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CHALLENGES ON THE CHOSEN PATH TO REGISTRATION UPGRADE FROM ISO 9001:2008 TO ISO 9001:2015

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FROM POINT A TO POINT B

- ## CHALLENGES ON THE CHOSEN PATH TO REGISTRATION UPGRADE TO ISO 9001:2015

- POINTS OF INTEREST ALONG THE ROUTE
  - Detail and roadmap

- DETOURES
  - Left or Right, Straight ahead???

- QUESTIONS

- Takeaway

The Planning Stage

- ➤ November – December 2015
- ➤ Insure that top management is on board with the transition
- ➤ from old to new (Staff Meeting)

- ➤ Obtain ISO 9001:2015 standard and register the document in your system

- ➤ Establish a team to undertake the task
  - ➤ Open Continuous Improvement Project to track progress
  - ➤ Outlined the desired outcome
  - ➤ Set the team (IT, Quality, Manufacturing, Senior staff rep., etc)
  - ➤ Complete Management of Change Review

Planning (continued)

- Arrange for Internal Auditor training for ISO 9001:2015 Standard process auditing.
  - In house or external?
  - Select trainer
  - Establish timing

- Conduct Gap analysis
  - Initial impact assessment of current system compared to the 2015 revision.

Planning (continued)

- Obtain ISO transition guidance
  - Multiple sources helped understand the changes (opinions of several)
    - White papers
    - Metric Stream
    - Etc.
- Review the changes in structure of the standard (numbering) and the additional requirements of ISO 9001:2015
  - Set up matrix of what current system has in documented system vs newl (where we met the standard requirements and what we were missing).

Communication

- January 2016 (10 months to target date)
- Communicate the results of the gap analysis with senior management.
- Establish time line
  - Goal – Recert full audit scheduled for October 3, 2016
    - Continue to meet 2008 version and add 2015 upgrade
- Communicate the objectives with work force
  - Staff meeting in January 2016
  - Plant wide meetings January 2016
- Improve value to customers and our organization

  - COMMUNICATE – COMMUNICATE – COMMUNICATE !!!

Gap Analysis Review

- *The Standard* is intended to help achieve excellence through stronger customer focus and improved business performance.
- Review the Gap analysis and understand changes required
- Understand the risk based thinking and how to incorporate in to the quality management framework.
- Team undertakes documentation revisions required
  - End of February 2016 to complete.
    - Management responsibility changes
    - Internal Audit – entire requirement base (1 full cycle)
    - Register revised/new docs
    - Training requirements

Implementation

- Team meeting (March 2016)
  - Insure necessary documentation is completed, registered and trained on
  - Internal auditors to verify training and competence
    - Changes to Management Review
      - Formal risk based activity
    - Review gap analysis action items for completion
    - Executive staff to verify internal audit schedule on time
      - Establish "finding" protocol and action timing
    - Communicate to all timeline to goal and progress stage

    - Communicate – Communicate, Communicate!!!

Test Drive – The rubber hits the Road

- Test the improvements to the system
  - Informal at first to highlight changes completed and still needed
    - Drive with a learners permit attitude (audit)
      - Slow and steady evaluation
      - Prepare for formal internal audit program

- Review gap analysis compliance
  - Address any missing items

- Kick Off Internal Audit Cycle

The rubber hits the road

- Internal Audit findings
  - Assign actions request
  - Communicate timing for closure
  - Verification activity
- Continue Cycle

- Continue to monitor training and identified activities of gap analysis completion

- <u>Executive staff reviews progress toward goal</u>
  - <u>June 2016 Management Review</u>

THE CHECKERED FLAG IS IN SIGHT

- Internal audit of Management activities to meet requirements
  - How is risk assessed
    - Management Review (Executive Staff) meeting minutes
    - Yearly Executive Staff Retreat
    - Monthly Executive Staff Management Review
      - Dash Board of Metrics and Critical Business Trending
      - Opportunities
        » Acquisitions
        » Expansions
        » Manpower

THE FLAG IS IN SIGHT

- Documentation method for objective evidence
  - New equipment, facility, business (MOC)
    - Form 433
    - Form 432
- How are needs and expectations of interested parties shown
    - Customer Surveys
    - Key Account visits
    - Plant wide meetings (3 shifts)
- Knowledge acquisition
    - Training matrix, Job descriptions

- Communicate – Communicate – Communicate !!

FINISH LINE -- YEAH

- Welcome 3rd party auditors and let the fun begin
  - Opening meeting
- Casual four days of auditing (2 people)
  - WHAT? How did that happen??
    - Daily review of activity
    - Findings?

- 4 days later, 20 gallons of coffee, lots of salad, 2 extra gray hairs

  - Thank goodness I don't smoke

The Results!!

