



Supplier Quality Assurance Handbook

Supplier Quality Assurance Handbook (SQAH)

Table of contents

1	Purpose	4
2	Applicability	4
2.1	Supplier Types.....	4
3	Means of Understanding	7
4	Resources	7
4.1	General.....	7
4.2	People.....	7
4.3	Infrastructure.....	7
4.4	Environment.....	7
5	Supplier Selection, Evaluation and Approval	8
5.1	Changes affecting GFMS Approval.....	8
6	Purchasing Process, flow-down to Sub-tiers and Control	8
7	Review of the Requirements for Products and Services: Contract Review	9
8	Design and Development: Advanced Product Quality Planning (APQP)	9
8.1	Applicability.....	9
8.1.1	Reviews.....	9
8.1.2	Deliverables.....	10
8.1.3	Product Risk Level.....	10
8.2	Stage 1 – Planning.....	10
8.2.1	Test Sample Inspection Planning.....	11
8.3	Stage 2 – Product Design & Development.....	11
8.3.1	Initial Sample Inspection Planning.....	12
8.4	Stage 3 - Manufacturing Process Design & Development.....	12
8.4.1	Initial Sample Inspection.....	13
8.4.2	Probation Period Inspection Planning.....	13
8.5	Stage 4 - Probation Period.....	13
8.5.1	Probation Period Inspection.....	14
8.6	Stage 5 – Series Manufacturing.....	14
8.6.1	Delta (Partial), Re-accomplishment or Renewal of Initial Sample Inspection ...	15
8.7	Design and Development Changes.....	15
8.7.1	Management of Design Changes.....	15
8.7.2	Management of Manufacturing Process Changes.....	16
9	Production and Service Provision	16
9.1	Control of Monitoring and Measurement equipment.....	16
9.2	Special Processes.....	16
9.3	Identification and Traceability.....	16
9.3.1	Serial Numbers.....	17
9.3.2	Product Marking.....	17
9.4	Packaging and Preservation of Product.....	17
9.4.1	Shelf Life and Limited Life Products.....	17
9.4.2	Safety Hazard and Prohibited material.....	17
10	Control of nonconforming outputs	18
10.1	Concession.....	18

Supplier Quality Assurance Handbook (SQAH)

10.2	Deviation Permit	19
10.3	Notification of Escape/Quality Alerts	19
11	Supplier Re-evaluation.....	19
12	Supplier Audit Process	19
12.1	Non-Conformities Management.....	19
12.2	Escalation	20
12.3	Right of Access.....	20
13	Control of Documented Information: Records Retention.....	21
14	GFMS Forms.....	21
15	Acronyms and Definitions	21
15.1	Acronyms	21
15.2	Definitions	22
16	Final Provisions.....	23

Supplier Quality Assurance Handbook (SQAH)

1 Purpose

The purpose of this document is to define the *Quality Requirements for Suppliers* of GFMS. These requirements are applicable in their entirety to Products and Services allocated to a GFMS Suppliers as well as to those attributed to the "Sub-tier" Suppliers.

These Requirements comply with ISO 9000 Standard Series and are complementary to Contractual, applicable Law and Regulatory Requirements.

Acceptance of products is contingent upon compliance with these Requirements. Any deviation is permitted at the sole discretion of GFMS and must be agreed with GFMS Supplier Quality Assurance using the specific "GFMS SQAH Compliance Matrix" (see Attachments).

2 Applicability

This document is applicable to all activities allocated to all the Types of Suppliers described in the following **Table 1** in accordance with a GFMS Contract/Purchase Order and/or any other associated documentation and *shall* be flowed-down to all Sub-tier Suppliers involved in fulfilment of the Contract/Purchase Order.

Table 1 describes:

- The minimum Quality Management System (QMS) Certification(s) that *shall* be held by the Supplier.
- The correlation between Supplier Approval Type granted by GFMS and activities performed by the different type of Suppliers.
- The applicability of all the Requirements based on the previous point.

The SQAH Requirements *shall* apply in addition to any Contract/Purchase Order Requirements; in case of conflict, the latter *shall* prevail.

2.1 Supplier Types

Designer: GFMS Supplier that:

- Design and manufacture Products for which they provide design, development, and validation against GFMS Functional Requirement Specifications and/or Drawings.
- Design and manufacture Products for which they hold the proprietary rights (e.g. Consumables, Catalogue parts).
- Manufacture raw materials (metallic and non-metallic).

Include "Consumable Suppliers".

Manufacturer: GFMS Supplier that manufacture, assemble, and test Products to drawings, 3D models, standards and/or process specifications for which they are not design responsible. The design requirements are provided by GFMS when GFMS is directly responsible for the design, or when GFMS have been granted manufacturing rights by another Design Responsible Organization.

Service Provider: GFMS Supplier that provide Services that contribute to aspects of Production which can include: Testing, Measurement services (no calibration), Engineering Consultancy/Services, Manufacturing engineering processes (e.g. machine tool programming), Technical publications, Training, Logistics and Distribution.

Supplier Quality Assurance Handbook (SQAH)

Distributor: GFMS Supplier that store and re-sell a Manufacturers' Products and manage their supply chain for the Quality aspect.

Agent: GFMS Supplier that represent a Designer and/or Distributor and arrange for their Products to be distributed.

Laboratory: GFMS Supplier used as an external calibration laboratory.

Supplier Quality Assurance Handbook (SQA)

SQA – Table 1 "Applicability Matrix"

