Back to School

Quality 101

A Framework for Quality Management: Using a system approach

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Objective

Provide an understanding of Quality Management Systems

- System approach to Quality Management

- ISO 9001as the framework

Quality Definitions

ASQ is a global community of people passionate about quality, who use the tools, their ideas and expertise to make our world work better. ASQ: The Global Voice of Quality.

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Quality Glossary - Q

Quality: "Subjective term for which each person or sector has its own definition".......

Technical
1. Product or service characteristics that impact its ability to satisfy stated or implied needs
2. Defect-free product or service

Juran – "fitness for use"

Crosby - "conformance to requirements"

Quality Management System (QMS): "A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management."

Processes

Resources

Quality
Management
System

Organization Structure

Documents

Coordinated activities to ensure Customer and Organization requirements are met

What is a process?

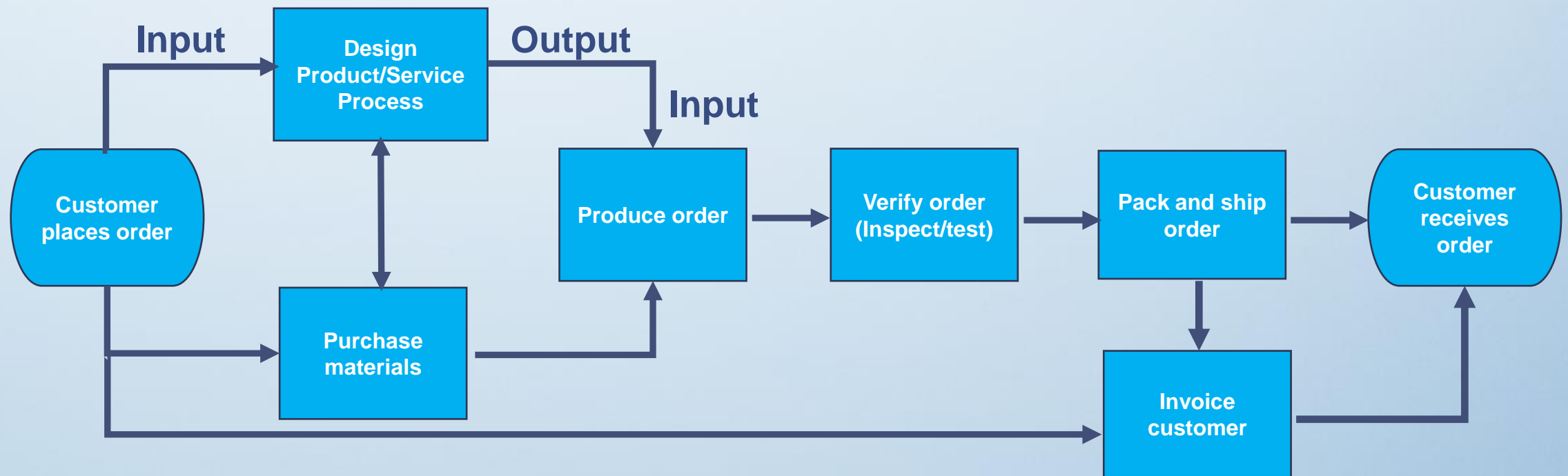A set of interrelated or interacting activities which transform inputs into outputs.

Processes

Resources

QMS

Organization Structure

Documents

Input

Materials

Specification

Process

Activities and tasks

Resources

Output

Product or Service

Processes

Resources

QMS

Organization Structure

Documents

A set of interrelated or interacting activities which transform inputs into outputs.