- Couple of document issues
- Quality Policy
- Preventive Maintenance
- CAR 30 day
- All finding completed and submitted final drafts 11/4/2016
- Reviewed by Registrar for acceptance and approval

- Approved and Certificate of Registration ARRIVES VIA EMAIL.
- Send congratulations to team and post in plant for all to see and place congrats on GRRP TV.

- Communicate – Communicate – Communicate !!

Take away auditors helps

- A lot of auditor training courses, books, white papers etc. encourage the use of checklists when conducting and audit. Though the checklists create consistency in the audit process, checklist may not cover all of the necessary items. Auditees become programmed to answer the questions due to repetitiveness.

- Auditors also may become to reliant on the checklist and that leads to a lack of being agile and responsive to situations.

- Use of checklist may help remember certain items to look at but do not make so big that now other questions or topics can't be covered.
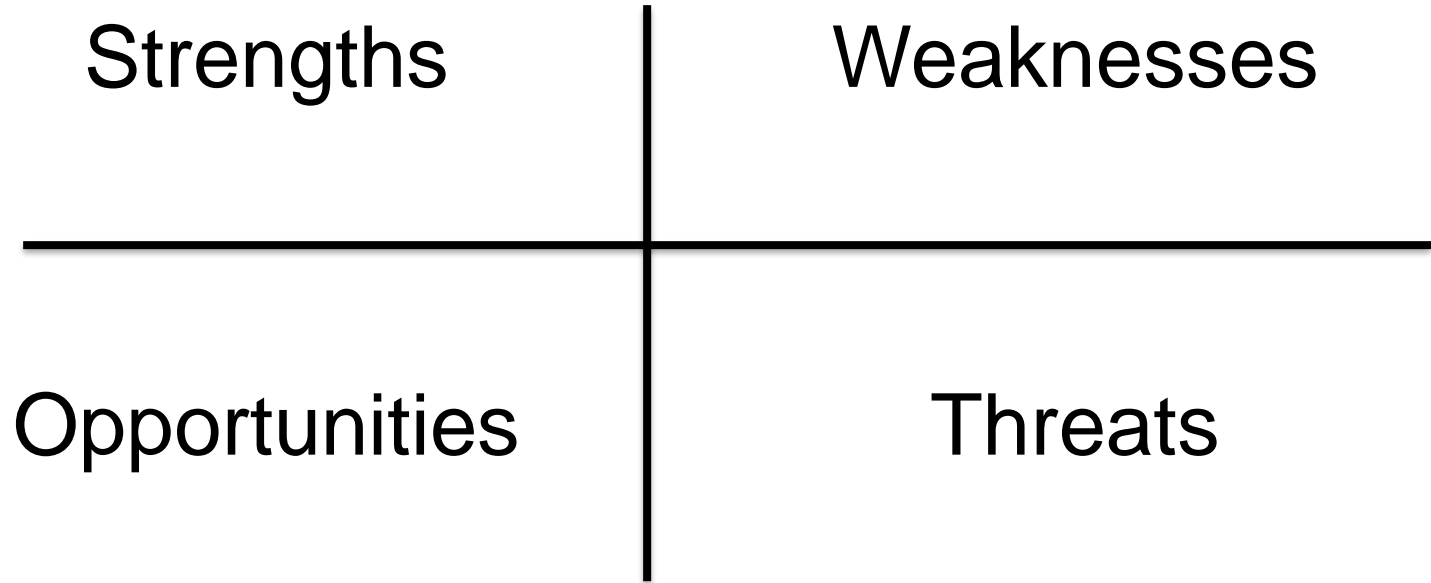
Auditors

- Give the auditor some freedom
  - Are the machines suitable for production?
    - Yes or No
  - How does the organization determine the suitability of the machines?
    - Now you will get a better answer which will be more valuable than Y or N.
  - Is there a Quality Policy for GRRP
  - Our auditors were asking wrong questions
    - Do you know your Quality Policy and how does the work that you do support the Quality Policy
      - Better question and also supports workers in that their jobs are important to meeting our corporate objectives.

- The inclusion of knowledge management in ISO 9001:2015 is designed to ensure that "knowledge shall be maintained and made available to the extent necessary." It's about time! Knowledge management isn't a fad, an elitist school of thought, or a corporate card catalog. It's "getting the right information to the right people at the right time" to deliver what is required, without defects. It's also about enabling collaboration between people and capturing critical knowledge for reuse. There is a strong intersection between knowledge management and quality. Both transform individual behaviors into stronger culture norms and can deliver changes in business performance. Both require change management to drive acceptance. And to be successful, both need strong governance, roles and responsibilities and methodology.