"SQA Handbook" Applicability Matrix		Supplier Activities							
		Design & Development and Manufacturing	Manufacturer of Raw Materials/Standard parts/Catalogue Parts	Manufacturing of GFMS Designed Parts	Manufacturers' articles stored and re-sold	Training Services	Technical, logistic, operational support and other services (including technical publications)	Calibration Services	Commercial office (only commercial relationship with GFMS)
Minimum QMS Certification Required (ISO) per Supplier Type/Activity		ISO 9001 with "Design and Development"	ISO 9001					ISO 17025	N/A
Supplier Types	<i>Designer</i>	X	X						
	<i>Manufacturer</i>			X					
	<i>Distributor</i>				X				
	<i>Service Provider</i>	X				X	X		
	<i>Laboratory</i>							X	
	<i>Agent</i>							X	
SQA Ch.	Title	Applicability							
6	Purchasing Process, flow-down to Sub-tiers and Control	X		X		X	X	X	
8	Design and Development: Advanced Product Quality Planning (APQP)	X		X					
8.1	Applicability	X		X					
8.1.1	Reviews	X		X					
8.1.2	Deliverables	X		X					
8.1.3	Product Risk Level	X		X					
8.2	Stage 1 – Planning	X		X					
8.2.1	Test Sample Inspection Planning	X		X					
8.3	Stage 2 – Product Design & Development	X		X					
8.3.1	Initial Sample Inspection Planning	X*		X					
8.4	Stage 3 - Manufacturing Process Design & Development	X*		X					
8.4.1	Initial Sample Inspection	X*		X					
8.4.2	Probation Period Inspection Planning	X*		X					
8.5	Stage 4 - Probation Period	X*		X					
8.5.1	Probation Period Inspection	X*		X					
8.6	Stage 5 – Series Manufacturing	X*		X					
8.6.1	Delta (Partial), Re-accomplishment or Renewal of Initial Sample Inspection	X*		X					
8.7	Design and Development Changes	X*		X					
8.7.1	Management of Design Changes	X*							
8.7.2	Management of Manufacturing Process Changes	X*		X					
9.1	Control of Monitoring and Measurement equipment	X*		X				X	
9.2	Special Processes	X*		X					
9.3	Identification and Traceability	X*	X	X	X				
9.3.1	Serial Numbers	X*		X					
9.3.2	Product Marking	X*		X					
9.4	Packaging and Preservation of Product	X*	X	X	X			X	
9.4.1	Shelf Life and Limited Life Products	X*	X	X	X				
9.4.2	Safety Hazard and Prohibited material	X*	X	X	X			X	
10	Control of nonconforming outputs	X*	X	X	X	X	X	X	
10.1	Concession	X*		X					
10.2	Deviation Permit	X*		X					
10.3	Notification of Escape/Quality Alerts	X*	X	X	X			X	
12	Supplier Audit Process	X	X	X	X	X	X	X	
12.1	Non-Conformities Management	X	X	X	X	X	X	X	
12.2	Escalation	X	X	X	X	X	X	X	
13	Control of Documented Information: Records Retention	X		X					

* Only for Designer, N/A for Service Providers (only Design Tasks)

Note: Ref. column "SQA Ch.": when chapters/paragraphs are not listed, it means that the entire chapter/paragraph is applicable for all Supplier Types.

3 Means of Understanding

The use of **shall**, **should**, **must**, **will** and **may** within this document *shall* observe the following rules:

- the word **shall** in the text denotes a mandatory requirement: deviations from such a requirement is not permissible without formal Agreement,
- the word **should** in the text denotes a recommendation or advice on implementing such a requirement of the document; such recommendations or advice is expected to be followed unless good reasons are stated for not doing so,
- the word **must** in the text is used for legislative or regulatory requirements and shall be complied with,
- the word **will** in the text denotes a provision or service or an intention in connection with a requirement contained in this document,
- the word **may** in the text denote a permissible practice or action; it does not express a requirement contained in this document.

These means of understanding are applicable in the entirety of this document.

4 Resources

4.1 General

The Supplier *shall* determine and provide resources needed for the establishment, implementation, maintenance and continual improvement of the Quality Management System. The Supplier shall consider:

- The capabilities of, and constraints on, existing internal resources;
- What needs to be obtained from external providers.

4.2 People

The Supplier *shall* determine and provide the persons necessary for the effective implementation of its Quality Management System and for the operation and control of its processes.

4.3 Infrastructure

The Supplier *shall* determine, provide, and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

Infrastructure can include:

- Buildings and associated utilities;
- equipment, including hardware and software;
- transportation resources;
- information and communication technology.

4.4 Environment

The Supplier *shall* determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

Supplier Quality Assurance Handbook (SQAH)

5 Supplier Selection, Evaluation and Approval

The Supplier Selection, Evaluation and Approval Process allows GFMS to evaluate the ability/capability of the Supplier to provide Products and Services in accordance with the applicable Requirements.

The Process is initiated by GFMS Procurement when a new Supplier is required as a result of the Company Strategy. The following topics may be object of the "Supplier Assessment": Business, Financial Health, Quality Management System*, Sustainable Development, Supply Chain, Manufacturing General, Manufacturing Specific Processes (critical), Costs.

During this phase of the Process the Supplier *shall* send the "GFMS SQAH Compliance Matrix" (see Attachments), filled and signed, to GFMS Procurement.

If the result of the Supplier Selection is positive, the Supplier Evaluation and Approval Process starts. GFMS Supplier Quality Assurance performs:

- "Supplier Risk Category Assessment" based on Product Risk Level (if applicable), Type of Supplier, QMS Certification(s).
- Evaluation of the "GFMS SQAH Compliance Matrix" filled by the Supplier. Any deviation/non-compliance is discussed directly with the Supplier.

As result of the evaluations above, GFMS Supplier Quality Assurance reserves the right to perform an Audit to Supplier Facility for determining capability and compliance with GFMS Quality Assurance Requirements and/or to assess Supplier QMS.

A GMFS internal "Steering Committee" is the final step in the Supplier Approval Process. If the Supplier is approved, a "Supplier Approval Declaration" is issued to identify: Approval Status, Supplier Type, Commodities/Material Groups, Limitations (if any).

Once a Supplier is approved by GFMS, approval is considered valid unless a Supplier:

- Fails to act in accordance with their Scope of Approval
- Fails to achieve a satisfactory performance level
- Does not receive a Purchase Order for 4 years

** All the Suppliers shall have a Quality Management System compliant with Table 1 as applicable for their Supplier Type. GFMS Supplier Quality Assurance shall evaluate any deviations.*

5.1 Changes affecting GFMS Approval

The Supplier shall send timely written notification to GFMS Supplier Quality Assurance in case of changes that can affect the approvals granted by GFMS, such as (but not limited to):

- Organization:
 - Relocation to new premises.
 - Change in the industrial organisation (partnership, Suppliers, design work sharing).
- Resources:
 - Substantial reduction in number and/or experience of staff.

The submitted changes will be assessed by GFMS to evaluate their impact on the approval status of the Supplier.

6 Purchasing Process, flow-down to Sub-tiers and Control

The Supplier is responsible for all Sub-Tier Suppliers activities related to the Products/Services they supply for GFMS.

Supplier Quality Assurance Handbook (SQAH)

GFMS Requirements *shall* be flow-down to, understood and implemented by Sub-tier Suppliers prior to commencing any activity. The Supplier *shall* monitor the correct implementation of such requirements by its Suppliers.

GFMS reserves the right to witness audits performed by Suppliers at Sub-tier premises. Moreover GFMS reserves the rights to prescribe their Suppliers.

7 Review of the Requirements for Products and Services: Contract Review

During Contract Review, the Supplier shall check their Scope of Approval, issued by GFMS, to ensure it is correct for the Contract/Purchase Order. Any misalignment between the received PO and the current Statement of Approval *shall* be notified to GFMS SQA and GFMS Procurement.

