

Context Analysis Guidance

Context analysis is an important tool for businesses of all sizes. It allows organizations to understand the external factors that may impact their operations and performance.

The purpose of a context analysis (sometimes referred to as a situational analysis) is to ensure an initiative is informed by all of the contextual factors that might affect its implementation and sustainability.

The context analysis should be completed at the first stage of the planning process. Regularly updating the context analysis throughout the year will help to ensure that your organization is able to identify and adapt to changes as needed.

The analysis should also be informed by consultations and dialogue with internal and external partners. This dialogue should ensure a broad range of perspectives is represented, which will often reveal new data sources or information.

Top management must consider their organization's context; the evidence of this may be adequately demonstrated by showing how the review outputs became the inputs into the QMS planning process (risk-based thinking and opportunity-based thinking).

The context analysis concludes by describing a SWOT, PESTLE or competitor analysis as appropriate that can be used to discover and highlight key considerations, and to identify strategic priorities for your business.

SWOT Analysis for Internal Issues

SWOT Analysis is a strategic tool that helps you to identify Strengths, Weaknesses, Opportunities, and Threats that are internal to your organization. This analysis is crucial for internal issue management, allowing your business to capitalize on strengths and opportunities while mitigating weaknesses and threats.

PESTLE Analysis for External Issues

For external issues, or issues that are outside of your organization's control, PESTLE Analysis is invaluable. It examines Political, Environmental, Social, Technological, Legal, and Economic factors that could impact your organization. By using PESTLE, your organization is better positioned to navigate the complexities of the external business environment.

Competitor Analysis

Competitive analysis is an assessment of the strengths and weaknesses of our current and potential competitors. This analysis provides our organization with both an offensive and defensive strategic context to identify opportunities and threats.

There is no requirement for the outputs of Clause 4.1 to be documented. If you discuss and consider your internal and external issues verbally during management review meetings, continue to do so. However, ISO 9001:2026 Clause 4.1 requires your organization to determine whether climate change is a relevant issue, and to monitor and review information about its internal and external issues. Record your decision on climate change (relevant or not, and why) in this analysis (see issue C12) and review it, together with the other issues, at planned intervals such as each management review.