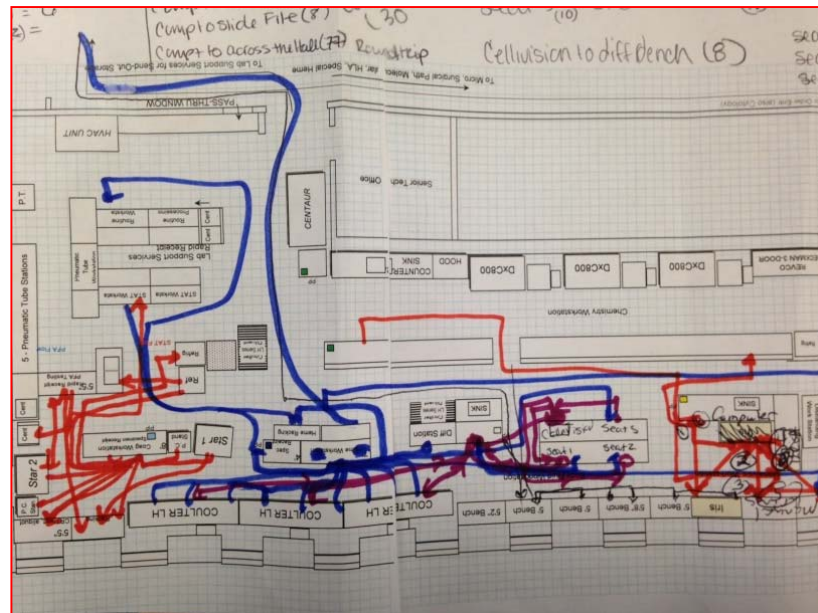
| Motion         | Before Automation | After Automation |
|----------------|-------------------|------------------|
| Steps          | 72,405            | 27,051           |
| Miles          | 41.1              | 15.4             |
| Time in Motion | 20.1 hours        | 7.5 hours        |



# Motion Reduction Kaizen

69 FTE's throughout 24 hours

| Motion         | Before Automation | After Automation | 63% Savings              |
|----------------|-------------------|------------------|--------------------------|
| Steps          | 72,405            | 27,051           | 45,345 steps             |
| Miles          | 41.1              | 15.4             | 25.8 miles               |
| Time in Motion | 20.1 hours        | 7.5 hours        | 12.6 hours<br>= ~1.5 FTE |





# Specimen Handling “Touches” Kaizen

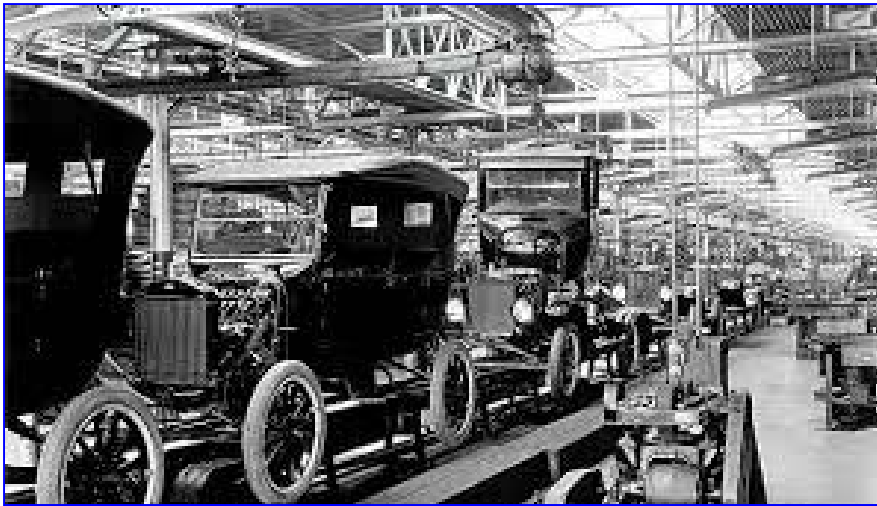
|   | # Touches<br>Barcode Ready | # Touches<br>Non-Barcode Ready |
|---|----------------------------|--------------------------------|
| Pre-Automation-Hematology                                     | 26                         | 28                             |
| Post-Automation-Hematology                                    | 2                          | 6                              |
| <b>Improvement</b> →  | <b>92%</b>                 | <b>78%</b>                     |
| Pre-Automation-Basic Chemistry                                | 15                         | 17                             |
| Post-Automation-Basic Chemistry                               | 3                          | 3                              |
| <b>Improvement</b> →  | <b>80%</b>                 | <b>81%</b>                     |
| Pre-Automation Basic Chemistry<br>Shared between 2 analyzers  | 34                         | 36                             |
| Post-Automation-Basic Chemistry<br>Shared between 2 analyzers | 2                          | 6                              |
| <b>Improvement</b> →  | <b>94%</b>                 | <b>83%</b>                     |

Almost There

Opportunity

# The Lean Solutions

1. Culture of people empowerment & structures that authorize action and accountability & proficiency in tools that solve problems
2. Minimal “touches”
3. Real-time metrics related to the “line” to promote human interaction and problem solving
4. Authority to standardize the “suppliers” to eliminate problems at the source representing over 90% of quality defects



# Why Bother?

**Essentially, many of the leading laboratories around the world all have access to the same technology and hardware.**

**Based on our laboratory culture, we strive to be different, to achieve higher levels of performance for our clinicians.**

**Because its more than a lab test,  
it's a patient waiting for a medical decision.**



# **BENEFIT OF LEAN MANAGEMENT**

# At the End of the Day

**“We get brilliant results from average people managing brilliant processes- while our competitors get average or worse results from brilliant people managing broken processes.”**



Fujio Cho  
Honorary Chairman  
Toyota Motor Corp

# IMPROVEMENT

As Leader,  
this is your  
JOB #1

**"Our system of management is not a system at all;  
it consists of planning the methods of doing the work as  
well as the work."**

***-Henry Ford***