- All processes have inputs and outputs
- Outputs often are inputs to next step

Input → **Design Product/Service Process** → **Output**

Input

Customer places order

Design Product/Service Process

Purchase materials

Produce order → **Verify order (Inspect/test)** → **Pack and ship order** → **Customer receives order**
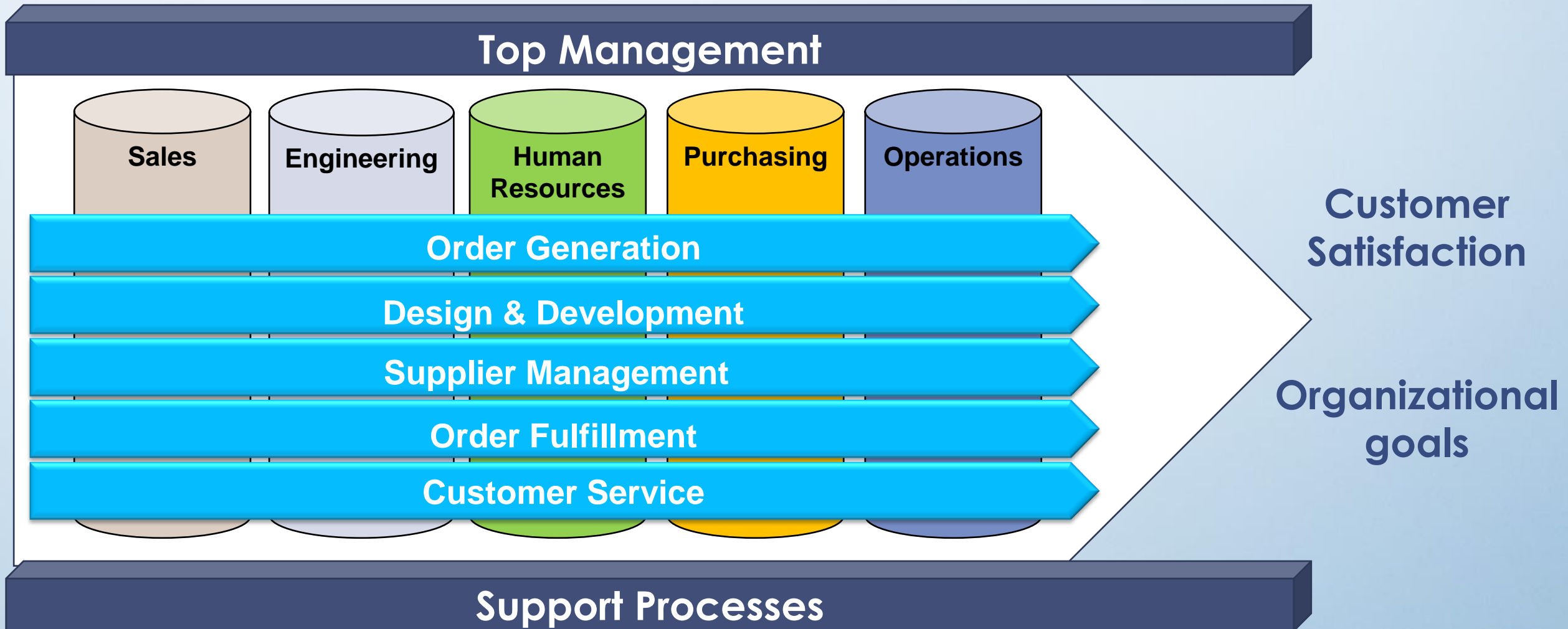
Invoice customer

What is a system?

A collection of processes working together to achieve a common purpose….

- Processes and interaction managed as a network

- Share resources

- Consistently operate as a network

Resources

Goal

Resources

System approach

Top Management

| Sales | Engineering | Human Resources | Purchasing | Operations |

Order Generation

Design & Development

Supplier Management

Order Fulfillment

Customer Service

Customer Satisfaction

Organizational goals

Support Processes
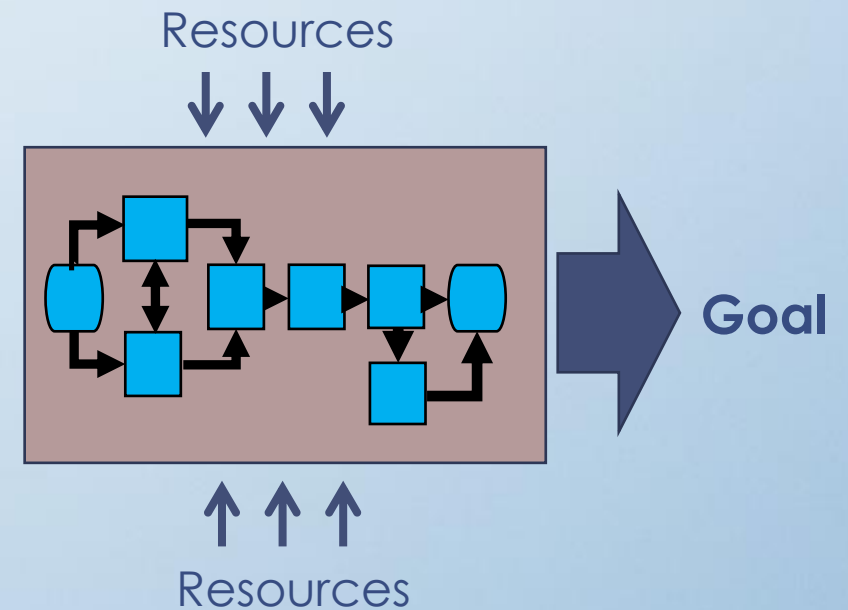
Benefits

The system approach

- Focuses collective effort on achieving goals and objectives

- Facilitates process improvement

- Effectively utilizes resources

- Enhances ability to consistently provide a quality product or service

- Enhances overall performance of organization

Quality System Standards

- Provide a practical model for Quality Management System (QMS)

