

10 Tips for a More Efficient USP 797 Compliant Cleanroom

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Disclaimer

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The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.”

Food for Thought

"Each problem that I solved became a rule which served afterwards to solve other problems."

- Rene Descartes

(1596-1650),

"Discours de la Methode"

Ten Tips for a More Efficient USP 797 Cleanroom?

- Tip #1: Be proactive...find the low-hanging fruit
- Tip #2: Identify Potential Overproduction
- Tip #3: Reduce Waiting Time
- Tip #4: Optimize Physical Plant Organization
- Tip #5: Define Work Processes
- Tip #6: Right Staff for Job
- Tip #7: Measure the Right Outcomes
- Tip #8: Perform Preventative Maintenance
- Tip #9: Plan ahead
- Tip #10: Ensure a Knowledgeable, Engaged Workforce

What is Lean?

- Principles, concepts, & techniques used for **elimination of waste**.
- Create a process that gives customers:
 - **exactly** what they need,
 - **when** they need it,
 - in the **quantity** they need,
 - in the right **sequence**,
 - **defect free**, and
 - at **lowest possible cost**.



Identify Waste: Lean's 8 Types of Wastes

1. **Overproduction:** making more than is required or making too early.
2. **Waiting:** Time staff/products wait while something is being completed; a hold on the process.
3. **Transportation:** Movement of the product when it is not required for processing.
4. **Non-Value-Added Processing:** Busy work or time/energy spent on activities that add no value.
5. **Inventory:** Related to overproduction; also relates to overstocking of component parts of product.
6. **Human Resource Underutilization:** Waste of people not being trained and used to their fullest or highly trained workers performing work that could be done by others.
7. **Defects:** Requirement of inspection and repair of products.
8. **Motion/Transportation/Handling :** Any movement of people or machines that does not add value to the product or service.

Analyze CSP Leadtime Continuum

- CSP Leadtime: Time from the inception of an order for a CSP to the time that the CSP becomes available to the patient.
- Apply lean methods by analyzing the workflow and steps throughout the “leadtime continuum.”



- From 2002 to 2010, a 300 bed hospital in Seattle, Virginia Mason Medical Center reduced their leadtime (for all drugs, not just CSPs) from 150 minutes to 11 minutes by applying lean methodology.

Map Leadtime Continuum Workflow

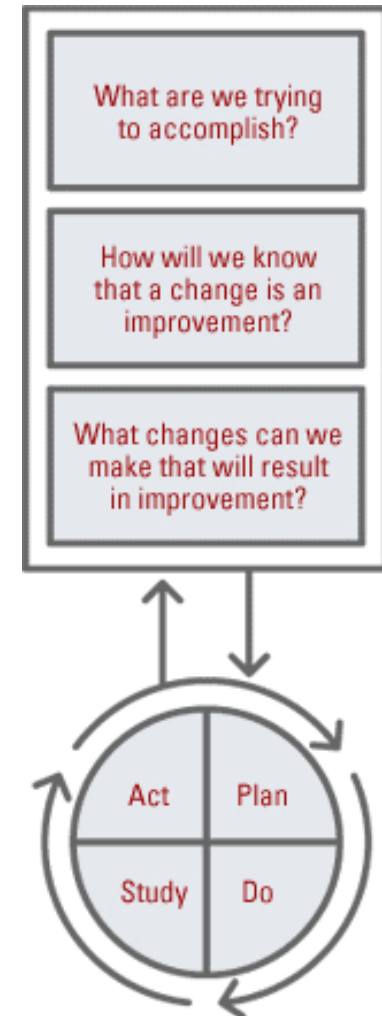
Goal: Eliminate waste by identifying processes that do not add value.

