



**WHITE MOUNTAIN PROCESS**  
**MIXERS, AGITATORS & BLENDERS 800-737-9619**

# WMP Quality Manual

## White Mountain Process

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## 1. Scope

This Quality Manual provides documentation for the Quality Management System (QMS) developed for White Mountain Process using ISO 9001:2008 Standards. This Quality Management System meets the requirement in the ASME BPE-2012 Bioprocessing Equipment Standard in section GR-3.

## 2. Table of Contents

1. Scope .....	2
2. Table of Contents .....	2
3. Review, Approval, and Revision .....	3
4. Quality Policy and Objectives .....	4
4.1 Quality Policy .....	4
4.2 Quality Objective .....	4
5. Organization .....	5
5.1 Company Introduction .....	5
5.2 Company Organization.....	5
5.3 Authority and Responsibility .....	6
6. References .....	6
7. Quality Management System Description.....	7
7.1 Overview .....	7
7.2 Company Processes .....	7
7.3 Process Sequence and Interaction.....	8
7.4 QMS Description .....	8
7.5 Quality Criteria.....	8
8. Management Review .....	9
8.1 Annual Review .....	9
8.2 Internal Audit .....	9
8.3 Updates and Revisions .....	9

### 3. Review, Approval, and Revision

Revision	Description	Authorized Signature	Date
1.0	Initial Release	Mike Matton	05/22/2014
1.1	Added ASME BPE-2012 Standard	Mike Matton	05/22/2014
1.2	Added goals for section 7.3 and added 7.5 QMS description		

Note: All signatures are on file.

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## 4. Quality Policy and Objectives

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### 4.1 Quality Policy

The most recent version of this Quality Manual and any applicable Documented Procedures will be submitted to each employee and subcontractor for review and signature. A review and audit by Management will occur annually and appropriate changes will be made to achieve the stated objective.

The President, Partners and Quality Control Manager (QCM) are responsible for making sure this Quality Manual and its related procedures are being followed at White Mountain Process (WMP). Every Employee and Subcontractor is responsible for adhering to this Quality Manual.

### 4.2 Quality Objective

The objective of WMP's Quality Policy is to achieve sustained profitable growth while consistently meeting and exceeding our customer's expectations.

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## 5. Organization

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### 5.1 Company Introduction

White Mountain Process (WMP) is a manufacturer of Mixers, Agitators, Blenders, Mechanical Seals, and High Purity Mixing Tanks. WMP serves industries including, but not limited to; Pharmaceuticals, Biopharmaceuticals, Cosmetics, Coatings, Food, Beverage, Chemicals and Petroleum. WMP also provides consulting and service expertise to its many clients.

### 5.2 Company Organization

WMP is privately held company with the President and Partner as stakeholders. Each position in the company is described below with reporting authority.

#### 5.2.1 President

The President is responsible for ensuring the profitability and viability of the company. He is also responsible for ensuring the Quality Management System outlined in this document is executed to ensure the company's Quality Objectives are achieved. The President is a stakeholder in the company and part of the Top Management Team.

#### 5.2.2 Partner

The Partner is a stakeholder in the company and part of the Top Management Team. The partner is responsible for maintaining the fiscal responsibilities including payroll and bank account management.

#### 5.2.3 Quality Control Manager

The Quality Control Manager is responsible for documenting the company's Quality Control System and Documented Procedures and Forms. The QCM is also responsible for performing the annual audit reporting the results to the President.

#### 5.2.4 Sales

Sales People are responsible for identification of customer needs, engineering an appropriate solution, preparing a proposal, and securing a purchase order. The Sales team reports directly to the President.

#### 5.2.5 Office Manager

The Office Manager is responsible for entering all purchase orders into the companies information system, issuing a job number, relaying all information to the Project Manager, issuing orders for vendors, issuing invoices to customers, and tracking all projects to ensure completion. The Office Manager reports directly to the

#### 5.2.6 Project Manager

A Project Manager shall be assigned to each project. The Project Manager is responsible for overseeing the manufacture of the equipment including vendors and contractors, including creating a documentation package, coordinating Factory Acceptance Test (FAT), Quality Assurance testing, and shipment to customer. The Project Manager is also responsible for coordinating any start up assistance or non-conformity resolutions. The Project Manager reports directly to the President.

#### 5.2.7 Website Manager

The Website Manager is responsible to ensure the continuous operation of the website for marketing purposes, updating information as requested, and troubleshooting any issues with regards to the operation of the website. The Website Manager reports directly to the President.