8 Design and Development: Advanced Product Quality Planning (APQP)

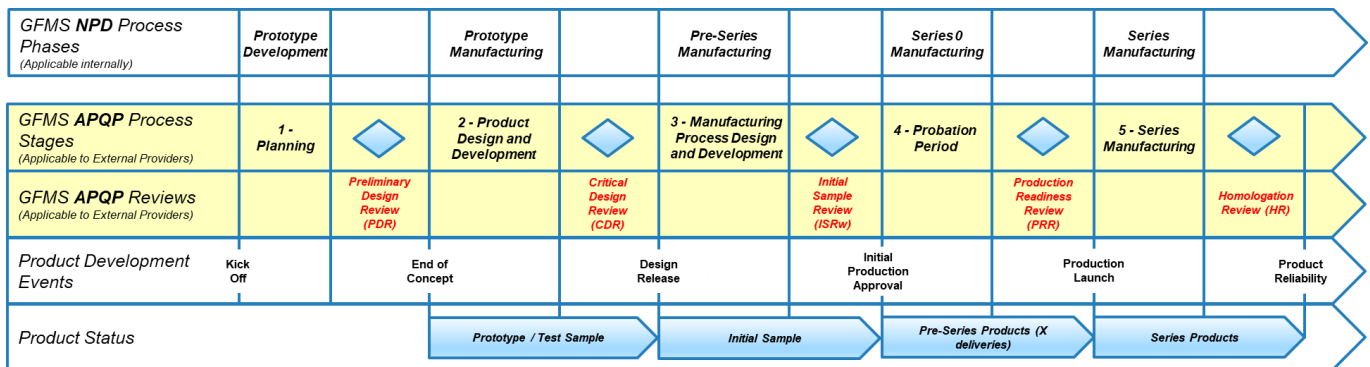
APQP Process defines the mandatory requirements for Suppliers of activities concerning design, verification and validation of GFMS Products.

These activities have the purpose to demonstrate:

- The compliance of each Product to the GFMS applicable requirements,
- The compliance of each Product to the Functional design requirements (Functional Validation),
- The ability of the Manufacturing Process to produce items in compliance with the Design Data Set (Manufacturing Process Verification and Validation).

APQP Process supports GFMS internal "*New Product Development*" Process applicable for every GFMS Designed Part, therefore the Supplier *shall* be "on-time" with all the activities needed to allow the completion of GFMS internal Process.

APQP Process consists of five "Stages" starting with conceptual product needs and extending throughout the product life cycle. Hereinafter a table that details both the above mentioned Processes and allows a comparison:



8.1 Applicability

APQP Process is generally applicable to all Suppliers of *Design & Development* and *Manufacturing* activities of GFMS Product including the Re-validations activities and modifications on Products already homologated.

APQP Process is not applicable to Suppliers of Raw Materials / Standard Parts / Catalogue Parts. However, GFMS reserves the right to execute verification and/or validation activities on these parts to ensure compliance with GFMS Requirements.

8.1.1 Reviews

The outputs from the Process stages *shall* be verified with formal *Reviews*, whose positive results confirm the completion of all anticipated activities, the due conformity to the applicable standards of the produced documentation and authorize the passage from a Stage to the following one. For each Review, the main activities are described, including the *Deliverables* to be supplied.

Supplier Quality Assurance Handbook (SQAH)

8.1.2 Deliverables

Within the APQP Process specific *Deliverables* are established, monitored and tracked to closure, while highlighting and mitigating risks as they are identified. The deliverables that *shall* be verified during all the reviews are listed in the "GFMS APQP Plan". The list of the applicable deliverables has to be defined/agreed by GFMS and the Supplier for every product during the *Stage 1 "Planning"* (this Stage is always applicable and is mandatory).

All the deliverables shall be written/filled in English Language and sent in PDF format.

GFMS Supplier Quality Assurance reserves the right to analyze/review all the documents (e.g. manufacturing instructions, work cycle, operating instructions) raised by Supplier for *GFMS Designed Part Design & Development* and/or Manufacturing activities.

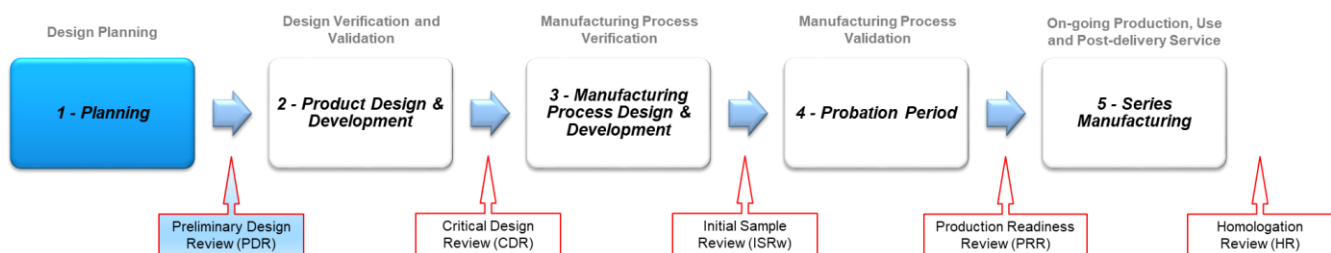
The following table identifies the "Submission and Acceptance Criteria" listed for the deliverables that are provided/defined by the Supplier and verified during the Reviews:

Submission Criteria	Level of GFMS Approval
Approval	Deliverable shall be formally approved by GFMS deputed people.
Acceptance	No GFMS formal approval required, but deliverable shall be signed for knowledge.
Available	Deliverable shall be available and verifiable during GFMS activities or progress meetings.
Review	No GFMS formal approval required, but comments can be raised.
Information	No GFMS formal approval required.

8.1.3 Product Risk Level

A "Risk-Based" approach drives the definition of Quality Control activities to be performed on the Product: the more critical the product, the more controls are applied. Therefore, the *Product Risk Level* determination (if applicable, depending from the GFMS Technical Unit/Plant) becomes the input for the definition of Control/Inspection Plans contents.

8.2 Stage 1 – Planning



Stage 1 – Planning: the goal of this Stage is to capture customer inputs, benchmark data, lessons learned, regulatory requirements, technical specifications, company know-how and strategy into a product concept and realization plan. This includes identification of the high-level technical, quality and cost targets.