- Map workflow ➡ Identify specific processes
- Identify which bring value and which do not
- Identify “low-hanging fruit” and apply rapid performance improvement (RPI) to each of the identified opportunities



Rapid Performance Improvement

- Use an rapid action items list (RAIL) and prioritize based on:
 - Cost
 - Difficulty
 - Leverage
 - Timeliness
- Work the plan
- Kaizen Blitz
 - Short, sustained activity around process improvement
 - The results are immediate, dramatic and satisfying



Map the Value Stream: Medication Processing and Delivery

- Orders written (MD, LIP)
- Orders processed on the units (paper-based, electronic order, CPOE)
- Orders received in pharmacy (WIP)
- Orders processed by pharmacist
- Labels generated
- **Medication picked and staged for compounding (order)**
- **Order checked**
- **CSPs compounded**
- **CSPs checked**
- CSPs sorted for distribution or storage
- **CSPs delivered to unit (Pneumatic tube, dumb-waiter, tech or courier)**

Tip #2: Identify Potential Overproduction

- Overproduction and/or early production of CSPs that may end up unused resulting in waste.
- Just-in-time (JIT) production is the opposite of massive amounts of anticipatory compounding.
- Are CSPs returned to the pharmacy, credited from the patient account and then destroyed?
 - Match demand with BUD and maximize drug dating



of Batch Runs per day

- Medication dispensing, CSP preparation and batch times
 - How many batch runs done daily? (Two, three, four, five?)
 - Two batch runs:
 - 7:00am batch – doses due from 12:00pm through 11:59pm
 - 1:00pm batch – doses due from 12:00am through 11:59am
 - Problem ➡ some doses may be prepared up to 18 hours in advance of anticipated administration
 - Resending missing doses-restocking
 - More frequent compounding and delivery results in increased frequency of doses delivered to correct location (transferred patients).
- Though it may be counter-intuitive, the economies of scale gained with large batch sizes (less frequent compounding) are not sufficient to overcome waste of product/time/effort involved.

of Batch Runs per day

- Evidence-Based Science

“Direct observation and data collection from the pharmacy information system were used on the existing i.v. room process, for every 12 hours batches. After a change to every-4-hour batch preparation and a modification of the schedule for delivering products to nursing units, data were again collected to determine savings of waste and costs. Fewer doses were prepared daily in the new batch process. The percentage of doses credited daily decreased from 26% to 18%, and pharmacy technician workload decreased by 3.05 hours. The reductions in waste led to a projected annual product cost saving of \$122,000 and a workload reduction of 0.5 technician fulltime equivalent. “

Jenkins A, Rowe E, Granko R, Pfeiffenberger T and Daniels R. Effects of a new sterile product preparation and delivery process on operational efficiency and cost. AJHP. 2010; October: 1645-9.

Tip #3: Reduce Waiting Time and Create Reasonable Expectations

- Reduce time when staff are waiting for someone else to complete their work before they can continue.
- Evaluate the quality of the activity staff perform.
- Eliminate or reduce “busy work” when staff are performing tasks that do not contribute value to the customer (patient, physicians, nurses, hospital).
- Traditional large anticipatory batch compounding is no longer thought to be desirable as it may result in:
 - ↑ Rework of CSPs (recycling)
 - ↑ Waste of time and materials
 - ↑ Pace of work during peak times potentially resulting in error
 - ↑ Idle time during periods of downtime or while RPh waits to check large batch being made

An Important Word about Communication

- Have reasonable turnaround times (TATs) been established for various order sets?
 - Stats
 - Within 30 minutes?
 - Chemo orders
 - Routine orders
- Have cut-off times been established for Parenteral Nutrition orders?
 - Are these cut-off times enforced
- Are TATs monitored and actively managed?
- Are pharmacy customer's aware of the established TATs?

"Finding Chemo"
- Out of Sight But Not Out of Mind

INTRODUCTION
Have you ever wondered where your chemotherapy comes from, or why it seems to be such a long process when you go in for your treatment? This information may help you understand what is involved in preparing the chemotherapy you receive by an injection into your veins. When it's time for your treatment to begin, a prescription is given to the pharmacist who will prepare your chemotherapy according to your personal prescription. What happens after the pharmacy department receives your prescription will vary slightly from hospital to hospital, but will generally be as follows.

