

QMD 001 – Quality Manual

Introduction

The company has established, documented and implemented a quality management system for the site, which is maintained in order to continually improve its effectiveness in accordance with legislation, international standards and best industry practice. The processes that contribute to meeting the requirements of these standards have been determined.

Scope

The scope of the Quality Management System includes all products, including intermediate products, manufactured on site and activities conducted on site.

These requirements are aligned with the policies and objectives of the site and the requirements of the international standard ISO 9001:2008.

Should the site be required to outsource any process that may affect product conformity to the defined standards of the Quality Management System then the site will assume control over this process. This is further defined in the Control of Sub-Contract Processes.

These processes and their interaction are documented within this manual. The manual sections are as follows:

1. Documents
2. Records
3. Measurement and Monitoring
4. Resources and Training
5. Document Control
6. Customer, Statutory and Regulatory Conformance
7. Record Control
8. Management Commitment
9. Responsibility and Authority
10. Management Review
11. Infrastructure and Work Environment
12. Contract Review and Planning
13. Design and Development

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14. Purchasing
15. Production
16. Identification and Traceability
17. Preservation of Product
18. Calibration
19. Customer Satisfaction

Documents

The Quality Management System controlled documents are as follows:

- QMD 001 Quality Manual
- QMD 002 Quality Policy
- QMD 003 Quality Objectives
- QMD 004 Control of Documents
- QMD 005 Control of Records
- QMD 006 Internal Audit
- QMD 007 Control of Non-Conforming product
- QMD 008 Corrective Action
- QMD 009 Preventive Action

Records

The Quality Management System controlled records are as follows:

- QMR 001 Management Review Minutes
- QMR 002 Training Record
- QMR 003 Product Release Record
- QMR 004 Design and Development Records
 - Results of the review of customer requirements
 - Design and development inputs relating to product requirements
 - Results of design and development reviews and actions
 - Results of design and development verification and actions
 - Results of design and development validation and actions
 - Results of the review of design and development changes
- QMR 005 Supplier Assessment Record
- QMR 006 Validation Record
- QMR 007 Identification and Traceability Record
- QMR 008 Register of Customer Property

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