Preliminary Design Review (PDR): the goal of this Review is to ensure the finalization at the Design and Development output meet the inputs Requirements. The deliverables that *shall* be verified during the PDR, if deemed applicable, are listed in the table below:

Deliverables	To be provided / defined by	To be received / evaluated / approved by	Submission Criteria
"GFMS APQP Plan"	GFMS (R&D + SQAE) <i>Supplier can supports the definition</i>	GFMS (R&D + SQAE)	N/A
Concept Sample	Supplier	GFMS (R&D)	Approval
Product "Key characteristics"	Supplier and GFMS (R&D)	GFMS (R&D)	Approval
Product Risk Level Scoring Chart	GFMS (R&D)	GFMS (R&D)	N/A

Supplier Quality Assurance Handbook (SQAH)

Design Validation Test Plan	Supplier and GFMS (IVA)	GFMS (IVA)	Approval
"GFMS APQP Inspections" - Plan ("Test Sample Inspection" scenario)	Supplier GFMS can supports the definition	GFMS (R&D + SQA)	Approval

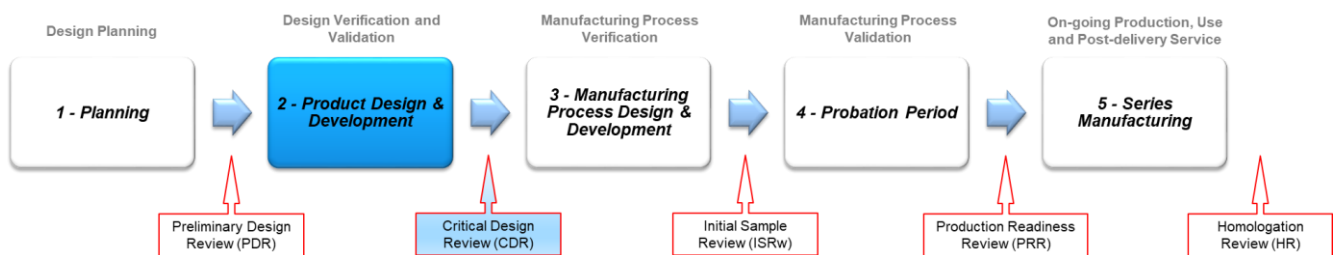


Forms to be used: GFMS APQP Plan, GFMS APQP Inspections.

8.2.1 Test Sample Inspection Planning

The Supplier *shall* plan the inspection activities prior to the manufacturing of the Test Sample using the "GFMS APQP Inspections" Form. The *Test Sample Inspection* Plan *shall* be evaluated and approved by GFMS before the manufacturing of the product starts.

8.3 Stage 2 – Product Design & Development



Stage 2 – Product Design & Development: the goal of this Stage is to translate the technical, quality and cost requirements into a controlled, verified and validated product design. Design validation is achieved using Prototype/Test Sample in test environments that can represent the GFMS’s installation.

Critical Design Review (CDR): the goal of this Review is to ensure that the resulting Product meet the Requirements for the specified application or intended use. The deliverables that *shall* be verified during the CDR, if deemed applicable, are listed in the table below:

Deliverables	To be provided / defined by	To be received / evaluated / approved by	Submission Criteria
Master Drawings	Supplier and/or GFMS (R&D)	GFMS (R&D)	Approval
Detailed Drawings	Supplier and/or GFMS (R&D)	GFMS (R&D)	Approval
Bill of Materials	Supplier	GFMS (R&D)	Approval
Datasheets of the Catalogue components used in the Design	Supplier	GFMS (R&D)	Review
Design Validation Test Report	Supplier	GFMS (IVA)	Approval
"GFMS Manufacturing Process Control Plan" (Preliminary version)	Supplier	GFMS (SQA)	Approval
Test Sample	Supplier	GFMS (SQA)	Approval
"GFMS APQP Inspections" - Report ("Test Sample Inspection" scenario)	Supplier	GFMS (SQA)	Approval
Prototype Report (SAP Quality Notification, if applicable)	GFMS (IPQC)	Supplier	N/A
"GFMS APQP Inspections" - Plan ("Initial Sample Inspection" scenario)	Supplier GFMS can supports the definition	GFMS (SQA)	Approval



Forms to be used: GFMS APQP Inspections, GFMS Manufacturing Process Control Plan.

Supplier Quality Assurance Handbook (SQAH)

8.3.1 Initial Sample Inspection Planning

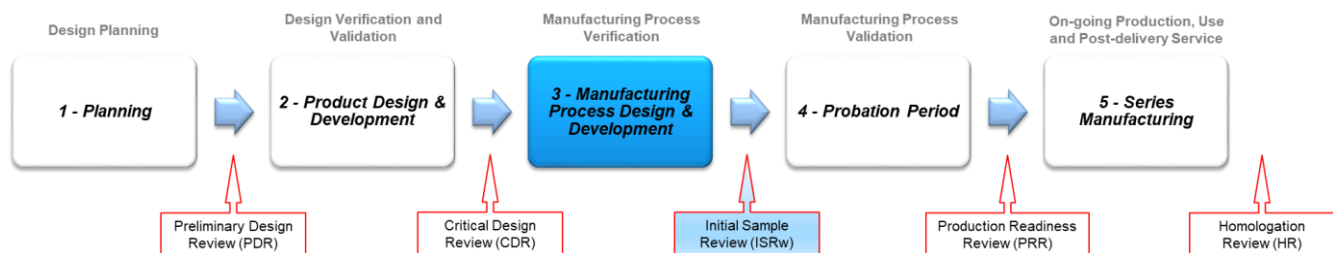
The Supplier *shall* plan the inspection activities prior to the manufacturing of the Initial Sample using the "GFMS APQP Inspections" Form. The *Initial Sample Inspection Plan shall* be evaluated and approved by GFMS before the manufacturing of the product starts.

In this Stage the Initial Sample "quantity" *shall* be defined, GFMS reserves the right to require a *Master Sample* (signed off by Supplier and GFMS) to be used as a benchmark for comparison to standard production parts if any part quality questions arise. The Master Sample will be stored in GFMS or to the Supplier Facility.

The Supplier should consider the following activities during *Initial Sample Inspection* planning:

- Determination of design characteristics inspection and sequencing for inspection of characteristics not measurable in the final product.
- Determination of objective evidence to be included in the ISI Report for each design characteristic.
- Determination that approved special process, laboratory, material, and GFMS required sources are identified, as applicable, and that the manufacturing planning, routing, and purchase document calls out the correct specification and relevant sources.
- Determination that key characteristics are identified, as applicable.
- Determination when part specific tooling are required. These tooling are identified, qualified, and traceable, as appropriate.

8.4 Stage 3 - Manufacturing Process Design & Development



Stage 3 – Manufacturing Process Design & Development: the goal of this Stage is to design and develop the production processes needed to produce product that consistently fulfil technical, quality and cost requirements while operating at the GFMS demand rate.