1 A specially trained pharmacist checks your prescription to make sure that the treatment is suitable, and all the doses are correct for you. The pharmacist may need to look at the results of your blood tests, or other tests the doctor has ordered and may also want to talk to you, or the doctor, about other medications you are taking, or about any allergies you may have to medications. The pharmacist can answer many of your questions about your medication.

2 Once the pharmacist is satisfied your prescription is correct, your chemotherapy can be prepared in a Sterile Production Centre. Some hospitals may send an order for your chemotherapy to be prepared by another hospital, or a special manufacturing company.

3 The pharmacist or technician in the Sterile Production Centre will produce a record sheet showing details of the drugs to be made which gives instructions for their preparation.

4 Records must be kept of all of the ingredients used to make your chemotherapy. The medication vials and equipment are then covered with sterile plastic before being passed into a sterile clean room through a special hatch.

5 Chemotherapy is prepared in a special cabinet inside the sterile clean room. The person preparing the chemotherapy must wear special, clean protective clothing. This helps to ensure the chemotherapy you receive is not contaminated. It takes about 5-10 minutes to dress up in these special clothes, and another 5-10 minutes to make sure the cabinet is cleaned and ready before making the first chemotherapy dose for the day.

6 The time taken to prepare some chemotherapy is between 30-45 minutes. After your chemotherapy is prepared, the finished product is labelled and packaged in a plastic bag by the pharmacist before being delivered to safety your treatment is to be given. If your chemotherapy is ordered from another hospital, or a special manufacturing company the prepared chemotherapy item has to be delivered to where you are having your treatment.

7 Your treatment can begin as soon as your chemotherapy has been delivered.

8 Why do some treatments take longer to prepare?
If this is your first treatment, the pharmacist needs to thoroughly check your treatment plan, dose, and blood test results. It may also be necessary to confirm some information with the doctor, talk to you about other medications you may be taking and explain how to take any additional medication at home.
It takes some time to clean and prepare the special room and cabinet at the beginning of the day and this may cause delays for you if your chemotherapy is the first batch to be prepared.
If you are participating in a clinical trial or research study there may be some extra paperwork to be completed before treatment can begin.
Sterile Production Centres require regular cleaning and maintenance, some of which may delay the production of chemotherapy from time to time. However, this is an important part of our quality assurance programme.
All staff who make and supply chemotherapy are specially trained in checking your prescription and making up the chemotherapy. Occasionally, if a new material is working extra time and supervision is required.

9 Some treatments can be made in advance. This may depend on the medication used, the type of treatment and the scheduled or regular intervals that the medication is given.
It may be possible to prepare treatment in advance to be ready upon your arrival. This may be possible for medications that are given:
• on a regular basis
• can be stored for the necessary time without going out of date
• can be used for another patient if you are absent and cannot have your scheduled treatment, time after preparation.
Many medications cannot be prepared in advance if the medications are expensive or cannot be stored for the required time.
Occasionally your dose will have changed after you see the doctor and your chemotherapy may need to be made in advance if it has been made in advance.

Can we make YOUR chemo in advance of your appointment?

Why all the precautions?
Chemotherapy can suppress your ability to fight infection. To prevent you developing a serious infection, it is important that products injected into your veins are sterile and clean. Careful steps are taken to make sure it stays that way. It is prepared using special procedures and is by means of a special machine controlled by software designed to prevent contamination. The person making your chemotherapy must wear a cap, mask and two layers of chemotherapy gloves.

