

# Lessons Learned through ISO 9001:2015

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# ISO 9001:2015 Certification Timeline



# Quality Management Principles:

- **Customer focus**
- **Leadership**
- **Engagement of People**
- **Process Approach**
- **Improvement**
- **Evidence-based Decision Making**
- **Relationship Management**

# Key Changes:

- **Leadership** – top management demonstrates...
- **Planning** – expanded to “strategic” approach
- **Risk-based Thinking** – from preventive actions to addressing risks and opportunities
- **Change Management** – embedded throughout the quality management system
- **Process Approach** – systematic definition and management of processes

# Leadership

**Top Management shall...(5.1):**

- **Take Accountability**
- **Ensure Integration**
- **Communicate Importance**
- **Engage, Direct, and Support**
- **Promote Improvement**



# Planning



## Business planning process:

- **SWOT Analysis (4.1)** – Strengths, Weaknesses, Opportunities, and Threats
- **Interested Parties Matrix (4.2)** – Interested Parties and their requirements/expectations
- **Risks and Opportunities Matrix (6.1)** – prioritize based on risk assessment
- **Business Plan (6.1)** – mitigate risks and capitalize on opportunities

# Risk-based Thinking

Organization determines:

- Plans to address risks and opportunities (6.1)
- Documented information necessary for QMS (7.5)
- Objectives (6.2)



# Change Management

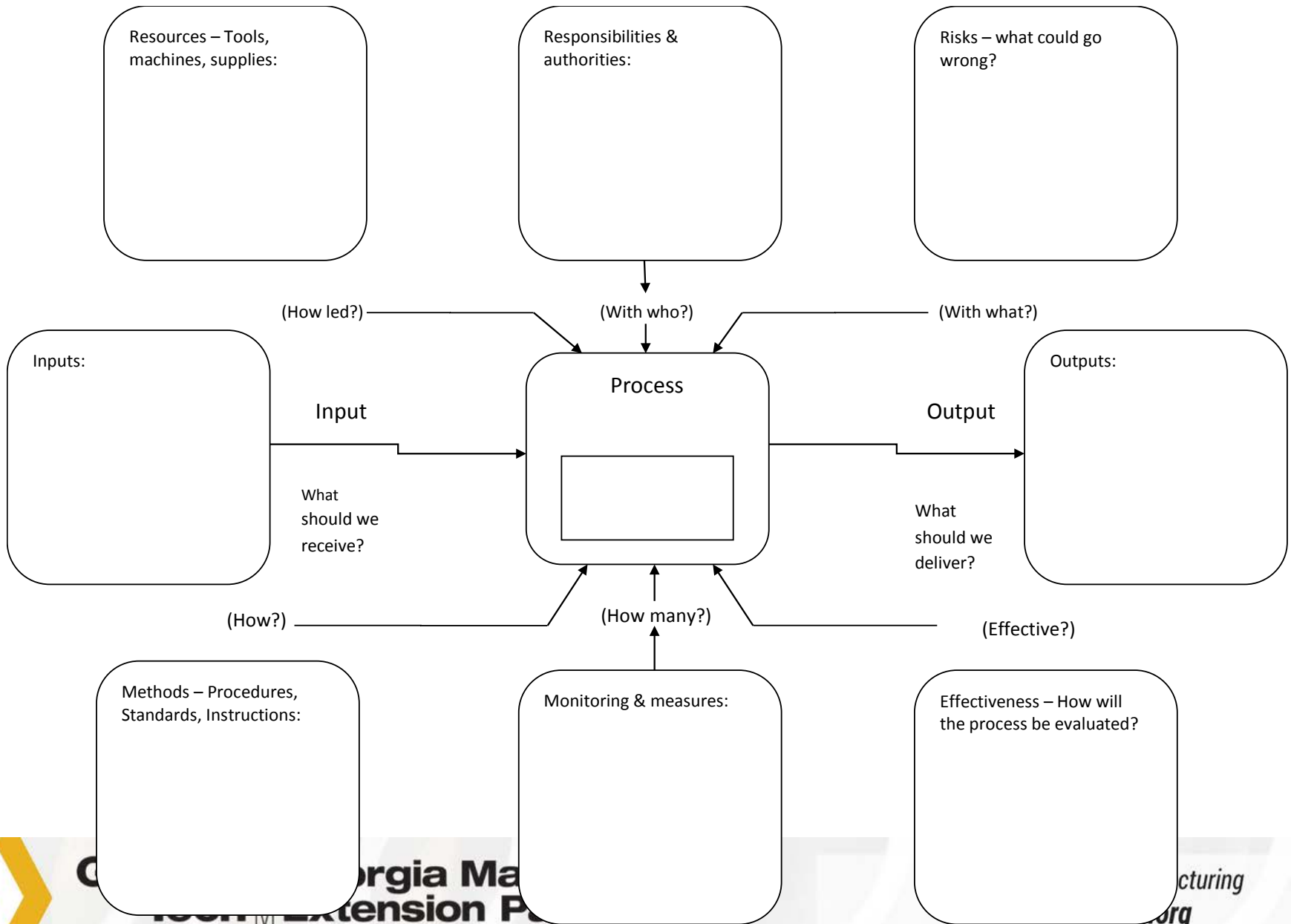
## Planning of Changes (6.3):

- **Purpose** – why are we making this change?
- **Impact** on the QMS?
- **Resources?**
- **Responsibilities** and Authorities?





# Process Approach (4.4)



# Keys to Success

- Top management involvement
- Cross-functional ownership
- Project management
- Continual improvement



# Questions?