Initial Sample Review (ISRw): the goal of this Review is to ensure the Manufacturing Process is able to produce Products that meet applicable Requirements. The deliverables that *shall* be verified during the ISRw, if deemed applicable, are listed in the table below:

Deliverables	To be provided / defined by	To be received / evaluated / approved by	Submission Criteria
"GFMS APQP Plan"	GFMS (SQAE) <i>Supplier can supports the definition</i>	GFMS (SQAE)	N/A
Initial Sample	Supplier	GFMS (IPQC)	Approval
"GFMS APQP Inspections" - Report <i>("Initial Sample Inspection" scenario)</i>	Supplier	GFMS (IPQC)	Approval
"GFMS Manufacturing Process Control Plan" <i>(Final version)</i>	Supplier	GFMS (SQAE)	Approval
Master Sample Signed Off	Supplier	GFMS (IPQC)	Available
Manufacturing Process Documentation (e.g. Work Cycle, Operating Instructions)	Supplier	GFMS (IPQC)	Review
Declaration / Certificate of Conformity	Supplier	GFMS (IPQC)	Review
"GFMS APQP Inspections" - Plan <i>("Probation Period Inspection" scenario)</i>	Supplier <i>GFMS can supports the</i>	GFMS (SQAE)	Approval

Supplier Quality Assurance Handbook (SQAH)

	definition	
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Forms to be used: GFMS APQP Plan, GFMS APQP Inspections, GFMS Manufacturing Process Control Plan.

8.4.1 Initial Sample Inspection

The Supplier *shall* use a representative item from the *first production run* of a new product to verify that the production processes, production documentation, and tooling have the capability to produce products that meet established requirements.

The Supplier *shall* report *Initial Sample Inspection* activities executed on the *Initial Sample* using the "GFMS APQP Inspections" Form. The *Initial Sample Inspection* Report *shall* be evaluated and approved by GFMS Incoming Quality Control before the shipment of the product to GFMS.

The delivery of the *Initial Sample* *shall* be clearly identified on the packaging.

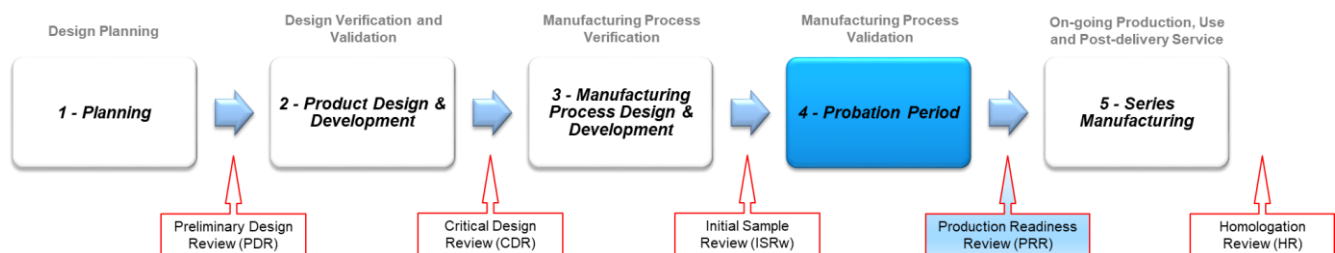
The Supplier *shall* conduct the following activities during product realization, when applicable, in support of *Initial Sample Inspection* to ensure conformance with design characteristics:

- Review documentation for the manufacturing process (e.g., routing sheets, manufacturing or quality plans, manufacturing work instructions) to ensure all operations are complete as planned and call out the correct specification, material types, conditions, and approvals.
- Review supporting documentation in the ISI (e.g., inspection data, test data, control plan) for completeness.
- Verify that the raw material certifications call out the correct specification, material types, conditions, and approvals.
- Verify that required GFMS approved sources (if applicable) are used.
- Verify that every design characteristic/key characteristic requirement is accounted for, uniquely identified, and has inspection results traceable to each unique identifier.
- Verify the design characteristics/key characteristic that are the output of the manufacturing process are measured, inspected, tested, or verified to determine conformance.
- Verify part marking is legible, correct in content and size, and properly located per applicable requirement (see purchase order/specification/drawing).

8.4.2 Probation Period Inspection Planning

The Supplier *shall* plan the inspection activities to be performed on the product (the number of deliveries is defined by GFMS Supplier Quality Assurance Engineer) using the "GFMS APQP Inspections" Form. The *Probation Period Inspection* Plan *shall* be evaluated and approved by GFMS Supplier Quality Assurance Engineer before the manufacturing of the product starts.

8.5 Stage 4 - Probation Period



Supplier Quality Assurance Handbook (SQAH)

Stage 4 – Probation Period: the goal of this Stage is to validate that product fulfils the design requirements and the production processes have demonstrated the capability to consistently produce conforming product at the GFMS demand rate.

Production Readiness Review (PRR): the goal of this Review is to confirm that the Manufacturing Process consistently produces a Product fulfilling the applicable Requirements, including key Product or Process characteristics, which are stable and capable at the desired level. The deliverables that *shall* be verified during the PRR, if deemed applicable, are listed in the table below:

Deliverables	To be provided / defined by	To be received / evaluated / approved by	Submission Criteria
"GFMS APQP Inspections" - Report ("Probation Period Inspection" scenario)	Supplier	GFMS (IPQC)	Approval
Declaration / Certificate of Conformity	Supplier	GFMS (IPQC)	Review
Homologation Report (SAP Quality Notification, if applicable)	GFMS (IPQC)	Supplier	N/A

Form to be used: GFMS APQP Inspections.

8.5.1 Probation Period Inspection

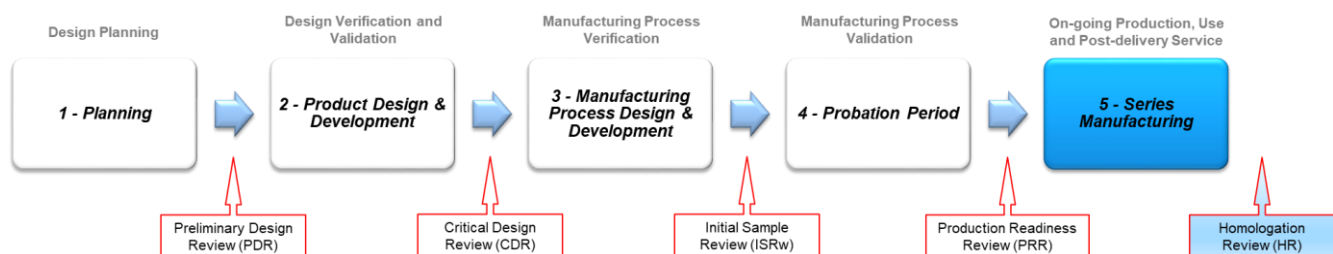
The "Probation Period Inspection" Report shall be evaluated and approved by GFMS Incoming Quality Control for every required delivery (as planned in Stage 3) of the product to GFMS.

