

Business Process Management:

*the Basis for Understanding
the Process Approach
to QMS and QOS*

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North Jersey
Section

The Global Voice of Quality™

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Introduction – A Competitive Marketplace

In the face of increasing regulatory requirements and ever-changing business climate in a global marketplace, business organizations need to incorporate efficient, quality-centric processes in order to be scalable and agile to remain competitive¹. For many organizations, efficient management of business processes is essential for growth.

1. Source: BPM in the Pharmaceutical Industry; www.instaintelligence.com

Introduction –

Managing business processes to operate efficiently could be challenging....

For organizations that are not structured with a process orientation, managing business processes to operate efficiently could be challenging, as management may not recognize the organization as a system of interacting processes where the output from one process will directly form the input into the next process.

Combined with a traditional structure in which work activities are managed vertically by function, quality problems¹ that occur at the boundaries of the functional departments could be overlooked.

1. Source: The Process Approach to QMS in ISO 9001 and ISO 9004; www.Asq.org/quality-progress/2001/12/standards-outlook/the-process-approach

Introduction

Guidance Applicable to this Need

Introduction:

ISO 9001&4 - Adoption of Process Approach

“One of the most important aspects of the year 2000 revisions of ISO 9001 and ISO 9004 was the adoption of the process approach to quality management systems.”

Written by Jeffrey H. Hooper, Quality Progress, December 2001 edition

- ISO 9001 is used when one is looking to establish a quality management system that provides confidence in one's organization's ability to provide products that fulfill customer needs and expectations.
- ISO 9004 is used to extend the benefits obtained from ISO 9001 to all parties that are interested in or affected by one's operations. Interested parties include employees, owners, suppliers, partners, and society in general.

Introduction: The Process Approach

The Process Approach is one of the eight quality management principles that managers can apply to improve their organizations' performance.

This principle states that a desired result is achieved more efficiently when activities and related resources are managed as a process. It is also a powerful way of organizing and managing activities to create value for the customer and other interested parties.

Source: The ISO 9000 Quality Management – Quality Management Principles; [www.iso.org/iso/iso_catalogue/management and leadership standards](http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards).

Introduction:

Quality Operating System / Business Operating System

Another set of guidance applicable to quality improvement efforts for products and services is the Quality Operating System (QOS), started in the mid-2000's, by the Ford Motor Company. It has evolved into a Global Quality Operating System that builds quality into every step of the vehicle design and manufacturing process¹.

QOS is also known as Business Operating System (BOS) in the business community.

1. Source: Ford's Global Quality Operating System Delivers World-Class Quality;
<http://corporate.ford.com/microsites/sustainability-report-200-08/economy.....>

Objective

“Business Process Management (BPM) is both a management discipline and a set of technologies that supports managing by process.”¹

For this presentation, we will focus on the part of BPM as a management discipline to provide the framework for understanding the Process Approach to Quality Management Systems and quality improvement efforts.

1. Source: ABPMP BPM CBOK® Version 2.0

Contents

- Value Chain
- The Process Approach
- BPM as a Management Discipline
- Example of a BPM Program
- BPM in the Pharmaceutical Industry
- Q & A

The Value Chain

Michael E. Porter, Competitive Advantage, 1985

The Value Chain - Competitive Advantage

- “ Every firm is a collection of activities that are performed to design, produce, market, deliver, and support its product. All these activities can be represented using a value chain.”
- “ Differences among competitor value chains are a key source of competitive advantage. “

The Value Chain - Value System

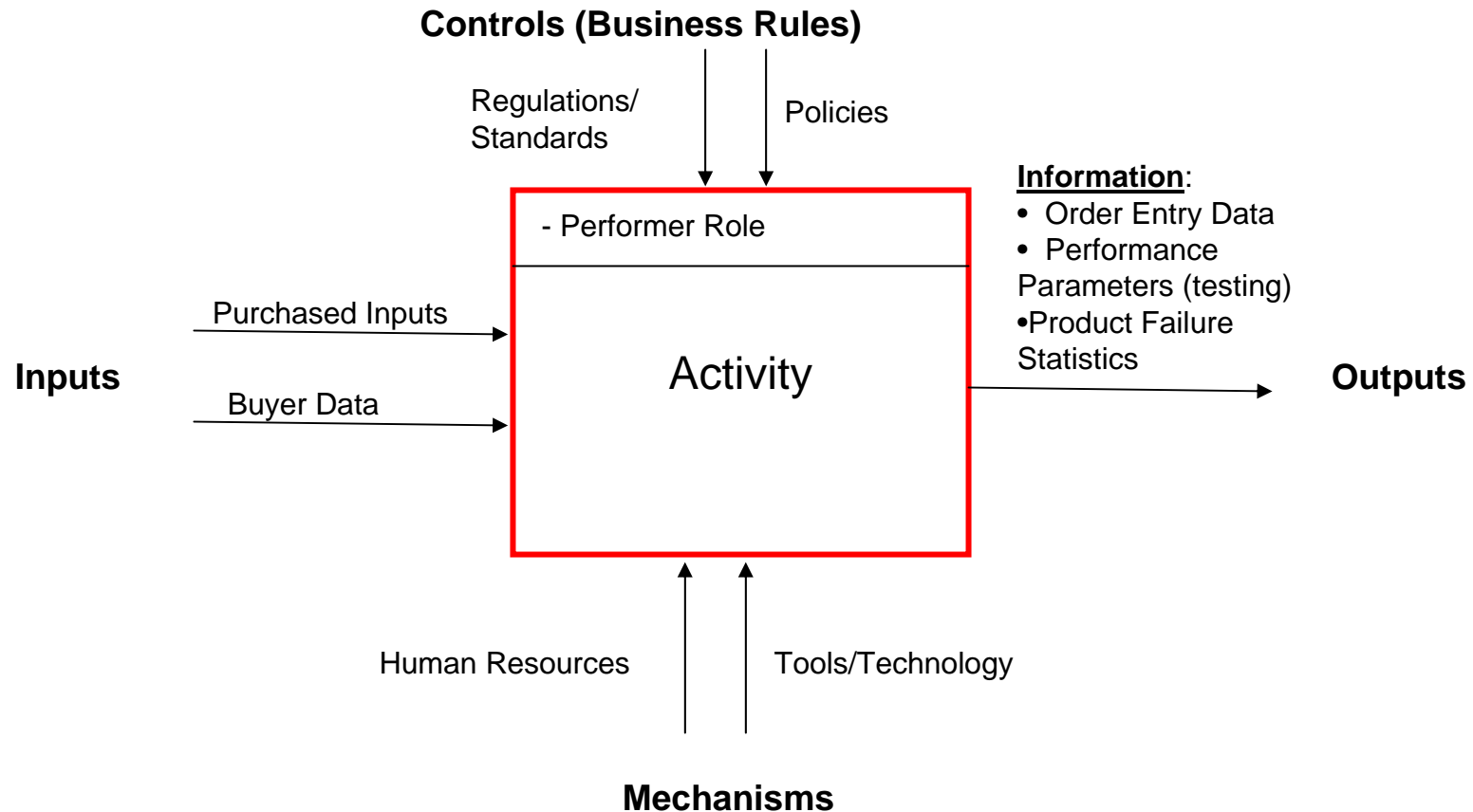
- “ A firm’s value chain is embedded in a larger stream of activities, called the value system.”
- “ Suppliers have value chains (upstream value) that create and deliver the purchased inputs used in a firm’s chain.”
- “ Suppliers not only deliver a product but also can influence a firm’s performance in many other ways. In addition, many products pass through the value chains of channels on their way to the buyer.”

