# Quality Management Systems: What Should I Expect From A Manufacturing Partner?

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**Challenge:** Finding a manufacturing partner with a well-implemented Quality Management System that ensures consistent manufacture and delivery of your product every time.

**Solution:** Promega holds multiple ISO certifications, demonstrating our commitment to providing our clients with a quality system capable of developing, manufacturing, testing and delivering high-quality products around the world.

**Benefits:**

- Improved predictability of product manufacture
- Product manufacture using documented processes and procedures by qualified, trained personnel provides consistent product performance
- In the event of non-conforming product, there are systems in place to facilitate any necessary product investigation
- Save time and money by utilizing your manufacturing partner's mature quality system instead of building your own controls

## Key Considerations in Choosing a Manufacturing Partner

Evaluating a potential partner's manufacturing capabilities requires an understanding of how that partner manages and controls their manufacturing operations to ensure your product is delivered on time—and to your specifications—every time. This White Paper describes quality system competencies you should look for and the benefits of partnering with a manufacturing partner with an established quality system.

## What is a Quality Management System and What Key Competencies Define a Well-Implemented System?

A quality management system (QMS) is a formal system with documented processes and procedures that describe organizational responsibilities for achieving quality objectives. A well-implemented QMS helps to coordinate a manufacturer's activities to effectively, efficiently and continuously meet customer and regulatory requirements.

A manufacturing partner who has implemented a quality management system will generally have the following procedures already in place:

- Detailed manufacturing and QC protocols
- Production and process controls
- Product certificate of analysis
- Traceable product batch records
- Product stability programs
- Product change control and notification processes
- Supplier evaluation and qualification program
- Equipment maintenance and calibration program
- Non-conforming product processes and procedures
- Qualified and trained product manufacture personnel

Depending on your product's intended use, these manufacturing controls may be enough to ensure consistent manufacture of your product over time. In some cases, the intended use of your product may require additional manufacturing controls. Some additional controls that may be required could be:

- Analytical (QC) method validation
- Process validation
- Intended use (assay-specific) QC testing
- Product design according to design controls

Because these additional controls may be specific to the product, they may add time or cost to implement.

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## What to Look For When Evaluating a Potential Manufacturing Partner?

When you are evaluating potential manufacturing partners who have implemented a robust quality management system, your potential partner should be able to:

- Summarize their quality managment system that minimally includes references to the list of procedures outlined above.
- Provide certification, performed by an independent third party, to an international standard, such as ISO9001, ISO13485 and ISO18385.
- Facilitate an on-site audit of their quality management system, as applicable.

An ideal manufacturing partner is willing to spend time consulting with you to ensure appropriate quality controls are in place to meet your intended use and regulatory requirements.



## What are the Benefits to Partnering with a Manufacturer with a Quality System?

One of the largest benefits to partnering with a manufacturer who regularly operates under a quality management system is the improved predictability of product manufacture. Manufacturing product utilizing documented processes and procedures with qualified and trained personnel provides for the supply of a consistently-performing product on time, every time. If there is an infrequent occurrence of non-conforming product, your partner already has systems in place to facilitate any necessary product investigations. You may choose to lean on a manufacturer with a mature quality system, which can save time and money by not having to build all these controls yourself.

## Put Our Quality Management System to Work for You

Promega first certified to international standards for quality management systems in 1998, and that commitment exemplifies our commitment to our clients, our business and all those who rely on and benefit from the use of our products. Our multiple ISO certifications has demonstrated to a third party that the organization meets all requirements of the standards and has implemented a quality system capable of developing, manufacturing, testing and delivering high-quality products around the world. The Promega Madison, USA, facility maintains certification to ISO9001 and ISO13485, the standard for the manufacture of medical devices. We also maintain certification in ISO18385, which focuses on minimizing the risks of human DNA contamination in products. Currently, 15 Promega facilities around the world have certified to ISO standards. You can have confidence in our ability to manufacture products and assay components reproducibly and to provide the required quality documentation.

To request information or arrange to visit Promega, please contact us at:

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