All deliveries during the Probation Period *shall* be clearly identified on the packaging.

In case Non-conformities on the Product are detected during the incoming inspection activities, GFMS Incoming Quality Inspectors can decide to extend the Probation Period and define all the activities/actions to be executed by the Supplier to ensure the Product conformity.

A Product is "Homologated" (ready for series production) when the results of both Stages 3 and 4 of the APQP Process are positive. *Initial Sample Review (ISRw)* and *Production Readiness Review (PRR)* are required in order to verify and validate the Manufacturing Process.

8.6 Stage 5 – Series Manufacturing



Stage 5 – Series Manufacturing: the goal of this Stage is to ensure GFMS requirements are continually fulfilled through the use of manufacturing process control, lessons learned and continuous improvement.

Homologation Review (HR): the goal of this Review is to ensure the compliance of the product with the applicable Requirements during series production, avoiding non conformities due to not evaluated/authorized changes on Design/Manufacturing characteristics or to a lapse in. The deliverables that *shall* be verified when HR is required, if deemed applicable, are listed in the table below:

Supplier Quality Assurance Handbook (SQAH)

<i>Deliverables</i>	<i>To be provided / defined by</i>	<i>To be received / evaluated / approved by</i>	<i>Submission Criteria</i>
Initial Sample	Supplier	GFMS (IPQC)	Approval
"GFMS APQP Inspections" - Report (*Initial Sample Inspection* scenario)	Supplier	GFMS (IPQC)	Approval
Manufacturing Process Documentation (e.g. Work Cycle, Operative Instructions)	Supplier	GFMS (IPQC)	Review
Declaration / Certificate of Conformity	Supplier	GFMS (IPQC)	Review
Homologation Report (*SAP Quality Notification, if applicable*)	GFMS (IPQC)	Supplier	N/A



Form to be used: GFMS APQP Inspections.

8.6.1 Delta (Partial), Re-accomplishment or Renewal of Initial Sample Inspection

The "Initial Sample Inspection" Requirement, once invoked, shall continue to apply even after initial compliance. The ISI requirements may be satisfied by a "partial" ISI that addresses only the changes from a baseline part number provided all other characteristics were conforming on the previous ISI and are produced by the original production processes.

When a partial ISI is performed, the Supplier *shall*, as a minimum, complete the affected fields in the ISI Report.

The Supplier *shall* perform a full ISI or a partial ISI for affected characteristics, when any of the following occurs:

- A change in the design characteristics affecting fit, form, or function of the part.
- A change in manufacturing source(s), process(es), inspection method(s), location of manufacture, tooling, or materials that can potentially affect fit, form, or function.
- A change in numerical control program or translation to another media that can potentially affect fit, form, or function.
- A natural or man-made event, which may adversely affect the manufacturing process.
- A lapse in production for one year shall require an update for any characteristics that may be impacted by the inactivity. This lapse is from the completion of last production operation to the actual restart of production.



Form to be used: GFMS Change Request, GFMS APQP Inspections.

8.7 Design and Development Changes

The Design of any product procured from a Supplier who is also the designer of the product, once validated (APQP Stage 2 and Critical Design Review successfully completed), becomes part of the Design Data of the GFMS product.

Alteration to any of the following data, which constitutes the Design Data, is considered a change to Design:

- Drawings and their lists necessary to identify the configuration
- Specifications and their lists necessary to identify the configuration
- Information on materials, processes, methods of manufacture and assembly

8.7.1 Management of Design Changes

All Design Changes *shall* be communicated to GFMS for Evaluation and Approval.

For each Design Change, the Supplier shall send to GFMS a "GFMS Change Request" completed with all the details needed to evaluate the Change.

Design Changes cannot be implemented until its approval is communicated by GFMS with signature on the above mentioned Form.

Supplier Quality Assurance Handbook (SQAH)

The changes below are pre-classified as very minor Changes to the Design Data. Only these specific changes do not require any GFMS approval before the implementation:

- Correction of Drawing clerical errors (e.g. Graphical errors; formal errors on quotations or references).
- Correction of Drawing Part list clerical errors (e.g. Formal errors; incorrect or superseded recall of materials or standards).



Form to be used: GFMS Change Request.

8.7.2 Management of Manufacturing Process Changes

All Manufacturing Process Changes *shall* be communicated to GFMS for Evaluation and Approval.

For each Manufacturing Process Change, the Supplier shall send to GFMS a "GFMS Change Request" completed with all the details needed to evaluate the Change.

Manufacturing Process Changes cannot be implemented until its approval is communicated by GFMS with signature on the above mentioned Form.

For changes affecting frozen manufacturing processes and changes on sources including the manufacturing site for the end item, the Initial Sample Inspection *shall* be partially or totally repeated and the manufacturing process shall be re-homologated. In this case, the Supplier shall resubmit to GFMS Supplier Quality Assurance the *Initial Sample Inspection* to highlight the introduced changes with respect to previous homologation.



Form to be used: GFMS Change Request, GFMS APQP Inspections.

9 Production and Service Provision

9.1 Control of Monitoring and Measurement equipment

The Supplier *shall* determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Traceability of calibration to Official National or International recognized standards instruments *shall* always be ensured.

9.2 Special Processes

The Supplier *shall* provide the validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.

Examples of Special Processes: Heat Treating, Chemical and galvanic treatments for protection and for surface preparation, Welding, Crimping of electrical contacts.

9.3 Identification and Traceability

All products have to be identified and traceable in accordance with the Design Requirements or as agreed with GFMS. The traceability system defined by the Supplier *shall* reduce the probability of the need to conduct a full product recall in the event of noncompliance.

This *shall* take into consideration the following:

- Traceability of the sub assembly parts/components (including raw material).
- Manufacturing methods, techniques and processes.
- Criticality, safety and reliability data.
- Complexity of design and processes employed.

Supplier Quality Assurance Handbook (SQAH)

9.3.1 Serial Numbers

When serialization is required, Serial Numbers shall be allocated and remain unchanged from the earliest, defined operation, throughout the life of the product.

Supplier *shall* ensure the assigned s/n is unique for each product part number and no duplication of s/n can occur.

9.3.2 Product Marking

Supplier *shall* ensure marking is always visible on the product, also after painting, as indicated in GFMS Drawing/Purchase Order.

9.4 Packaging and Preservation of Product

All products *shall* be preserved, packed, identified and shipped according to the Purchase Order requirements or, if not specified, to the best commercial rules.