The Value Chain – Value Activity

“ Every value activity employs purchased inputs, human resources (labor and management), and some form of technology to perform its function. Each value activity also uses and creates information, such as buyer data (order entry), performance parameters (testing), and product failure statistics. Value activities may also create financial assets such as inventory and accounts receivable, or liabilities such as accounts payable. ”

Source: Competitive Advantage; Michael E. Porter;1985; page 38.

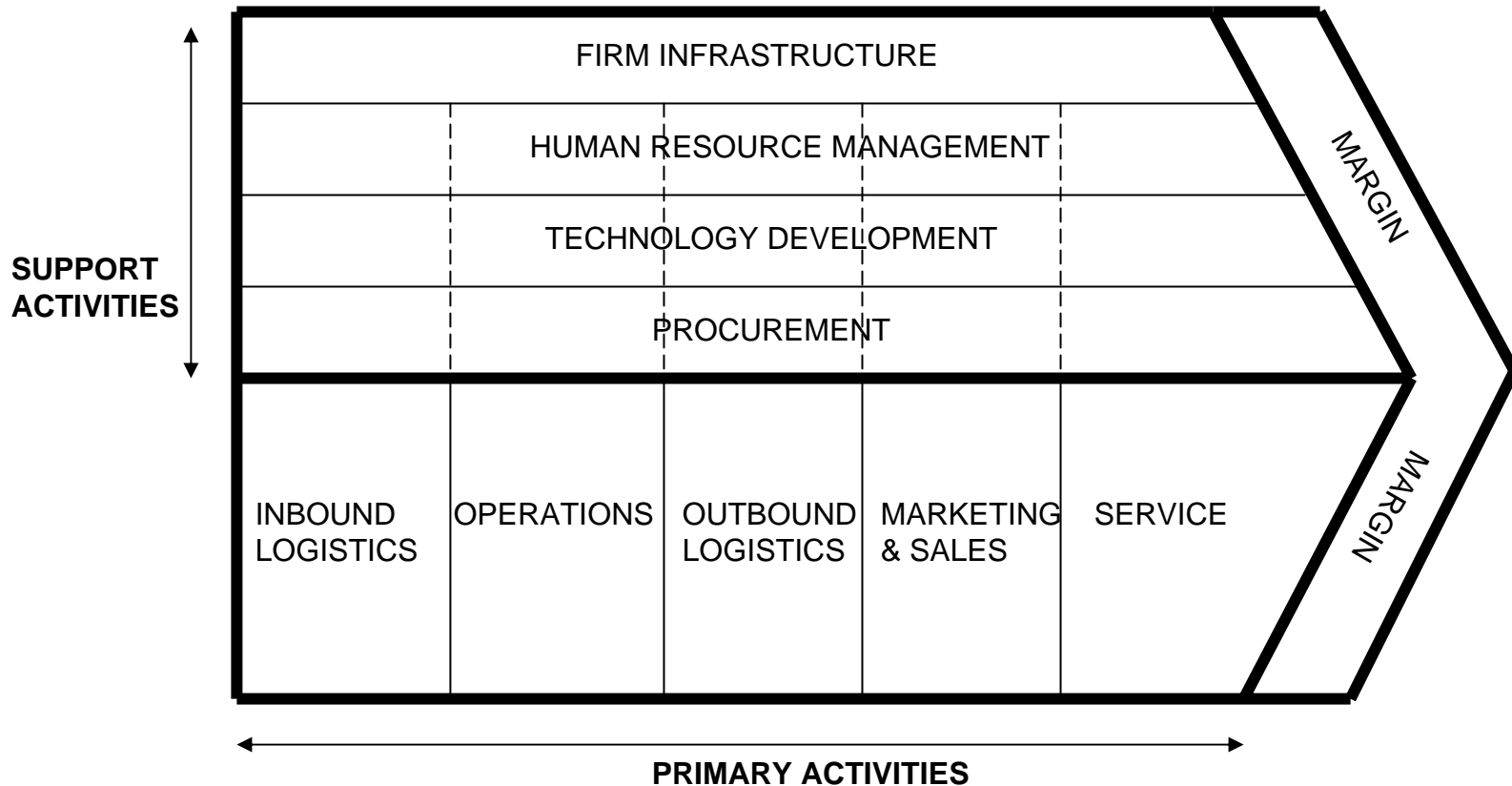
Value Chain – Activity Components



The Value Chain – Linked Activities

- “ Identify the linkages among activities that are central to competitive advantage. “²
- “ Firms competing in related industries must have a horizontal organization that links business units together that supplements but does not replace the hierarchical organization to manage and control them.”³

The Generic Value Chain



ISO 9000 Quality Management System

Principle 4. Process approach

Principle 4. Process Approach

- “ A desired result is achieved more efficiently when activities and related resources are *managed as a process.*”
- Purpose – to enhance an organization’s effectiveness and efficiency in achieving its defined objectives.

