



# Business Case for PAT

# Business Case: Starter Point

- What is a business case?
  - A **structured** proposal for **business improvement** that functions as a decision package for **organizational decision-makers**. A business case includes an analysis of business process performance and associated needs or problems, proposed alternative solutions, assumptions, constraints, and a risk-adjusted cost-benefit analysis
  
- Typically has four main components:
  - A problem,
  - Impact of the problem,
  - A solution,
  - Mitigative/ results of the solution

# Business Case: Starter Point

- Business Case: Do we need one to do PAT?
- Yes... overwhelming reason is that we are “changing” processes and that comes at a cost. A cost that needs to be someway outweighed by the benefits.
- Without a business case, no real compelling reason for companies to embrace PAT – still just a “guideline” with explicit mention of “voluntary participation”

# Business Case: Starter Points

- Various considerations
  - New Processes vs Legacy Processes
  - PAT **project** vs PAT **program**. How easy is it for a company to commit resources to a structured program vs a single project. What business case does one need for a dedicated PAT group managing the overall program, vs capital for implementing a PAT **project**.
  - Does size matter?
  - Who develops the business case?

# Business Case: Starter Points

- LEGACY PROCESSES
- **Typical Problem Statements:** Write-offs, low yield, cycle times, inventory, compliance, **variability**...
- **Impact of the Problem:**
  - Increased WIP, increased capital interest, loss in revenue, increased rejects...
  - Impact of variability: Use of process capability metrics
- **Solution:**
  - On-line analytics (CAPITAL)
  - Engineering/Scientists (Expense)
  - Data Management System (CAPITAL and EXPENSE)
  - After PAT Support... How many people factor that in to their calculations?
  - ALL THESE ELEMENTS ADD TO THE COST OF CAPITAL FOR A PROJECT

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## ■ IMPACT OF SOLUTION

- Reduced QC testing
- Improved cycle times
- Reduced write-offs
- Improved yield
- Headcount reduction
- Reduced maintenance - better understanding, better diagnostics
- Reduced variability – not easily translated into \$\$\$
- Regulatory Relief??
  
- Faster time to market
- Parametric Release
- Reduced frequency of inspection

# Business Case: Starter Points

- New processes – Business case for QbD?
- Easier or more difficult?
- How does one quantify the benefit/cost? What is the cost of quality and compliance on a new process?
- Validation in the new paradigm is intuitively expected to produce benefits – some very well articulated qualitative business cases out there. Change process within design space can be done without filing/validation – will also lead to lesser rejects.
- Use of legacy data to justify future projects.