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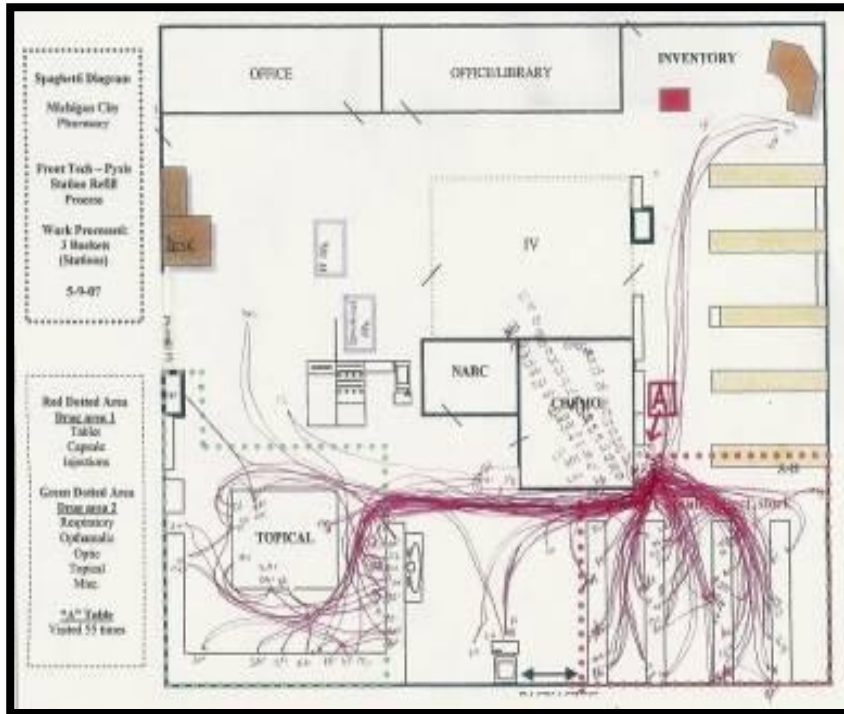
Tip #4: Optimize Physical Plant Organization

- Minimize movement of product from one step to another.
- Rethink layout to ensure efficient workflow.
 - Printer location
- Allow sufficient room to dedicated activities like labeling.
 - Does this occur in the buffer area?
- Restock compounding room regularly to reduce time lost picking components needed frequently.