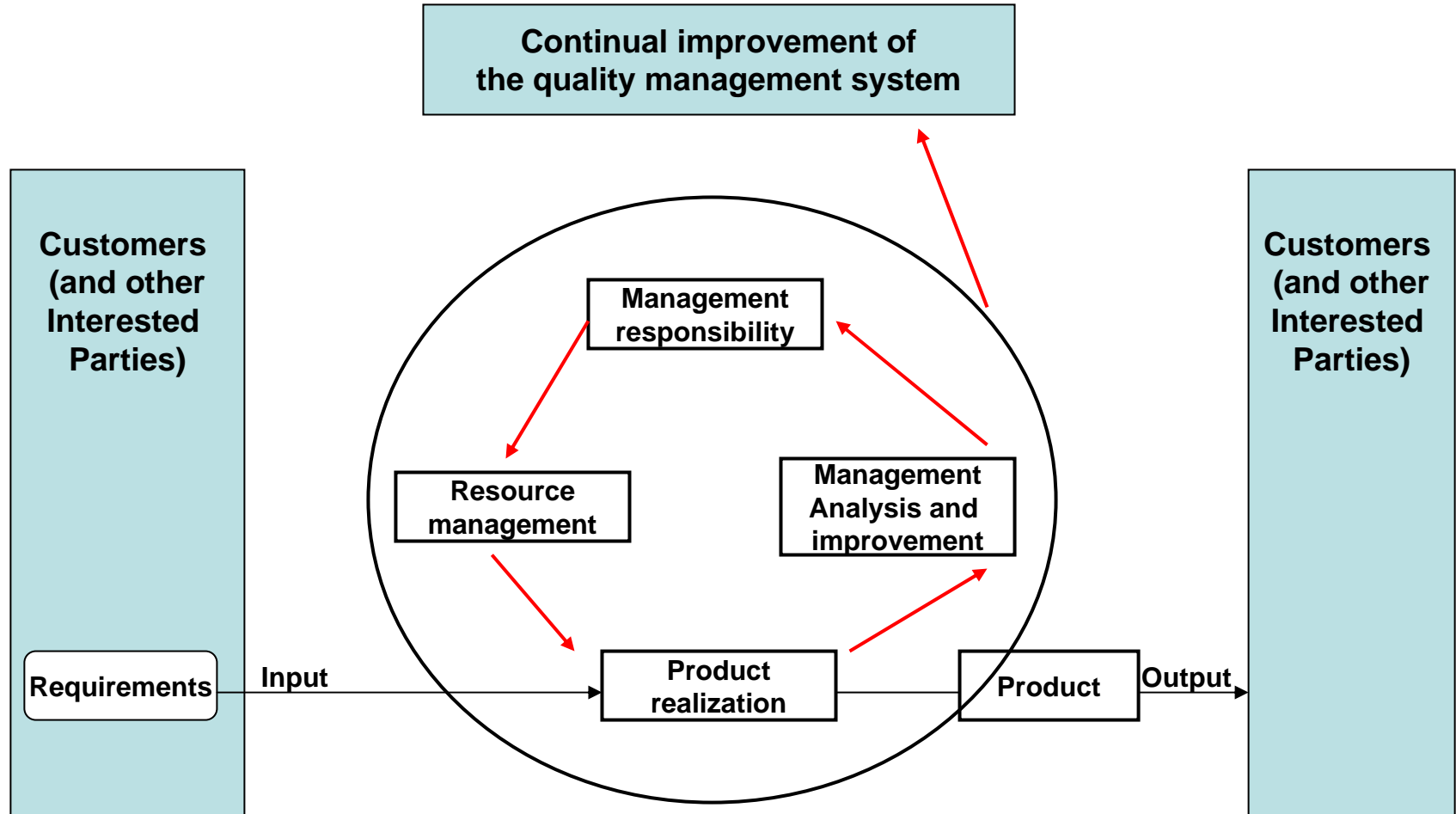
Principle 4. Process Approach – Definition

A “process” can be defined as a “*Set of interrelated or interacting activities, which transforms inputs into outputs*”. These activities require allocation of resources such as people and materials.

Principle 4. Process Approach – Types of Processes

- **Processes for management of an organization.**
These include processes relating to strategic planning, establishing policies, setting objectives, providing communication, ensuring availability of resources needed and management reviews.
- **Processes for managing resources.**
These include all those processes for the provision of the resources that are needed for the processes for managing an organization, for realization, and for measurement.
- **Realization Processes**
These include all processes that provide the intended output of the organization.
- **Measurement, analysis and improvement processes.**
These include those processes needed to measure and gather data for performance analysis and improvement of effectiveness and efficiency.