- Assist organizations in establishing and achieving sound quality practices

- Provide methods for organizations to achieve and demonstrate quality performance to customers

- Industry specific QMS standards
  - Aerospace
  - Automotive
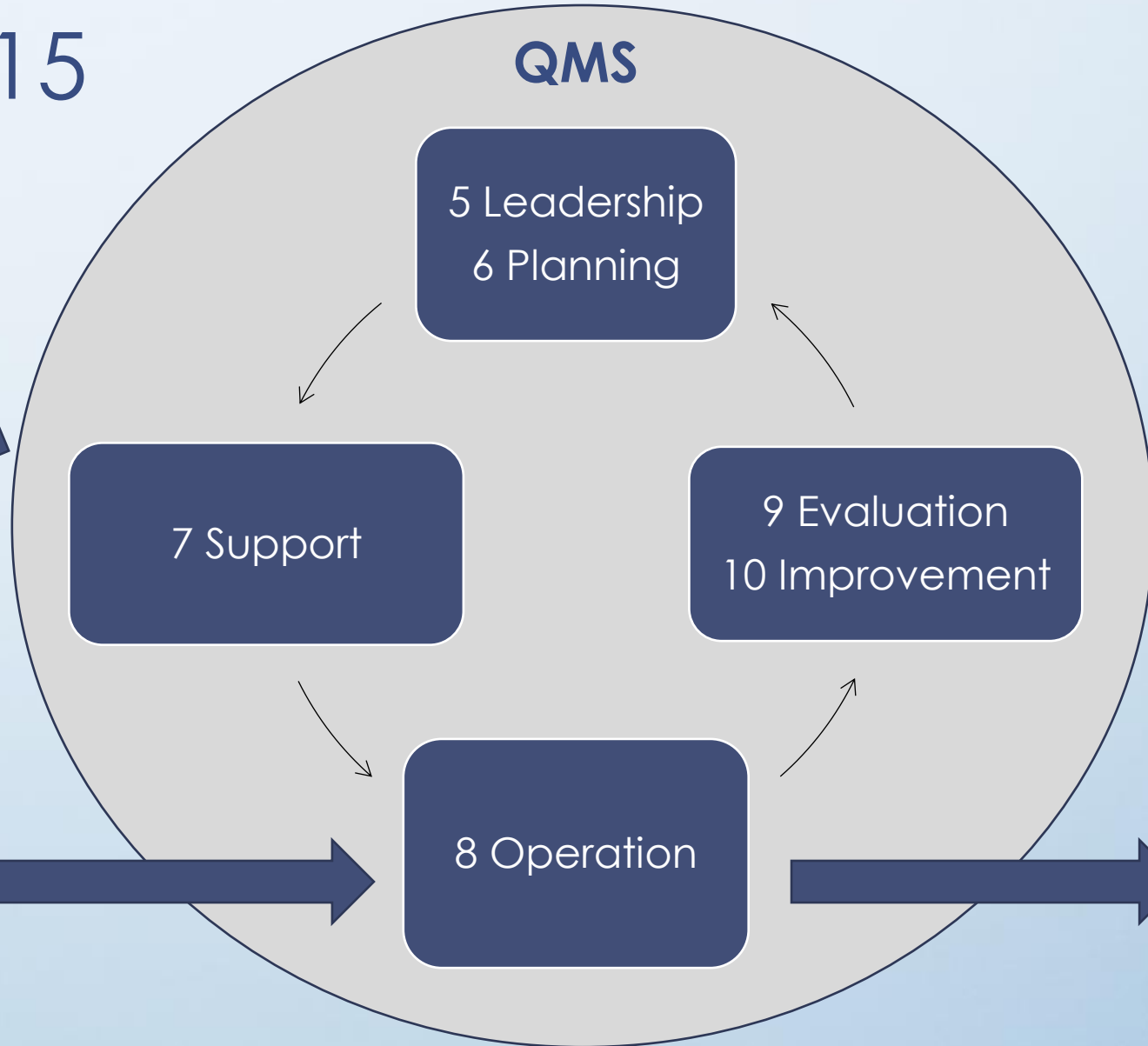 - Medical