The type of packaging *shall* be defined by the Supplier taking into due consideration: environmental and shipping stresses that can affect parts during shipping, transportation and warehouse handling. Internal packaging and conditioning should be adequate to ensure the proper storage life for the parts. In the case of a sealed package, the external marking shall indicate all the data related to the part (identification, shelf life, curing date etc).

Do not use materials that can cause deterioration/corrosion during storage and/or delivery to GFMS and/or their Customers.

In case of fragile parts (extremely shock sensible), packaging shall be adequate to prevent damages.

If the packaging contains shelf life parts, the package shall report packaging date and shelf life.

Products that are (or contain) Electrostatic discharge Sensitive Devices (ESD) or operate at high voltage shall be clearly marked accordingly and packaged in accordance with National and International specifications.

9.4.1 Shelf Life and Limited Life Products

Product shall be supplied with the required shelf life/calendar life unless otherwise specified in the applicable material specification/engineering requirements or otherwise agreed.

Limited life materials shall be identified and controlled by Supplier so that 'out-of-life' materials are not used to manufacture GFMS Parts/Products.

9.4.2 Safety Hazard and Prohibited material

A Supplier *shall* provide clear identification, instruction for usage, control, training and disposal in accordance with National and International standards if an product is a safety hazard (e.g. Beryllium copper, lithium batteries etc.). Material Safety data sheets shall be provided for chemical products.

Any product or packaging delivered to GFMS shall be compliant in terms of hazardous material or substances forbidden by supplier Country laws and European Community as per:

- Regulation (EC) n. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (**REACH**), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
- Regulation (CE) n. 850/2004 on persistent organic pollutants ("POP").
- Regulation (CE) n. 1005/2009 on substances that deplete the ozone layer.
- European Directives Nos. 2002/95/EC and 2011/65/EU (hereinafter referred to as **RoHS**): Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.
- European Directive No. 96/29/EURATOM: Basic Safety Standards for the Protection of the Health of workers and the General Public Against the Dangers Arising from Ionizing Radiation.

Supplier Quality Assurance Handbook (SQAH)

10 Control of nonconforming outputs

The Supplier *shall* ensure that outputs that do not conform to the applicable requirements are identified and controlled to prevent their unintended use or delivery.

The Supplier *shall* take appropriate action based on the nature of the Non-conformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The Supplier *shall* deal with nonconforming outputs in one or more of the following ways:

- Correction;
- Segregation, containment, return, or suspension of provision of products and services;
- Informing GFMS Incoming Parts Quality Control (in any case);
- If needed, obtaining authorization for acceptance under Concession.

GFMS Quality Control will issue a Quality Notification to the Supplier for any Non-conformity detected but not identified by Supplier. The Supplier *shall* notify GFMS Quality Control the Root Causes, the Actions and that amendments to the process have been/will be put in place to prevent the occurrence. The "GFMS 8D Report" *shall* be completed by the Supplier, when required by GFMS Quality Control, respecting the provided "time frame".

If a corrective action is required and not taken within the date requested by GFMS Quality Control (30 days if not differently specified), an escalation process can be initiated.

If the agreed days' timescale cannot be met, the Supplier shall inform GFMS Quality Control (within 10 days if not differently specified) explaining the reasons for the delay.

Non-conforming products, with their identification (e.g. labels), shall be held in a secure quarantine area until an approved, written disposition is given. A "split batch" may be used to allow acceptable articles to continue the manufacturing process.

Unless otherwise formally agreed, non-conforming products shall not be delivered until the notification of non-conformity is accepted and disposition issued by GFMS Quality Control. In case this last authorizes the Supplier to deliver a non-conforming product with an open non-conformity, this status has to be recorded on the accompanying documentation.

When a Quality Notification is acknowledged by the Supplier, GFMS reserves the right to charge the costs incurred for Non-conformity related activities.



Form to be used: GFMS 8D Report.

10.1 Concession

A "GFMS Permission Request" have to be prepared and submitted to the GFMS Supplier Quality Assurance. Once the Concession is evaluated, the Supplier will receive it back by GFMS SQA.

The Supplier *shall* implement the authorized repair/rework and shall give evidence of that work done to the GFMS SQA. A Concession may refer to more Serial Numbers for the same defect in order to allow a faster management of the products.

A Concession shall not contain more defects and/or descriptions. In the presence of more defects or more descriptions for the same defect, more Concessions shall be issued since different decisions to use for each defect cannot be managed within the same Concession.

In case a product is manufactured under an authorized Deviation Permit, and a request for a Concession is needed, a copy of the approved Deviation Permit has to be attached to the request for Concession.

In case the Concession number has to be marked, it has to be done before to deliver the parts. The marking method shall be the same indicated in the drawing/specification otherwise indicated on the concession itself.

Supplier Quality Assurance Handbook (SQAH)



Form to be used: GFMS Permission Request.

10.2 Deviation Permit

A "GFMS Permission Request" have to be prepared and submitted to the GFMS Supplier Quality Assurance. Once the Deviation Permit is evaluated, the Supplier will receive it back by GFMS SQA in charge of it with all the relevant dispositions.



Form to be used: GFMS Permission Request.

10.3 Notification of Escape/Quality Alerts

The Supplier shall send a Quality Alert (written on their company headed paper and on its own format) to notify GFMS any circumstances that might affect integrity of the products already delivered.

Such information *shall* be sent to the contacts below:

- GFMS Commodity Manager
- GFMS Supplier Quality Assurance Engineer
- GFMS SQA mailbox: supplier.quality.PLANT NAME@georgfischer.com

The Supplier shall ask and receive an acknowledgement of such communication.

11 Supplier Re-evaluation

All approved Suppliers *shall* be subject to surveillance and revalidation by GFMS Supplier Quality Assurance according to following criteria:

- Supplier Risk Category (assigned during Approval Process).
- Performances (mainly Quality and Delivery, continuously monitored and summarized in a "Vendor Rating").
- Specific program requirements and criticality of the types of product/services supplied to GFMS.

The process of Supplier Re-evaluation *shall* be carried out through the interactions of the following activities:

- Surveillance Audit at the Supplier Facility
- Continuous Improvement activities (promoted/supported by GFMS Supplier Development Department).

12 Supplier Audit Process

Where an audit at the Supplier Facility is determined to be necessary, this is undertaken to obtain evidence of the suitability and effectiveness of the potential Supplier's QMS and compliance with GFMS SQA (Supplier Quality Assurance Handbook) and if the Supplier does not hold a QMS Certification, compliance to the GFMS QMS.

In order to make the audit as effective as possible, specific "GFMS Supplier Audit Checklist" can be used by the Auditor based on the Type of Supplier.

Results of the audit *shall* be formally documented by GFMS SQA Auditor with a "GFMS Supplier Audit Report".