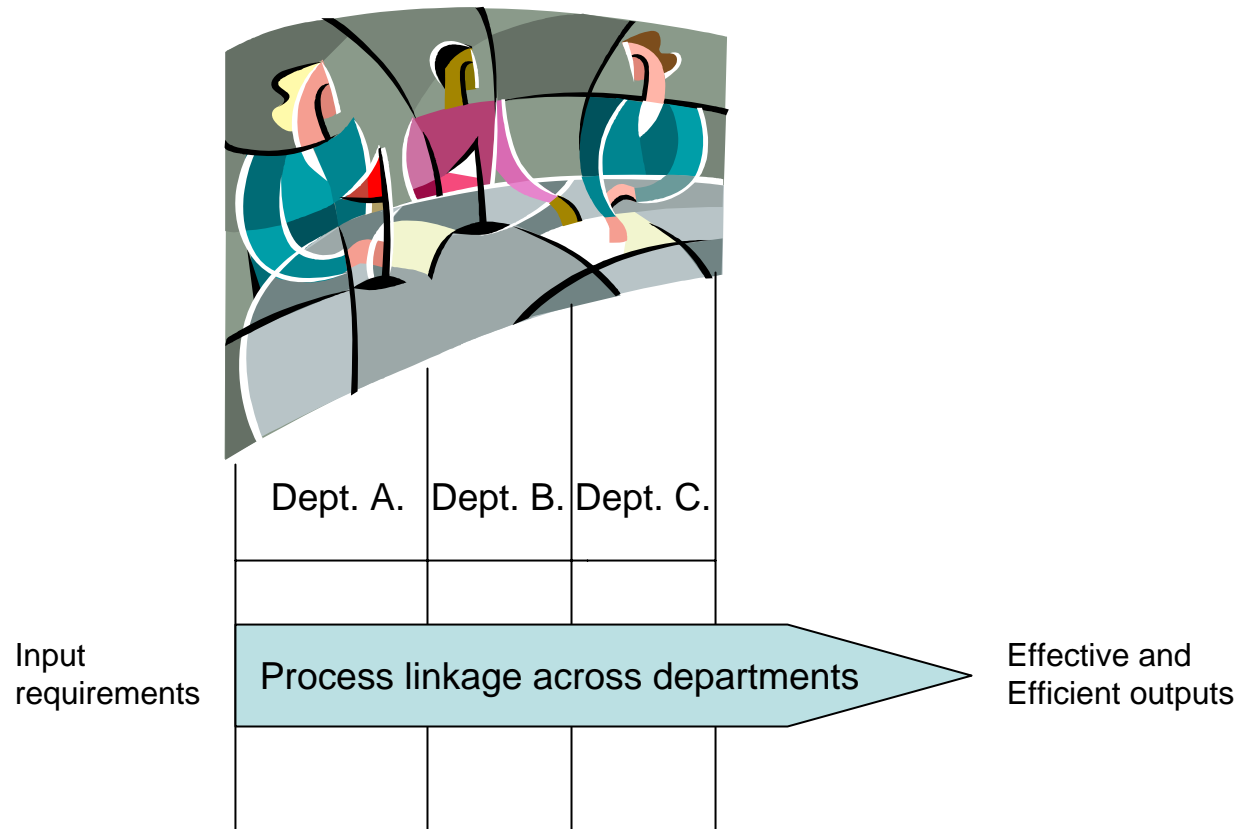
The ISO 9000 Process Approach



Principle 4. Process Approach – Understanding the Process Approach

- A process approach is a powerful way of organizing and managing how work activities create value for the customer and other interested parties.
- Organizations are often structured into a hierarchy of functional units. Organizations are usually managed vertically, with responsibility for the intended outputs being divided among functional units.
- The process approach introduces horizontal management, crossing the barriers between different functional units and unifying their focus to the main goals of the organization. It also improves management of the process interfaces.

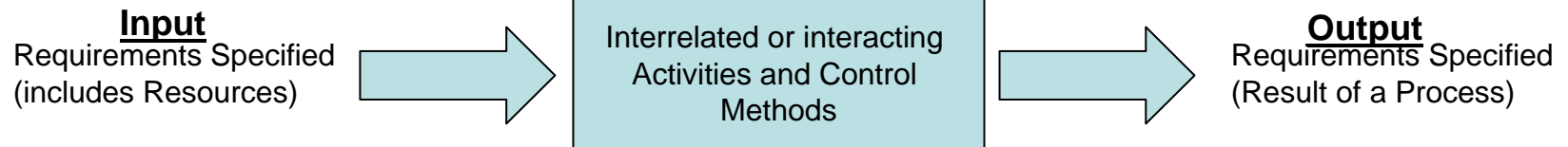
Principle 4. Process Approach – Process Linkages Across Departments



