

HD Microsystems

General Quality Guideline (GQG)

Table of Contents

1. Introduction

- 1-1 Introduction / Purpose of our GQG
- 1-2 Public HD MicroSystems Quality Policy
- 1-3 Scope

2. Basis

- 2-1 Quality Management System
- 2-2 Management Responsibility

3. Manufacturing

- 3-1 Product Development
- 3-2 Product Assurance
- 3-3 Process Monitoring
- 3-4 Identification and Traceability
- 3-5 Delivery Specification

4. Support system

- 4-1 Nonconformance control
- 4-2 Change Control (Product, Process)
- 4-3 Purchasing and Supplier Management
- 4-4 Compliance (laws and regulations or official standards)
- 4-5 ESH (Environment, Safety, and Health)

5. Record of change

1. Introduction

1-1 Introduction / Purpose of our GQG

HD Microsystems General Quality Guidelines (GQG) describe activities for improving the quality of our products, service commitments, and customer satisfaction.

The GQG provides a general and concise outline of HDM's quality system to customers, suppliers, and other interested parties.

1-2 Public HD MicroSystems Quality Policy

HD MicroSystems Quality Policy

At HD MicroSystems, (HDM), every employee owns quality. By listening to and collaborating with our customers and partners, HDM is committed to continually improving our products, services and quality management system. As an industry leader for novel polymer coating solutions, HDM is dedicated to providing reliable, innovative and sustainable technology to meet our customer's needs and enhance customer satisfaction. We will do so safely and responsibly with the goal of creating value for our customers, partners and society.

1-3 Scope

The GQG's apply to HDM's quality assurance activities for our products and service to meet customer expectations. HDM is committed to following these quality guidelines.

These quality guidelines outline HDM's quality policy. The content shall not affect HDM's warranties, remedies, or applicable terms of sale.

2. Basis

2-1 Quality Management System

HDM's quality operation fulfillment for product realization and customer service is established in its Quality Management System (QMS), which aligns with ISO9001:2015. HDM QMS covers manufacturing capability, infrastructure, production control, product control, procurement, design and development, packaging, delivery, and business implementation. HDM QMS is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

HDM uses QMS to monitor quality execution/output and ensure continuous improvement.

Continuous Improvement is recognized as a core component to effectively execute HDM's QMS and is a primary focus in product realization, customer service and QMS itself.

HDM measures its execution, conformance, and effectiveness to QMS through internal audits with a defined schedule as well as third party and customer audits.

2-2 Management Responsibility

HDM's senior leadership provides organizational direction related to quality for product realization and customer service.

All levels of HDM's leadership takes a role in quality improvement and QMS execution. They are involved in reviewing and driving effectiveness/efficiency of quality improvements with the customer's best interest in mind.

Resource management is a crucial element of HDM's leadership organization

for product realization and customer service. This includes driving a quality mindset to all levels of the organization down to the operating floor. It is important for all HDM employees to understand the critical roles they play in quality improvement and customer service.

Risk management is also an important key item of HDM's leadership organization. Risk evaluation and mitigation are executed by utilizing tools such as PCF (Product Commercialization Framework), risk analysis methods, FMEA, etc.

3. Manufacturing

3-1 Product Development

HDM applies Product Commercialization Framework (PCF) for product development. The PCF process starts with the customer voice / needs, proceeds to new product design and eventually moves to process development with a business feasibility survey and validation. New products are then manufactured, qualified, and released to customers and the market.

The PCF process is divided into stages with a gate review conducted between each stage. HDM's senior leadership approves each gate.

3-2 Product Assurance

HDM products are assured by utilizing controlled measurement systems and compliance with defined product specifications to meet customer expectations and guard against escape. Continual improvement opportunities are assessed using statistical techniques.

To ensure product assurance, all products for customers are reviewed by outgoing quality control (OQC). All Quality Control testing activities are conducted with structured metrology and applied to process monitoring.

All QC metrology tools are controlled, maintained, and calibrated per ISO9001:2015 requirements.

HDM provides a Certificate of Analysis (CoA) for each product delivered to the customer certifying conformance to their requirements.

Every product bottle is labeled with unique identification as well as corresponding environmental health and safety (EHS) information for customers and responsible parties.

