



Solutions in Operations

*How do you design,
manage, and improve your
key products and work
processes?*

*How do you ensure effective
management of your
operations?*



QMS Gap Analysis

Have you ever taken a trip to a new place never before visited without a map? Probably not. The map provided not only a starting point, but a direction, important connections during the way, and the final destination. Without the map, there is a good chance you would not have arrived at your destination.

The same rings true for a gap analysis for the quality management system. Without an initial starting point and a summary of the discrepancies in the quality management system, there may exist a flaw or several flaws that can affect the effectiveness of the system and ultimately your certification. The gap analysis, once completed, will give you a map of where the system is deficient and provide a basic map of what needs to be addressed.

Focusing efforts and resources for a Quality Management System based on a gap analysis will not only save time but allow the correct application of resources to target areas that need work based on the gap analysis review. The gap analysis provides a plan and springboard for action - a map for any implementation efforts and further development of the quality management system.

In addition to an assessment of the current ISO standard, the gap analysis will consider the effects of additional quality and regulatory compliance that can affect the products and services you manufacture.

WORKING WITH IMEC

To assist companies, IMEC reviews all available Level 1 & Level 2 documentation (Quality Manual and Procedures) to determine compliance to the requirements of the appropriate standard. In addition, we work with key management and staff of all functional areas to determine the degree to which a Quality Management System has been implemented.

Based on a company's size, as well as the number and complexity of its processes, a gap analysis can require:

| Standard | Description | Audit Days |
|-----------|---------------------------|--------------|
| ISO 9001 | Quality Management System | 1.5 - 2 days |
| AS 9100 | QMS Aerospace | 2 - 3 days |
| TS 16949 | QMS Automotive | 3 - 6 days |
| ISO 13485 | QMS Medical Device | 3 - 3.5 days |
| ISO 50001 | QMS Energy Management | 2 - 3 days |

POTENTIAL BENEFITS

IMEC's analysis will provide management:

- A written report that compares the current QMS to the requirements of the specified standard
- An understanding of the gaps between the current system and the standards requirements
- An analysis of the effort necessary to implement a system compliant with the standard

NEXT STEPS

Once the gaps between the company QMS system and the respective standard have been identified, IMEC works with company management to determine the next steps for the QMS implementation. This includes the effort necessary to achieve compliance and designing a strategy for filling the necessary gaps that the company wants to achieve compliance.

For more information, contact IMEC at 888-806-4632 or info@imec.org.