### 5.3 Authority and Responsibility

The President has ultimate authority to ensure all of the systems, methods and procedures contained in this Quality Manual are followed by all employees, sub-contractors, and vendors.

## 6. References

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The following references are used in this Quality Manual as part of our Quality Management System (QMS).

- ASME BPE-2012 – Bioprocessing Equipment Standard
- ISO 9001:2005 - QMS Fundamentals and vocabulary
- ISO 9001:2008 - QMS Requirements
- ISO/TR 10013:2001 - Guidelines for QMS documentation
- WMP-1005-DOC – Documentation Procedure
- WMP-6004-SAL - Sales Acquisition Procedure

- WMP-6005-OEP - Order Entry Procedure
- WMP-6006-OFP - Order Fulfilment Procedure
- WMP-6007-CFP - Customer Follow Up Procedure
- WMP-6008-PRP - Project Review Procedure

## 7. Quality Management System Description

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### 7.1 Overview

This Quality Manual is the overall document for the Quality Management System at WMP. .

### 7.2 Company Processes

The following processes are performed in the following order;

#### 7.2.1 Sales Acquisition (WMP-6004-SAL)

Sales acquisition is the procedure to find and follow sales leads, get customer specifications, design a solution fitting the customer's needs, setting the price, estimating the costs, preparing a proposal and acquiring a Purchase Order.

#### 7.2.2 Order Entry (WMP-6005-OEP)

Order Entry is the processing of the project into the information system, sending an order acknowledgement to the customer, assigning a serial number or job number, creating a project file in the company directory, and notifying the Project Manager.

#### 7.2.3 Order Fulfilment (WMP-6006-OFP)

Order Fulfilment is selecting purchased items from vendors, establishing a work plan and project timeline, preparing the customer Documentation Package, facilitating a Factory Acceptance Test if necessary, ensuring all quality control tests are performed and documented, directing the shipment, and overseeing any start up assistance required.

#### 7.2.4 Customer Follow Up (WMP-6007-CFP)

Within 30 days of the customer's receipt of the equipment, a customer survey should be completed establishing the customer satisfaction and correcting any non-conformity which have been reported.

### 7.2.5 Project Review (WMP-6008-PRP)

A project review carried out by the Project Team (Sales, Project Manager, and Office Manager) to assess the on-time performance, customer satisfaction, cost analysis and determine if any corrective actions or quality plans should be developed.

## 7.3 Process Sequence and Interaction

The processes in section 7.2 generally occur in the order listed. There may be exceptions which will require the Project Manager to track changes to this process. Interaction may occur typically with changes in customer specifications as the project is proceeding. The Project Manager is responsible for updating all related documents.

## 7.4 QMS Description

The Quality Management System has been developed in accordance with the ISO 9001:2008 standard, section 4.1 and uses the process approach in ISO 9001:2008, section 0.2. For each critical process in the company a Documented Procedure was developed along with a process for measuring criteria for quality control and improvement.

## 7.5 Quality Criteria

### 7.5.1 Customer Satisfaction

On-time delivery has been determined to be one of the key factors in Customer Satisfaction and will be tracked as a critical factor. Other areas of customer satisfaction are determined as the result of customer surveys and discussions with customers relating to needs assessment.

### 7.5.2 Sales Volume

Sales volume refers to the level of sales required to sustain and profitably grow the company to its objectives. The key measurements are sales volume quoted, percentage of quotes closed, and sales cycle length.

### 7.5.3 Target Margin Attainment

Target margins are critical to maintain the profitability of the company and ensure its objective of continuing to meet customers' needs in the future. The key measurements are the cost of the project versus estimates, the quoting process,



and the cost of fixing non-conformities. A project review is critical to ensuring this quality objective is met.

#### 7.5.4 Continuous Improvement

Continuous improvement in the efficiencies of the company processes and the reduction of costs help improve the company's profitability. Constantly surveying customers for improved or new products also helps meet the customers need for improving their own processes.

## 8. Management Review

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### 8.1 Annual Review

This Quality Manual will be reviewed annually each year by January 31<sup>st</sup> by the QCM and President. Updates and revisions will be written by the QCM and approved by the President.

### 8.2 Internal Audit

There will be an internal audit annually each July performed by the QCM and results reported to the President.

### 8.3 Updates and Revisions

Updates and revisions will be issued as needed according to the QCM. All persons in possession of the Quality Manual will be sent a copy of the updated or revised version with instructions on discarding older versions.