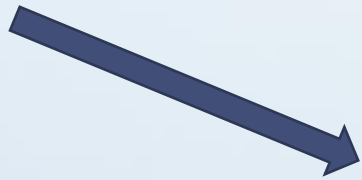# Quality System Standards

ISO 9001:2015

Defines requirements for a Quality Management System

Provides framework for

- System approach
- Business Management

ISO 9001:2015

4 Context of organization

QMS

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement

8 Operation

Customer requirements

Products and services

ISO 9001:2015

4 Context of organization

Defines organization

- Mission/Vision
- Issues affecting the results
- Markets served
- Relevant parties – customers, suppliers, employees – their needs and expectations
- QMS Processes

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement

8 Operation
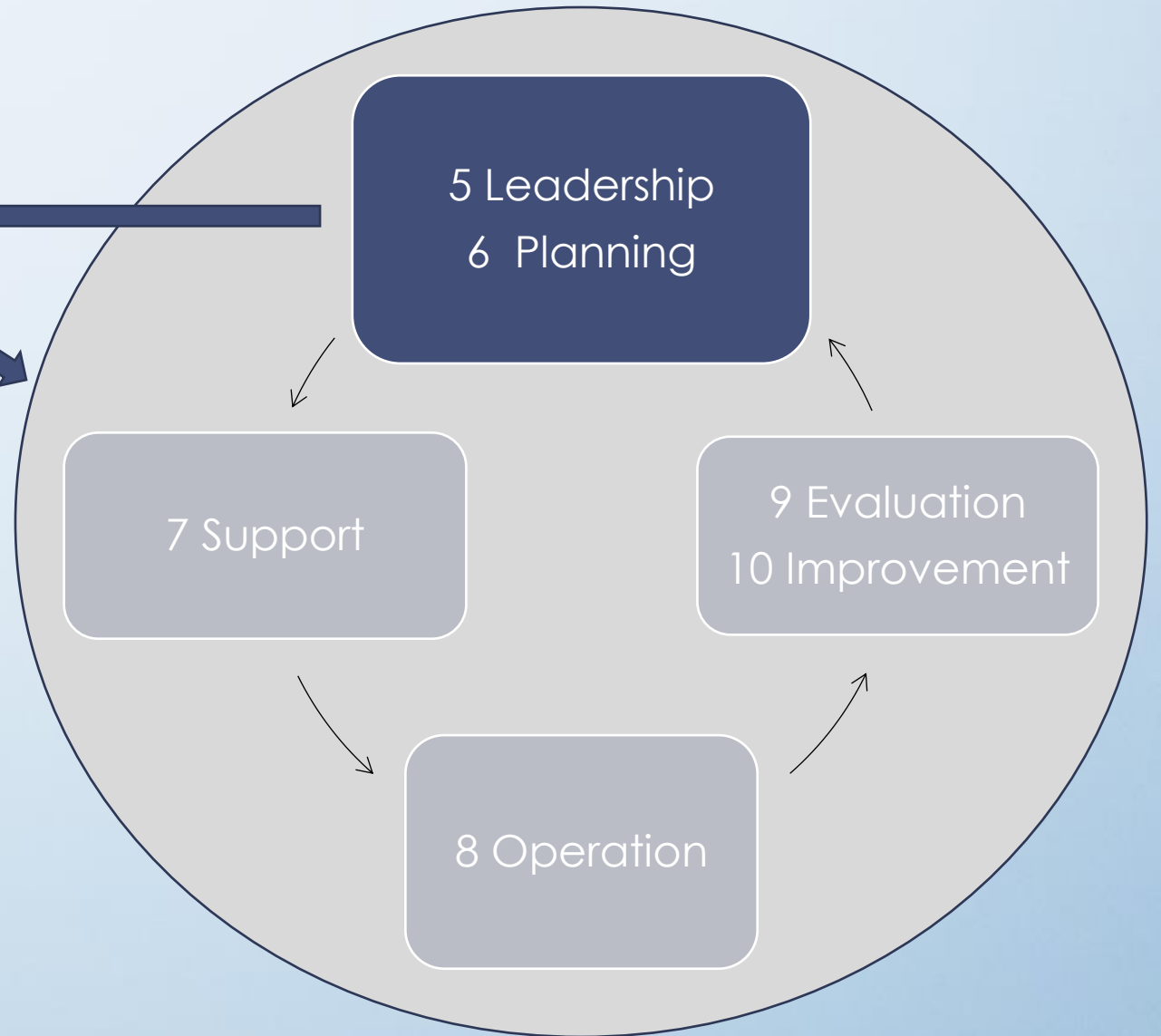
ISO 9001:2015

5 Leadership

Defines Top Management's responsibilities
- Leadership - provide direction
- Commitment - provide resources
- Accountability - responsible for effectiveness/results

