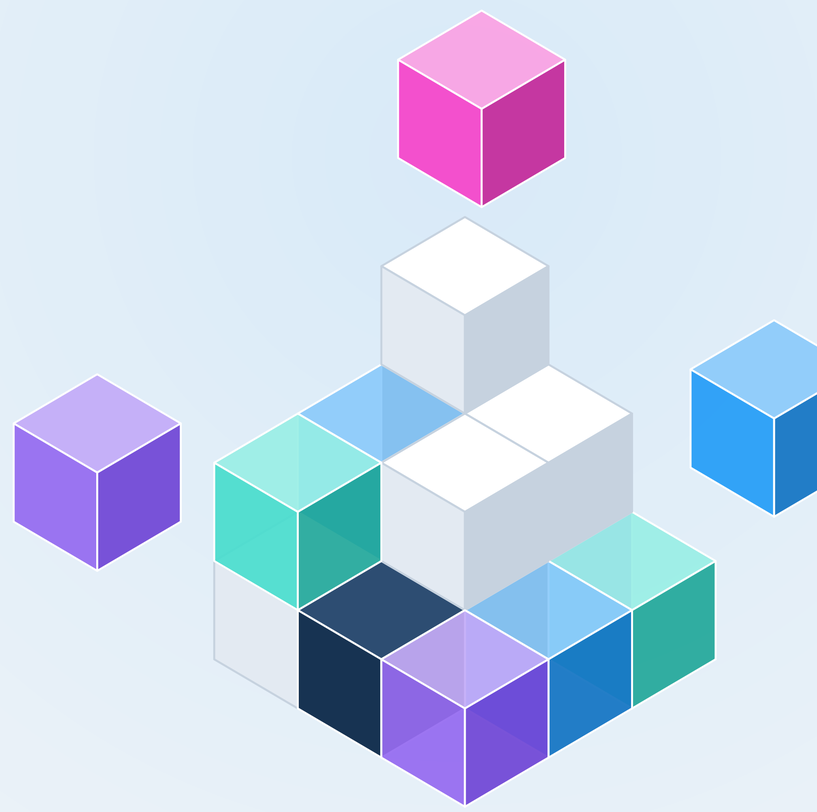
Operations Insider

OPERATIONSINSIDER.COM

QUALITY MANAGEMENT

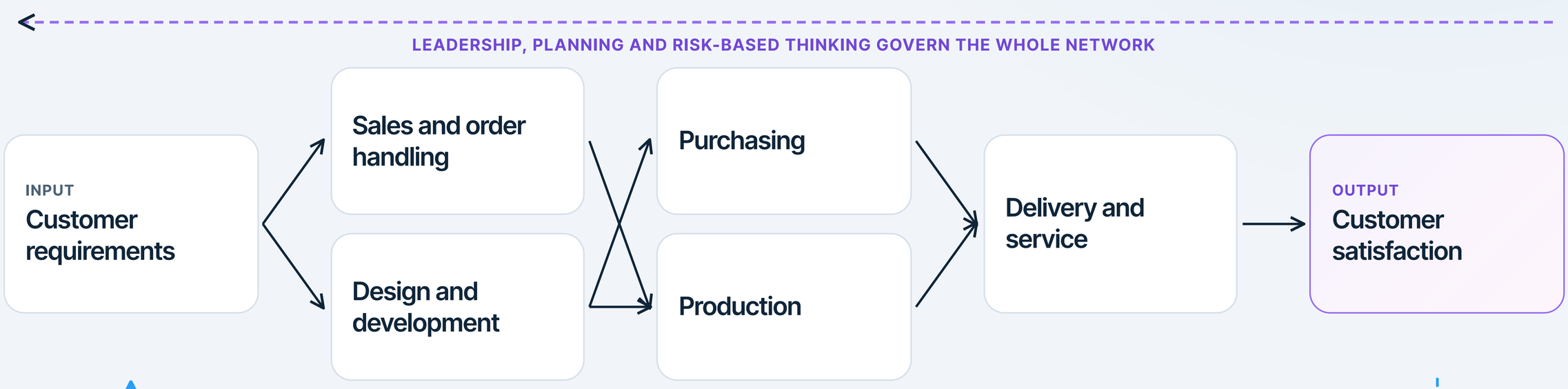
ISO 9001 Process Approach

The ISO 9001 process approach manages an organization as a network of interacting processes, each with an owner and measures, steered by risk-based thinking and the PDCA cycle.



01 THE CORE MODEL

PROCESS NETWORK · MANAGED AS ONE SYSTEM



Process

Interrelated activities that turn inputs into intended outputs.

Risk-based thinking

Plan actions on risks and opportunities instead of reacting to failures.

PDCA

Each process, and the system as a whole, runs plan-do-check-act.

02 CERTIFICATE OR SYSTEM

The standard asks for a working system, not a binder of procedures.

PAPER SYSTEM — REAL SYSTEM

DOCUMENTS FOR THE AUDITOR

- − Procedures nobody follows
- − Audits find paperwork gaps only
- − Management review as a formality

PROCESS APPROACH IN USE

- + Each process has an owner and KPIs
- + Interfaces between processes managed
- + Reviews decide on real improvements

03 WORKED EXAMPLE

CONTRACT MANUFACTURER · ONE PROCESS IN THE NETWORK

PROCESS
Purchasing
owner: head of purchasing

→ INPUT
Approved demand
from production planning

→ KPI
Supplier delivery
reviewed monthly

→ RISK
Single source
second source qualified

04 MANAGEMENT TAKEAWAYS

01
Name an owner per process
Owners manage performance and interfaces, not just documents.

02
Manage the handoffs
Most problems arise between processes, not inside them.

03
Use the review to decide
Management review should change priorities and resources.

05 COMMON MISTAKE

LIMITATION

Writing for the auditor
A system built to pass audits adds bureaucracy without improving quality for customers.