Source: The ISO 9000 family – core standards; www.iso.org

Principle 4. Process Approach – Generic Process

EFFECTIVENESS OF PROCESS =
Ability to Achieve Desired Results



Monitoring and Measuring

EFFICIENCY OF PROCESS =
Result Achieved vs. Resources Used

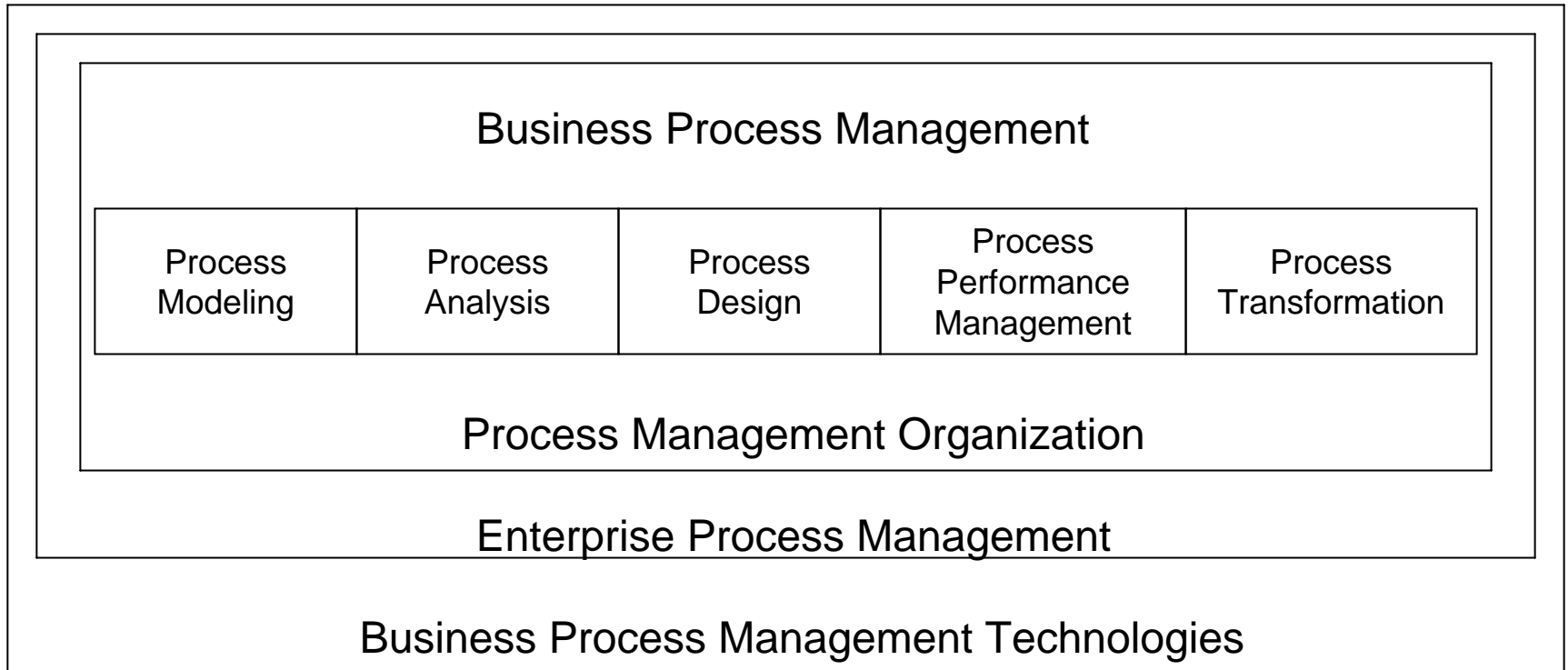
A major feature of the process approach is in the management and control of the interactions between processes and the interfaces between the functional hierarchy of the organization.

Business Process Management (BPM)

What is BPM?

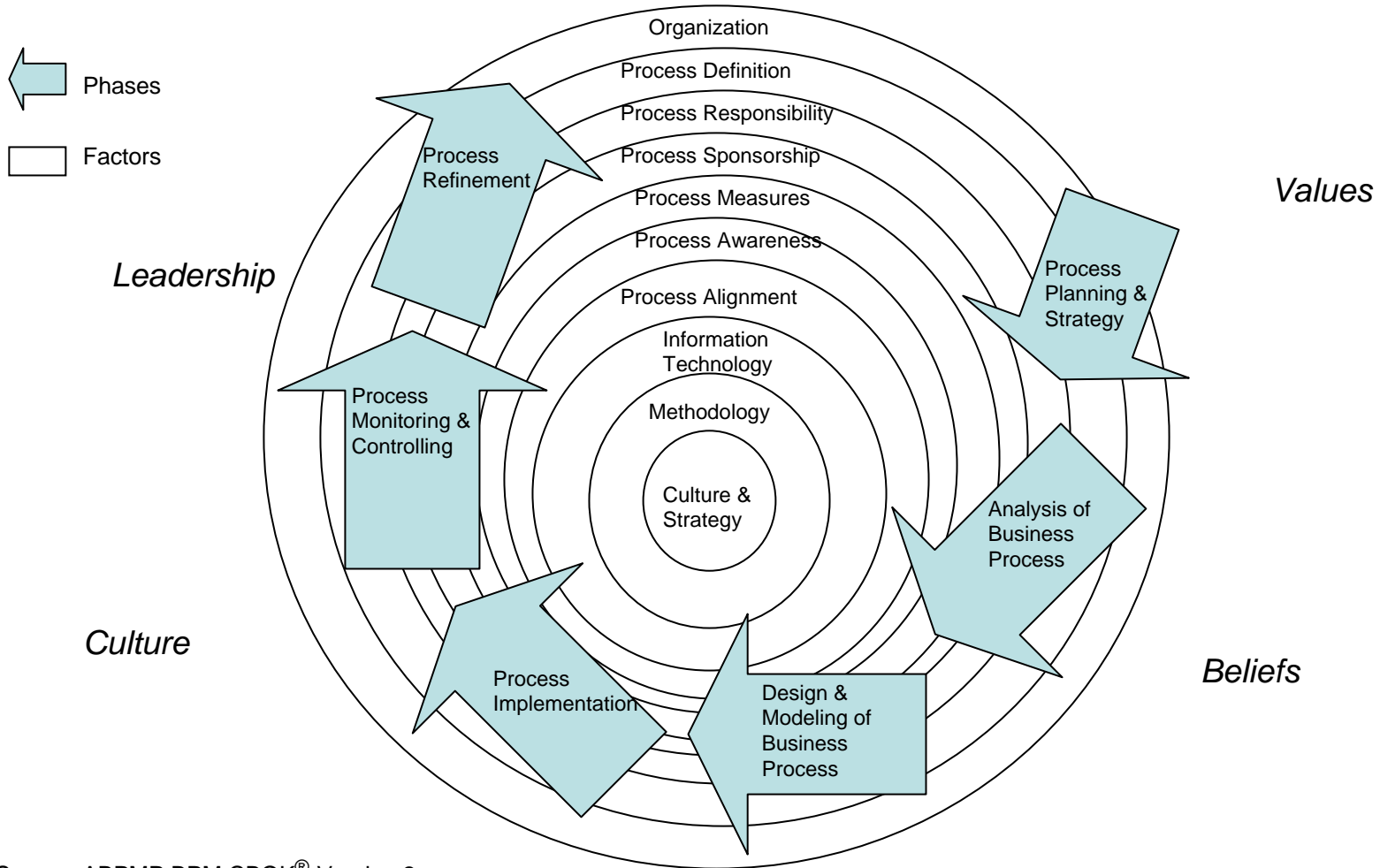
As defined in the ABPMP BPM CBOK[®], Business Process Management (BPM) is a disciplined approach to identify, design, execute, document, measure, monitor, and control both automated and non-automated business processes to achieve consistent, targeted results aligned with an organization's strategic goals.