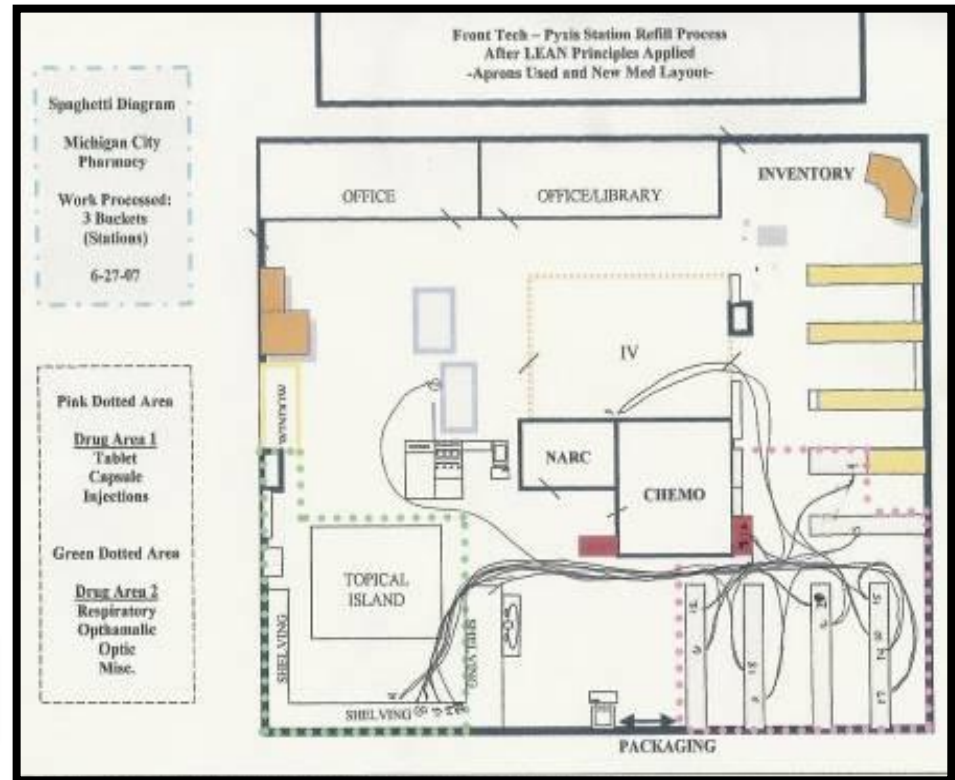


Optimize

Current Condition



Pilot Condition



Tip #5: Define Work Processes

- Standardization is the cornerstone of quality and efficiency.
- Are policies and procedures detailed and in writing?
- Do staff know PnPs? Do they follow them? How do you know?
- Simplify number of drug/dose/diluent combinations.
- Standardize compounding methodology.
- Break out routine standardized compounding from “custom” doses.



Define Work Processes

- Ensure compliance with detailed and standardized processes.
- If no one inspects performance to ensure that procedures are followed, then they must not be that important.
- “We never have time to do it right but we ALWAYS have time to redo it.”



Without consistency there can be no quality!

Tip #6: Right Staff for the Job

- Ensure that the right staff are used for each component activity.
- Promote and maximize the role of support staff.
 - The use of tech to check tech when feasible
- Routinely using pharmacists to perform duties that can be performed by pharmacy technicians is an example of under utilized skill.



Right Staff for the Job

- Specialized staff versus “everyone rotates through the cleanroom”
 - Recognize “Master Performers”
 - Technicians
 - Pharmacists
 - Clinical vs. Distribution Roles
- Holding pharmacists accountable to comply with cleanroom procedures
 - Example: Proper garbing procedures during order checking process

No exceptions! Zero tolerance!

Tip #7: Measure the Right Outcomes

- **Measurement is Not a Noun**

- First, measurement is not a noun; it's a verb. Pharmacy operations can't just "do measurement," they have to measure outcomes that are clearly defined and linked to strategies.
 - Ensure safe and efficient patient care
 - Have medication available when nurse needs/wants them for the patient.
 - Complying with regulations
- Outcomes are changes in attitude, condition, behavior, status, reputation or cost that result from some intervention or strategy.
- Too many departments end up just "doing measurement" or doing busy work tracking a bunch of processes or activity indicator.
- If these metrics are not tied to any **meaningful** outcomes, they carry little currency and no explanatory value.

You can't improve quality if you don't measure it!

- What are your performance metrics and are you measuring the right outcomes?
 - Turnaround times per order set
 - # of missing dose (What is the cause of these requests?)
 - CSP per day/ unit of time
 - Cost of wasted doses
 - Number of med errors / unit of time
 - Correct prescription labels
 - Complete and accurate documentation
 - Batch records -Components used, lot # and expiration dates)
 - Compliance records -Cleaning, Environmental Sampling, Facility Performance Metrics (Δ pressures, temps)

Tip #8: Perform Preventative Maintenance

- Reduce or eliminate downtime caused by malfunction of physical plant and equipment.
 - HVAC
 - Pressure Δ 's, temperatures
 - Primary Engineering Controls
 - LAFWs, BSCs, CAIs, CACIs
 - ACDs
 - Complete and accurate component libraries
 - Equipment
 - Refrigerators/Freezers/Incubators



Tip #9: Plan ahead

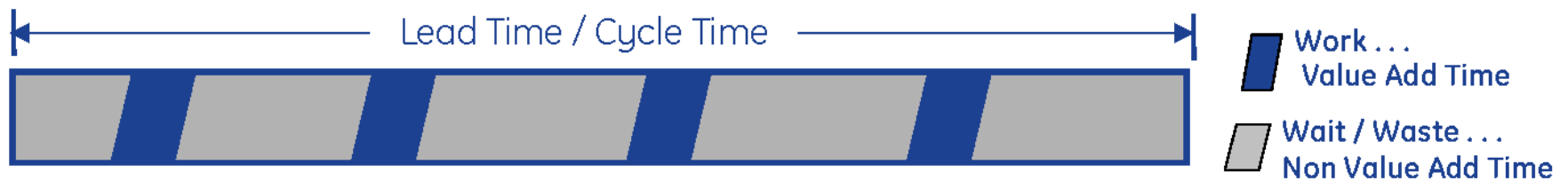
- Failure to plan ahead cripples many businesses.
- Design flexible, JIT systems that can respond to demand variability.
- Break the habit of stockpiling component and finished CSP inventory as guard against demand variability since this process:
 - is more likely to cost your operation significant dollars due to waste and
 - Often does not effectively meet need during times of peak requirements anyway.