12.1 Non-Conformities Management

Where a "GFMS Non Conformity Report" (NCR) is raised as a result of an Audit finding, the following non-conformity categories are used:

Non Conformity categories	Finding	Document
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Supplier Quality Assurance Handbook (SQAH)

Level 1	Evident and objective non-conformity with respect to the requirements of the applicable standards and/or procedures that will have a potential impact on a safety and/or contractual requirement. Corrective and containment actions shall always be required.	NCR
Level 2	Evident and objective non-conformity with respect to the requirements of the applicable standards and/or procedures that is not classified as Level 1. Corrective and containment actions shall always be required.	NCR
Level 3	Isolated non-conformity with respect to the requirements of the applicable standards and/or procedures that is not classified in the preceding Levels. Only containment action shall be required.	NCR
Preventive Action Only	Event that indicates a possible failure of the QMS and that can be subject to future NC. Preventive action shall always be required.	NCR

Notes:

- A number of Level 2 non-conformities against one requirement (e.g. similar non-conformities associated to different sites or different departments / functions / processes within a single site) can represent a total breakdown of the systems and can be considered a Level 1 non-conformity.
- Where a Level 1 Non-conformity is raised, the GFMS Statement of Approval shall not be issued until the non-conformity is closed to the satisfaction of the GFMS Auditor.

A "GFMS Non Conformity Report" (NCR) is completed by the Auditor for each Non-conformity clearly stating the description of the Non-conformity. The Form is forwarded to the Supplier for completion of Root Cause Analysis (5 Whys method), at minimum identifying 3 levels of "Whys" and Corrective action/Preventive action (as appropriate). The completed form shall be returned to the Auditor by the Supplier within 21 calendar days from forwarding. In case of a Level 1 Non-conformity is raised, the response period will be reduced to 5 calendar days or less (at Auditor's discretion).

NC Categories	Owner	Root Cause Analysis (Max Calendar Days)	Containment Action Definition/Implementation (Max Calendar Days)	Corrective/Preventive Action definition (Max Calendar Days)	Corrective Action Closure (Max Calendar Days)
1	Supplier	5	5	5	21
2	Supplier	21	21	21	80
3	Supplier	21	21	N/A	N/A
Preventive Action	Supplier	N/A	N/A	21	80

12.2 Escalation

It is a Supplier responsibility to monitor the timing for the definition and implementation of request for corrective action.

Where a Supplier does not respond to the request for corrective action in the planned times, an "escalation process" will be initiated from GFMS SQA to the Supplier Top Management and may lead to contractual consequences.

12.3 Right of Access

GFMS *shall* have the right of access to any Supplier involved with GFMS Products, included any Sub-tier Supplier.

The Supplier *shall* provide GFMS Customers (or the Customers authorized representatives) and/or Regulatory Authorities rights of access to premises where GFMS work is being performed. Such access *shall* be used to verify that the activities being undertaken meet the requirements of the GFMS contracts/orders. The Supplier *shall* provide suitable accommodation facilities and assistance.

Supplier Quality Assurance Handbook (SQAH)

BoM	Bill of Materials
CDR	Critical Design Review
CoC	Certificate of Conformity
GFMS	Georg Fischer Machining Solutions
HR	Homologation Review
IPQC	Incoming Parts Quality Control
ISI	Initial Sample Inspection
ISO	International Standardization Organization
ISP	Initial Sample Plan
ISR	Initial Sample Report
ISRw	Initial Sample Review
NCR	Non Conformity Report
PDR	Preliminary Design Review
PO	Purchase Order
PQ	Project Quality
PRR	Production Readiness Review
QMS	Quality Management System
R&D	Research & Development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SQA	Supplier Quality Assurance
SQAE	Supplier Quality Assurance Engineer
SQAH	Suppliers Quality Assurance Handbook

15.2 Definitions

For the purposes of this document, the following definitions shall apply:

Catalogue Part / Product: commercially available items intended by design to be procured and utilized without modification (e.g., common electronic components).

Concession: permission to use or release a Product or Service that does not conform to specified requirements. A concession is generally limited to the delivery of products and services that have nonconforming characteristics within specified limits and is generally given for a limited quantity of Products and Services or period of time, and for a specific use.

Control plan: documented description linking manufacturing process steps to key inspection and control activities. The intent of a control plan is to control the design characteristics and the process variables to ensure product quality.

Deliverables: Items (outputs) completed as part of the APQP Process.

Deviation Permit: permission to depart from the originally specified requirements of a Product or Service prior to its realization. A deviation permit is generally given for a limited quantity of Products and Services or period of time, and for a specific use.

External Provider: (also called "Supplier") provider that is not part of the organization.

GFMS Designed Part: part designed, developed and validated against GFMS Functional Requirement Specifications and/or Drawings.

Supplier Quality Assurance Handbook (SQAH)

Initial Sample: (also called "First Article" or "First Production run") the initial group of one or more parts that are the result of a planned process designed to be used for future production of the same parts.

Initial Sample Inspection: planned, complete, independent, and documented inspection and verification process to ensure that prescribed production processes have produced an item conforming to engineering drawings, digital data, planning, purchase order, engineering specifications, and/or other applicable design documents.

Initial Sample Inspection Report: the forms and package of documentation for a part number, sub-assembly, assembly, or installation including Initial Sample Inspection results after the qualification of the part.

Key characteristic: an attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

Master Sample: is a final sample of the product that is inspected and signed off by the customer. The master sample part is used as a benchmark for comparison to standard production parts if any part quality questions arise.

Serial Number: unique number or alpha-numeric code that is one of a series, used to provide identification of a Product to enable traceability.

Special Process: any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Standard Part: a part manufactured in compliance with an established government or industry-accepted specification that contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

Sub-tier Supplier: any Supplier in the First-tier Supplier's supply chain.

Test Sample: (also called "Prototype") is required in order to provide compliance of the prototype part with the applicable design data.

Validation: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification: confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

16 Final Provisions

Confidentiality: the Parties (GFMS/Supplier) *shall* not disclose to third parties nor use for any other purposes than those contemplated by this SQAH any information or documents received from GFMS/Supplier during the term of this SQAH. All information disclosed by GFMS/Supplier shall remain its exclusive property. This undertaking shall survive the termination of this SQAH for a period of at least five (5) years, to the extent the pertinent information has not entered the public domain.

Severability: should any provision of this SQAH be or become invalid or unenforceable, the validity or enforceability of all other provisions shall not be affected. In this case, the invalid provision is replaced by a provision consistent with the original commercial intention of the Parties.

Amendments: no change or addition to any provision hereof shall be binding unless in writing and signed by the Parties. The requirement of the written form may also only be modified or waived in writing.