BPM – Knowledge Areas



The Business Process Management knowledge area focuses on the core concepts of BPM, such as key definitions, end-to-end process, customer value, and the nature of cross-functional work.

BPM Lifecycle

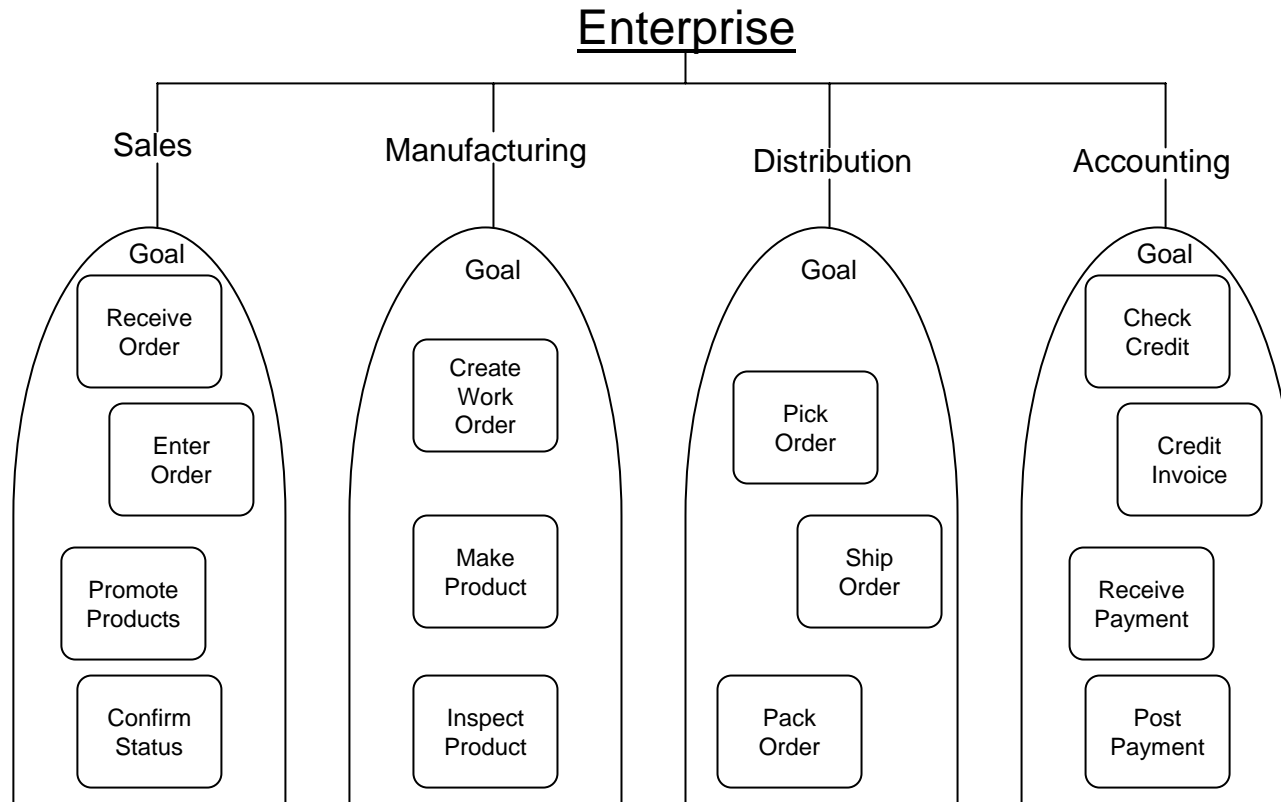


Source: ABPMP BPM CBOK® Version 2

Core Concept of BPM

Function vs. Process View
(end-to-end work)