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Calculate Takt Time

- The pace of production needed to meet customer demand
 - What is the turnaround time from receipt of order to medication being at a location that the nurse will be looking for it and at the time she needs to give it to the patient?



Tip #10: Ensure a Knowledgeable, Engaged Workforce

- Maximize the unique skills and qualities of each staff member.
- Comprehensive orientation
- Ongoing training related to job activities
- Continual competency verification
- Reward staff who identify “near misses” and make proactive suggestions for improvement.



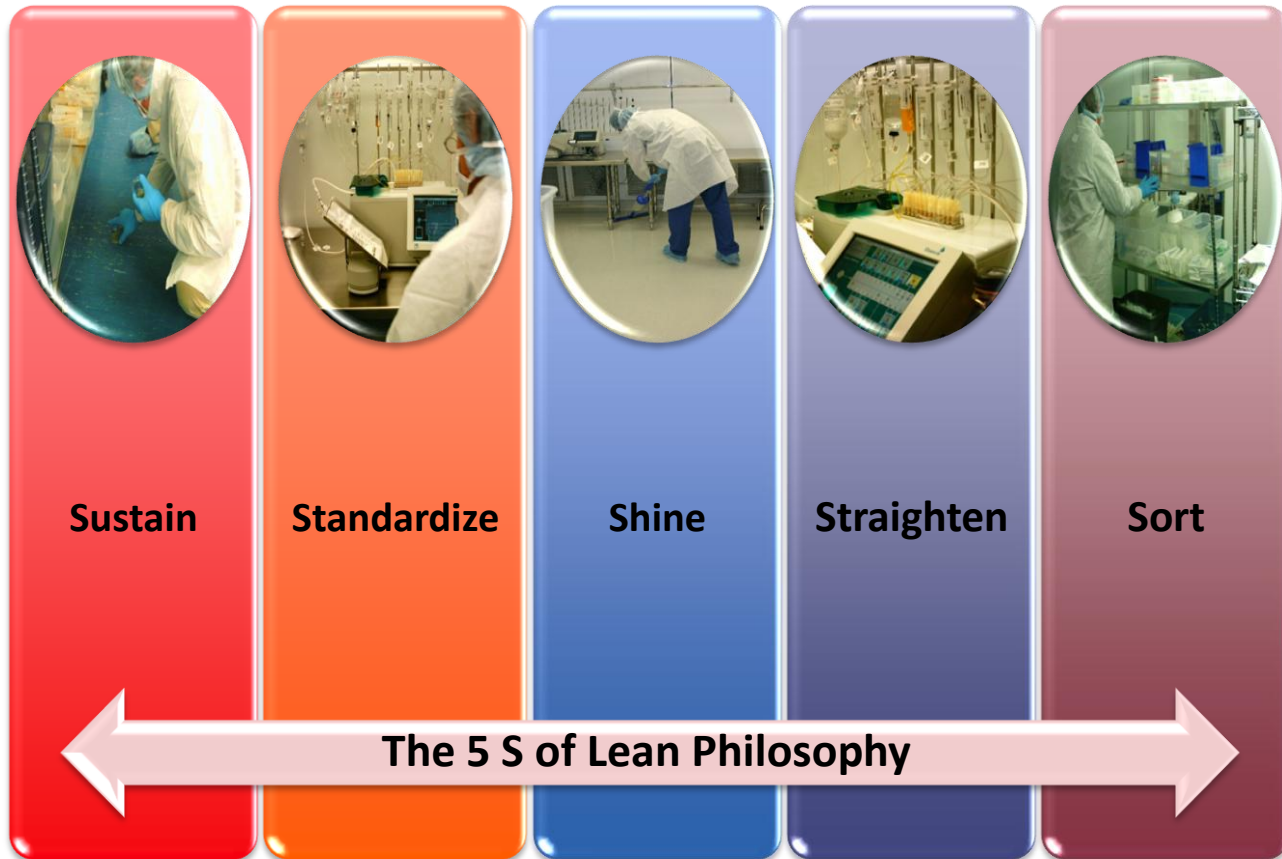
Create a Quality Culture!

