Operational Planning and Control: The Backbone of Consistency

Operational Planning and Control is the foundation for consistently delivering products and services that meet defined requirements. It's where the 'Plan' and 'Do' stages of the PDCA cycle come to life. Without it, there's a risk of disconnect between customer expectations and actual outcomes.

Take a clinical testing laboratory as an example. Delivering reliable results depends on careful planning — ensuring the right protocols, equipment, and trained staff are in place. Control measures like temperature monitoring help maintain sample integrity throughout the process.

Similarly, in a biotech or medtech manufacturing setting, planning may include equipment qualification, material traceability, and data integrity checks to ensure consistency and compliance.

Step 1: Determine Requirements

Operational planning begins by identifying all applicable requirements. While customer specifications are key, other requirements may come from:

- Regulatory or statutory bodies
- Internal policies
- Industry-specific standards

Clear communication with customers is essential to fully understand their needs. Before committing to supply, it's critical to review all requirements to confirm your organisation has the capability to meet them.

Step 2: Gather Inputs for Planning

Effective planning requires multiple inputs, including:

- Defined customer and regulatory requirements
- Risk assessment results (covered in our previous lesson)
- Resource availability: equipment, personnel, and organisational knowledge
- Process capabilities and limitations
- Historical performance data
- Measurement and monitoring requirements

Example: A lab introducing a new test method would consider validation needs, equipment specs, analyst competencies, reference materials, detection limits, and potential interferences—all critical to designing a reliable process.

Step 3: Define Acceptance Criteria

Once planning inputs are gathered, the next step is to define clear, measurable criteria for:

- Process performance
- Product or service acceptance

These criteria set the standard for what "good" looks like and guide verification activities.

Example: A biotech company producing diagnostic kits might set acceptance criteria such as:

- Storage stability between 2–8°C
- Incubation time of 30 minutes ± 2 minutes
- Clear colour change in positive controls
- No reaction in negative controls
- Results readable within 15 minutes

Such criteria make it easy for staff to verify conformity in each production batch.

Step 4: Implement Controls

To ensure planned processes operate as intended, controls must be put in place. These may include:

- Documented procedures and work instructions
- Monitoring and measurement at key stages
- Competent, trained personnel
- Suitable infrastructure and environment
- Validation and verification steps
- Preventive measures to minimise errors

Example: A food testing lab ensures reliable allergen testing by:

- Physically separating work areas
- Training analysts in specialised procedures
- Validating test methods
- Calibrating equipment daily

- Using positive and negative controls
- Requiring peer review before result release

These layered controls protect the accuracy and integrity of results.

Step 5: Maintain Documented Information

Meeting QMS standard requires documented evidence that processes are followed and requirements are met. The level of documentation depends on organisational size, process complexity, and associated risks. Documentation should support control,without becoming a burden.

Examples include:

- Procedures and test methods
- Calibration and maintenance logs
- Competency records
- Test reports

Digital quality management systems can improve access, control, and version management.

Step 6: Manage Change Effectively

Change is inevitable, and QMS requires it to be controlled. Organisations must:

- Plan and assess the impact of changes
- Obtain necessary approvals
- Communicate changes clearly
- Monitor outcomes to confirm success
- Address unintended changes as needed

Example: A lab implementing a new analyser would:

- Conduct impact assessments
- Validate the method against previous systems
- Retrain staff
- Update procedures
- Run parallel testing

- Monitor quality indicators throughout

This structured approach ensures results remain accurate during transitions.

Common Pitfalls

Some typical challenges include:

- Failing to integrate planning into the wider quality system
- Starting work without confirming requirements
- Missing or vague acceptance criteria
- Treating change reactively instead of proactively
- Ignoring risk and control effectiveness during planning

Example: An environmental testing facilityaccepted a PFAS project without validating its methods. Their equipment couldn't meet detection limits, causing delays and client dissatisfaction.

Best Practices for Effective Planning

- Involve frontline staff. They offer practical insights into what works.
- Use risk-based thinking to apply controls where they matter most.
- Set up feedback loops to evaluate and improve plans.
- Balance flexibility with control. Avoid over-engineering.
- Consider supplier capabilities during planning.
- Align planning with your quality objectives.

Tip: Hold regular review meetings with technical, quality, and management teams. Review data, feedback, and nonconformities to identify improvements and keep planning aligned with evolving needs.

Conclusion

Operational Planning and Control bridges customer expectations with consistent, conforming outcomes. It defines what needs to be done, how it's controlled, and how performance is evaluated.

Key principles:

- Plan based on comprehensive, validated requirements
- Set measurable acceptance criteria
- Implement proportionate controls
- Maintain documented evidence
- Continuously review and improve

When done well, operational planning creates a smooth, reliable path from customer requirements to delivery, forming the core of a strong quality management system.