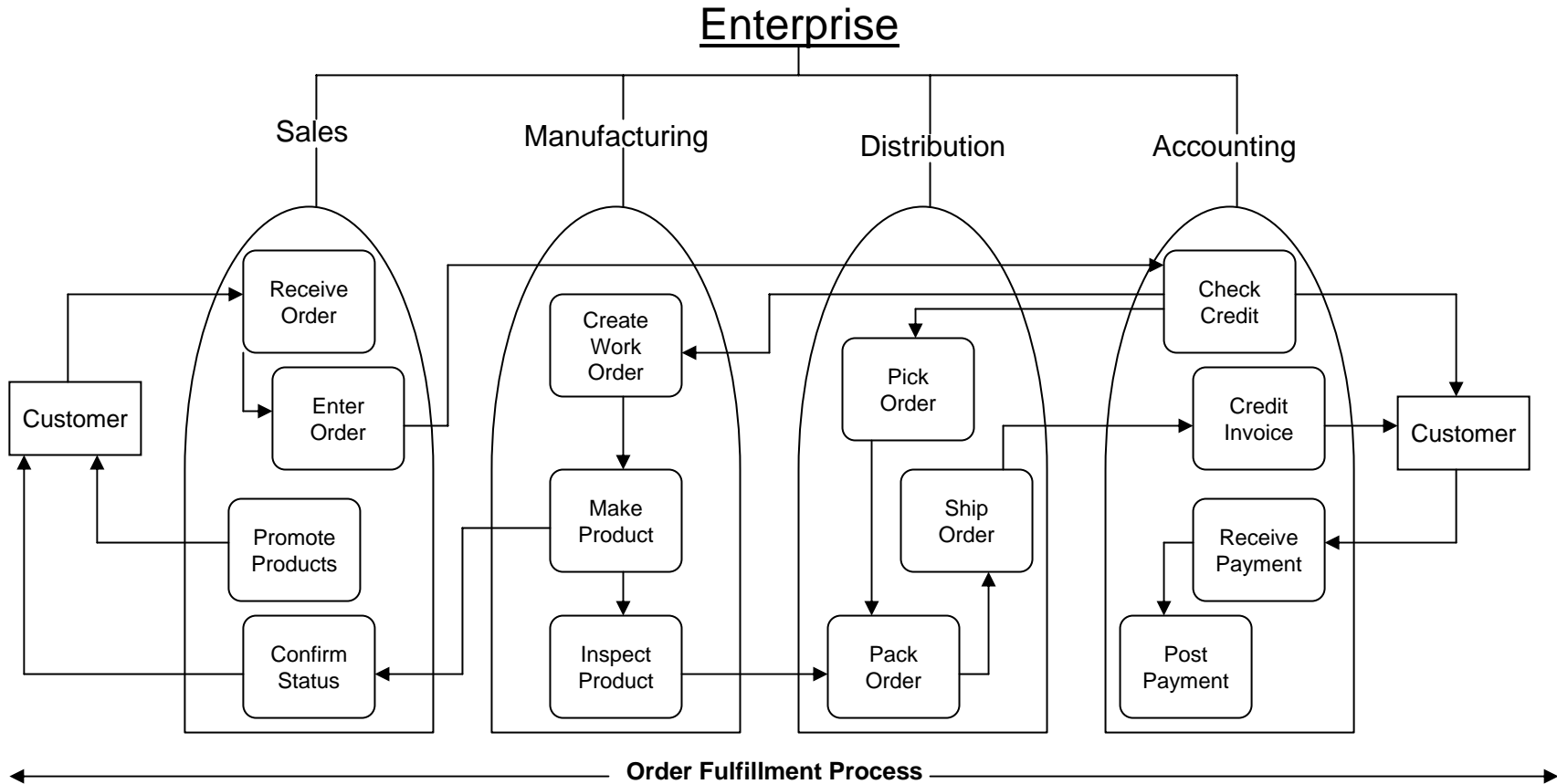
Functional View



In traditional organizations, each function strives to meet its goals and optimizes its operation.

Source: Business Process Analysis Improvement; The Inteq Group, Inc.

Process View



Activities + Relationships Between Activities = A Business Process

Source: Business Process Analysis Improvement; The Inteq Group, Inc.

Processes and Activities

- Types of Processes
 - Primary Processes
 - Support Processes
 - Management Processes
- Types of Activities
 - Value Added
 - Handoff
 - Controls and Control Activities

BPM Critical Success Factors

- Alignment of Strategy, Value Chain and Business Process
- Goals
- Executive Sponsorship/Governance
- Process Ownership
- Metrics, Measures and Monitoring
- Institutional Practices

Illustration of a BPM Program

Example of a BPM Program

ABC Services, an Information Technology organization of a major bank, was facing a dynamically changing marketplace where its customers had a choice in the selection and retention of their service providers.

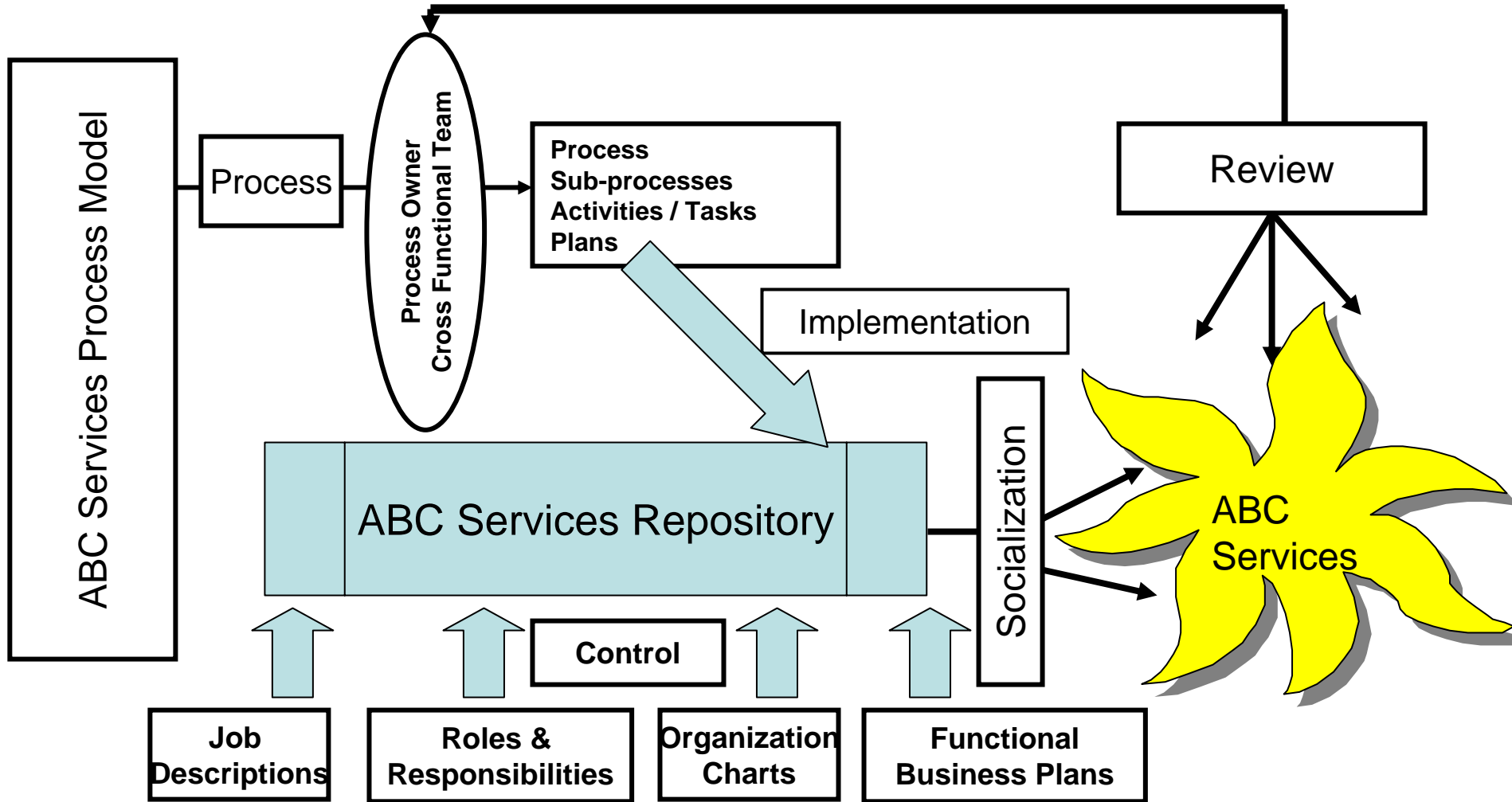
Example of a BPM Program – Transformation

ABC Services transformed its management and operating practices to ensure the continued delivery of enabling, innovative, and flexible technologies.