- **When auditing look for job descriptions, training logs, job knowledge from OJT, all employees are applicable, President to Janitor.**
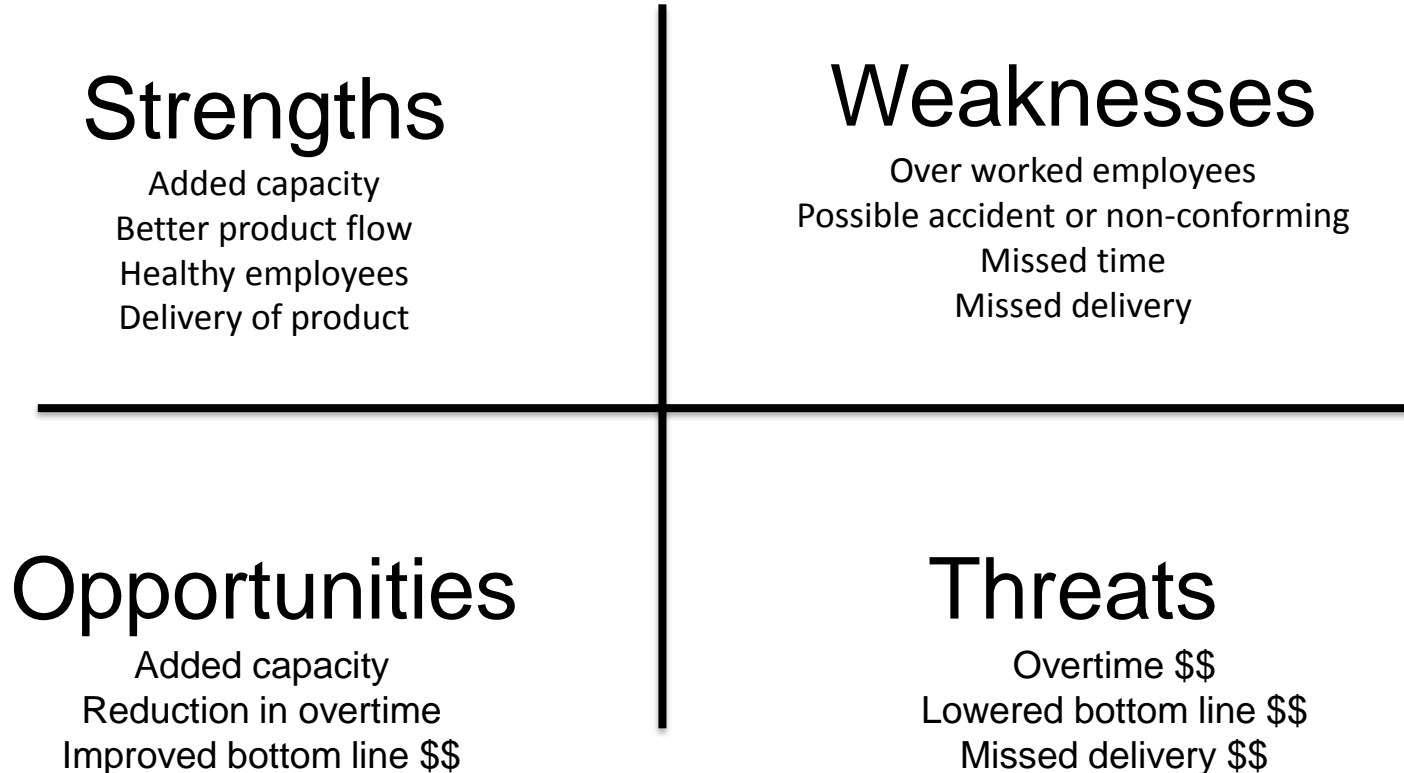
SWOT Diagram

<u>SWOT (Risk Assessment)</u>

Strengths	Weaknesses
Opportunities	Threats

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SWOT Diagram

Example Addition/capacity

Strengths

Added capacity
Better product flow
Healthy employees
Delivery of product

Weaknesses

Over worked employees
Possible accident or non-conforming
Missed time
Missed delivery

Opportunities

Added capacity
Reduction in overtime
Improved bottom line $$

Threats

Overtime $$
Lowered bottom line $$
Missed delivery $$

Adding Auto 5 and adding to building will improve capacity. Re-mapping of product flow will improve movement, accessibility and storage for shipments ⬆

REFERENCE MATERIAL

- International Organization for Standarization
  - Correlation matrices between ISO 9001:2008 and ISO 9001:2015
    - www.iso.org/tc176/sc02/public
- Perry Johnson Registrars, Inc.
  - ISO 9001:2015 vs. ISO 9001:2008
  - A side by side comparison
    - WWW.pjr.com (iso9001-comp rev (1.2) 9-29-15
- MetricStream
  - IOS 9001:2015
    - The 10 Core Elements of and Enterprise Quality Management System
- Denis Devos Associates
  - Risk Based Thinking
- **ASQ World Conference (May 2017)**
  - Denise Tobitaille
    - ISO 9001:2015 Tips for a Smooth Transition
- 9001 Academy
  - Email information (strahinja@adviser.com)

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Thank You!

Questions?

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