6   Planning

Plans and actions to
- Achieve goals and objectives
- Address risk and opportunity

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement

8 Operation

Processes for managing the organization

STRENGTHS OPPORTUNITIES
SWOT analysis
WEAKNESSES THREATS

ISO 9001:2015

7 Support

Resources needed for the maintenance and continual improvement
- People – competent
- Infrastructure/work environment
- Monitoring /measurement tools/methods
- Organizational knowledge
- Documents
- Communication

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement

8 Operation -

Processes for managing resources

ISO 9001:2015

8 Operation

Processes needed to provide product/service

- Customer orders/contracts
- Design and development
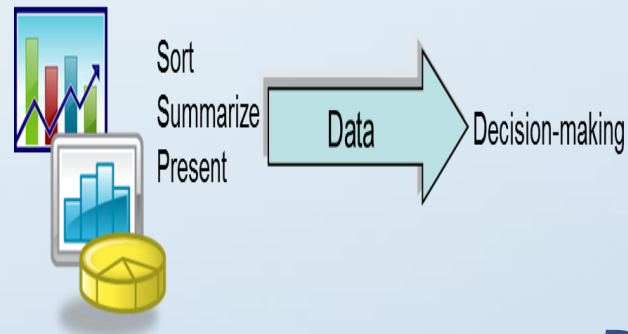- Purchasing
- Production
- Delivery
- Control of nonconforming

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement
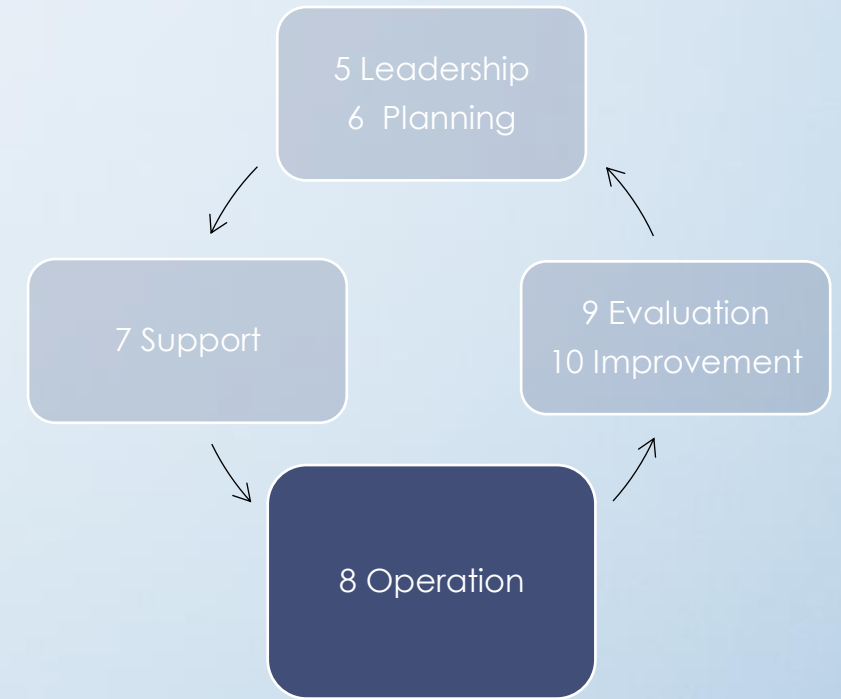
8 Operation