As part of this transformation, ABC Services implemented an IT process management model to drive customer focused product delivery and competitive prices.

This process model augmented ABC Services functional organization by making the delivery of products and services across functional areas.

Example of a BPM Program – Process Implementation Framework



Example of a BPM Program – Process Implementation Activities

- Develop process diagrams.
- Define process measurements.
- Develop Process Guide.
- Develop awareness training materials.

BPM in the Pharmaceutical Industry

BPM In the Pharmaceutical Industry – Trends and Challenges

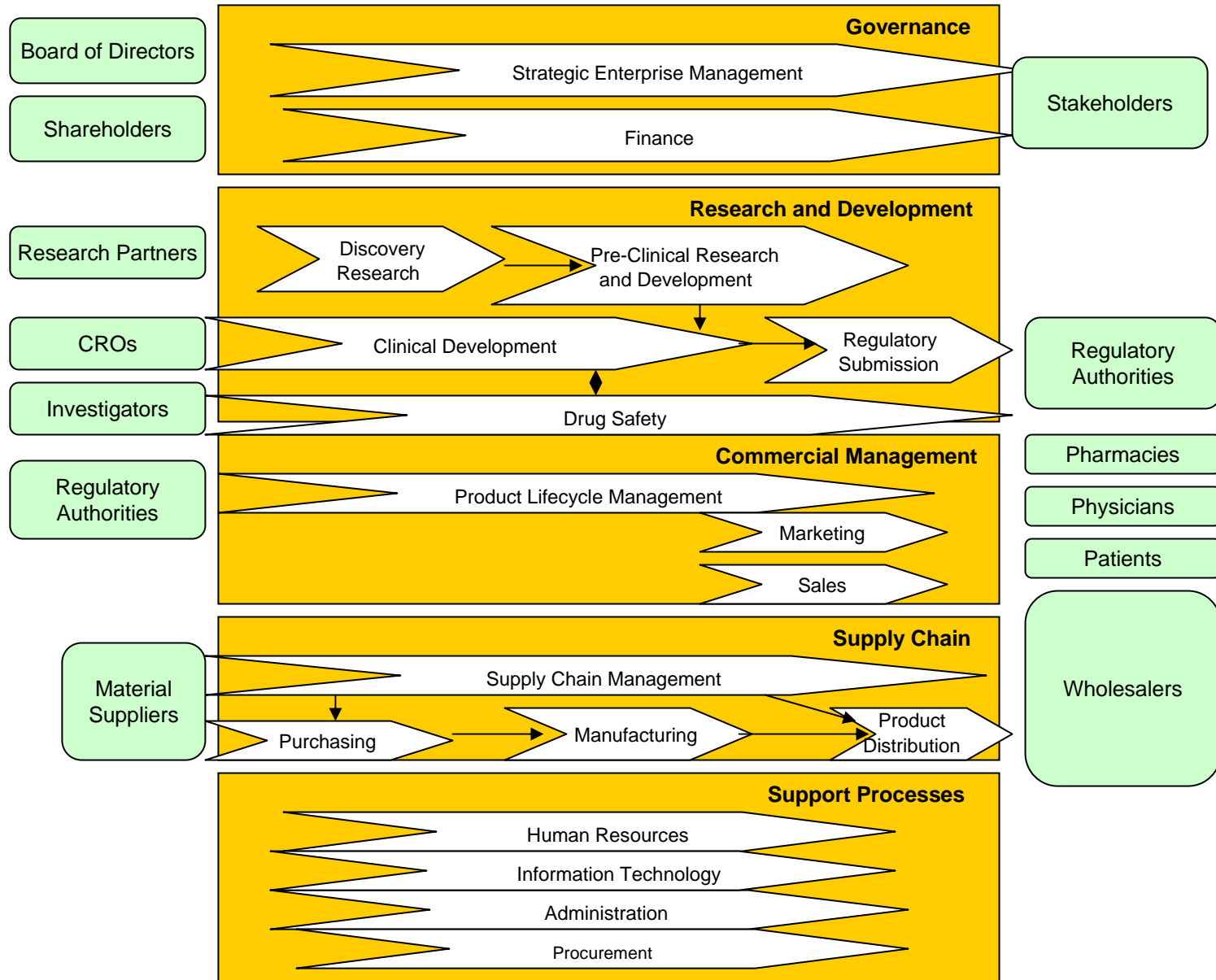
The Pharmaceutical Industry is experiencing increased pressure to change at fundamental levels caused by several issues. Some of which include:

- There is constant pressure to cut drug development cost and cycle time.
- Customers and payers are demanding more innovative pharmaceutical products at more competitive prices.
- The cost of doing business is rising, making harder to meet industry's aggressive revenue growth targets.
- Regulations are tighter.
- Gaps exist between people, back-end systems and critical processes and initiatives.

BPM In the Pharmaceutical Industry – Trends and Challenges

To analyze how BPM can help organizations in meeting these challenges, one needs to understand the Pharmaceutical value chain.

Pharmaceutical Value Chain: Level-0 Process Map



Sources: (1) Business Process Management in Pharmaceutical Industry; WIPRO Council for Industry Research

(2) BPM in the Pharmaceuticals Industry; www.instantintelligence.com

(3) ALTANA Pharma Group; Presentation by Dr. Kai A. Simon, 27-09-2006

Q & A