3-3 Process Monitoring

HDM uses process measurement and monitoring for manufacturing process control. It is executed using controlled systems and in compliance with standard process conditions.

HDM utilizes SPC for process control of critical parameters to ensure stable processes and commercialization. SPC is also used as a tool for process capability monitoring and out of control management.

All equipment, instruments, and facilities for product realization and assurance are maintained in their compliant conditions. This is done using structured maintenance control systems and procedures (including preventive).

3-4 Identification and Traceability

HDM products are identified through all steps of production, including raw material, in-process, packaging, shipping and delivery to customers to ensure quality record traceability. All products use a resource planning tool for traceability

HDM has a record retention process that retains quality records and product identification data to ensure information is available for customer and/or other inquiries.

3-5 Delivery Specification

HDM filtered products are bottled in a cleanroom environment. Bottles are packed into specified shipping containers, using standard packaging materials and methods to protect against unexpected temperature change and damage during transportation.

Product delivery to customers is done in a timely manner according to customer needs and requirements. HDM ships globally on a regular basis and follows all regional regulations and hazardous transportation requirements using qualified personnel.

HDM products are preserved in a temperature-controlled storage environment through shipping and delivery to customers. Shelf life is managed using First In First Out (FIFO) protocols.

4. Support system

4-1 Nonconformance control

HDM's product realization process focuses on quality event prevention and detection, including nonconforming product containment to prevent escapes to customers.

When a nonconformance occurs in our process, products, quality management system (QMS), or due customer complaint, HDM will take necessary steps to correct the issue according to standard procedures and/or customer requirements.

For customer complaints or customer issues, HDM will respond promptly and work with the customer to ensure an appropriate solution to meet their needs.

HDM nonconforming products control process also includes recurrence prevention. Corrective and preventive action (CAPA) process is designed to ensure problem understanding, containment, root cause analysis, corrective action, preventive action, and validation based on standard methods.

4-2 Change Control (Product, Process)

Change may be necessary for better production control, stabilized product quality, customer requirements, and continuous improvement in QMS. To execute a change and prevent risk, a well standardized change management process (MOC) is applied.

HDM's process change notification (PCN) process is well defined and standardized. Through the PCN process, changes will be controlled with the customer while respecting CSR's (customer specific requirements). While HDM makes every effort to notify customers of upcoming PCN's, situations outside of HDM's control could impact the timing in which notification can

happen.

4-3 Purchasing and Supplier Management

HDM recognizes product quality is dependent on the quality of purchased raw materials and supplier services. HDM works hard to manage supplier performance through supplier risk analysis, second source qualifications of critical raw materials, regular evaluation of safety stock, change management expectations of suppliers, SPC on critical raw material parameters, supplier audits, etc.

HDM controls raw material quality through an established acceptance system that includes SPC on critical raw materials parameters.

HDM also appropriately evaluates outsourcing or consignment activities to ensure these services meet our requirements.

4-4 Compliance (laws and regulations or official standards)

All HDM employees comply with domestic and foreign laws, rules, and regulations. HDM is committed to act with fairness, ethical standards, and a sense of responsibility.

Chemical Management and Restricted Chemical and Material (RCM) control are important key functions for HDM products and operations (new product development, production, raw material product, and product delivery). All Chemical substances are used in a manner that comply with government regulations in each country/region as well as customer specific requirements.

HDM fully complies with the Responsible Business Alliance (RBA) requirement.

HDM products and operations are foreign to Conflict Minerals, but we

always pay attention to them.

HDM assumes responsibility for confidentiality to our customers and stakeholders. HDM will not pass on any specific information of customers or stakeholders to third parties without the authorized owner's permission.

4-5 ESH (Environment, Safety, and Health)

HDM maintains an unwavering commitment to protecting our environment as well as the safety of our employees, vendors, customers, and communities. HDM believes all incidents are preventable and strives for zero injuries, occupational illnesses, and incidents.

HDM follows all laws and regulations for countries in which we operate, but HDM is also committed to environmental sustainability and continuous improvement goals for health and safety.

5. Record of change

Rev.		Effective date
0	Established Rev 0.0	2023/02/10