Processes for planning, carrying out and controlling operations

ISO 9001:2015

9   Evaluation

Monitor, measure and evaluate performance of QMS

- Customer satisfaction
- Internal Audits
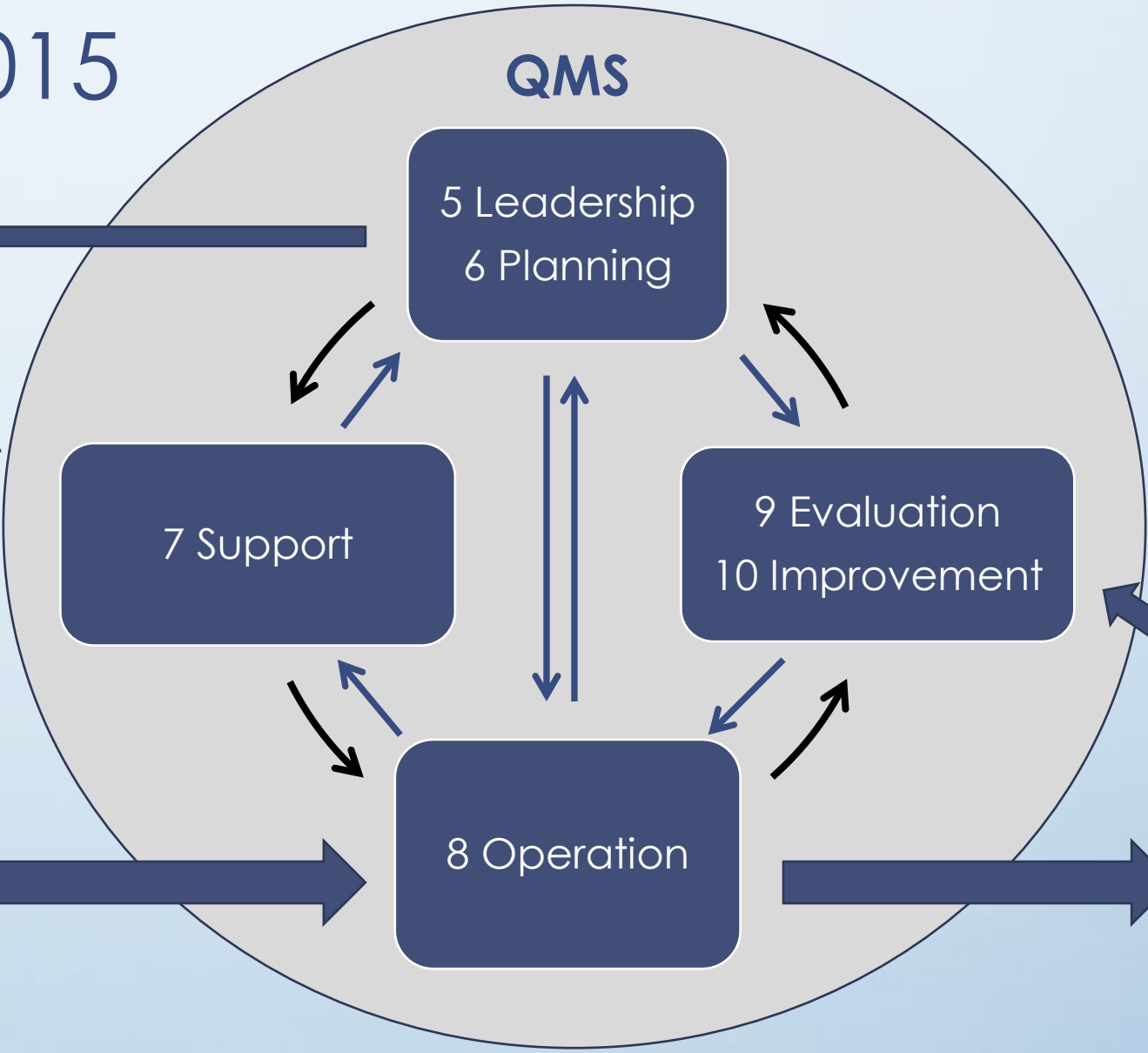- Management review
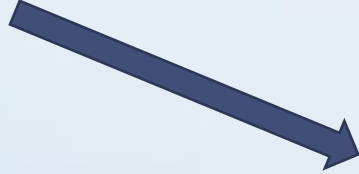
10 Improvement

Continually improve

- Customer satisfaction
- Products/services
- QMS

Sort Summarize Present → Data → Decision-making

5 Leadership
6 Planning

7 Support

9 Evaluation
10 Improvement

8 Operation

Processes for monitoring effectiveness and improving QMS

ASQRS Quality Conference September 2016

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ISO 9001:2015

ASQRS Quality Conference September 2016

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Summary

A system approach to Quality Management is an effective way to meet customer expectations and achieve business goals

ISO 9001provides the framework

Thank you!

Resources

ASQ website
http://asq.org/knowledge-center

ISO website – ISO TC/176/SC2 Home page
http://isotc.iso.org/livelink/livelink/open/tc176
SC2public