Some Thoughts on Highly Reliable Organizations

- **Don't be tricked by your success**
 - Be preoccupied with your failures. React early and quickly to anything that doesn't fit with your expectations.
- **Trust your gut**
 - Navy aviators often talk about "leemers," a gut feeling that something isn't right. A pilot feels puzzled, agitated, or anxious. Even though he doesn't know exactly what's wrong, he knows that he needs to abort the mission. Typically, those leemers turn out to be good intuitions: Something, in fact, is wrong.
 - They encourage members to be wary of success, suspicious of quiet periods, and concerned about stability and lack of variety, both of which can lead to carelessness and errors.
- **Defer to your experts on the front line**
 - Allow decisions to migrate to frontline expertise rather than managers.

Habits of Highly Reliable Organizations <http://www.fastcompany.com/magazine/58/chalktalk.html?page=0%2C0>

5 “S” your operation



Excellence is an art won by training and habituation. We do not act rightly because we have virtue or excellence, but we rather have those because we have acted rightly. We are what we repeatedly do. Excellence, then, is not an act but a habit.

Aristotle

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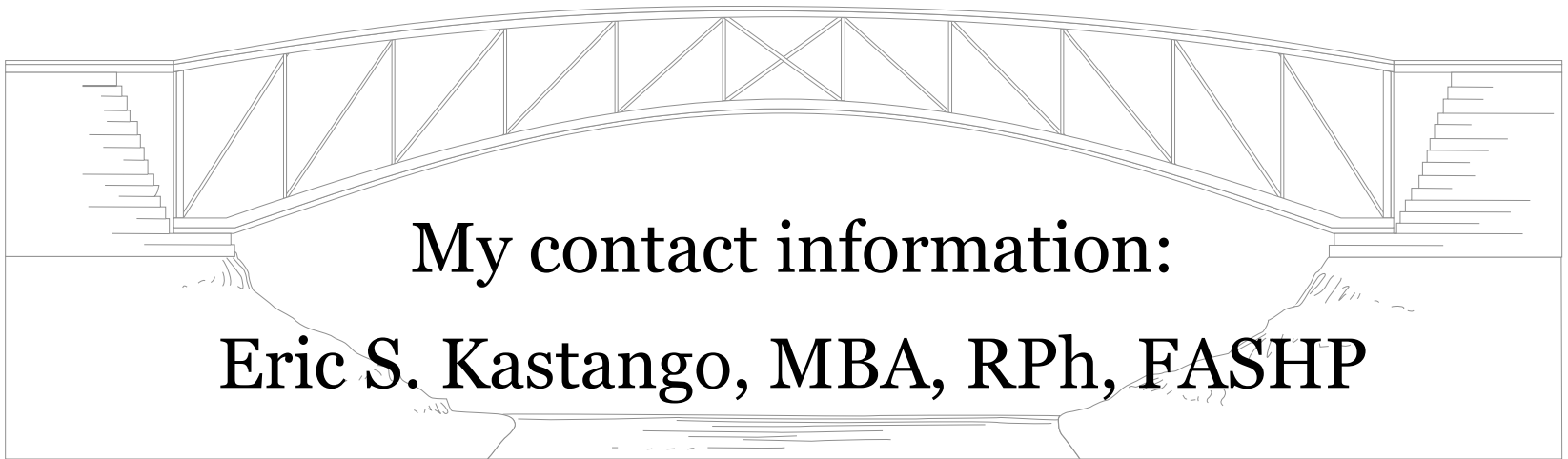
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Thank you



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