Q-CODE QV6 QUALITY REQUIREMENTS
SUPPLIER'S MANUFACTURING PROCESS QUALIFICATION (SMPQ)

The following are the quality requirements for product purchased under Q-code QV6. Please reference the Plexus Supplier Quality Manual DCS 10503 for additional details and purchasing requirements. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below and resubmit appropriately for any product or process change.

The supplier shall refer to the Medtronic Feature Level Quality Impact Assessment (FLQIA) for the part number being purchased to determine the Quality Impact Level of each feature on the part drawing. The below table will then be used, along with the requirements that follow in this Q-code, to determine the applicable qualification requirements for each feature. (Note: the supplier should contact the Plexus buyer to obtain a copy of the FLQIA for the part number being purchased if one has not already been provided.)

Feature Level Quality Impact	Data Type	Initial Qualification				
		Min Number of Lots Required*	MSA Required	Min Sample Size/Lot	Capability Assessment Required	Acceptance Criteria
Critical	Attribute	3	Yes	149	No	c = 0
	Variable	3	Yes	15	Yes	Ppk ≥ 1.67
	100% ongoing	1	Yes	100%	No	c = 0
Major	Attribute	3	Yes	59	No	c = 0
	Variable	3	Yes	15	Yes	Ppk ≥ 1.33
	100% ongoing	1	Yes	100%	No	c = 0
Minor	Attribute	1	No	29	No	c = 0
	Variable	1	No	15	Yes	Ppk ≥ 1.00
	100% ongoing	1	No	100%	No	c = 0
Negligible	Attribute	1	No	5	No	c = 0
	Variable	1	No	5	No	c = 0

*Note: Where 3 lots are required, this is 3 PQ runs. Additional OQ runs may be required to satisfy process validation requirements (see section F).

QUALIFICATION

Before a product will be released for production, the supplier will be required to demonstrate the product meets specifications and has control of variation in order to reliably produce good product. Refer to the table above for the minimum number of manufacturing lots required for the qualification. The following steps and deliverables are required of the supplier. The supplier is required to submit the qualification documentation and receive approval from Plexus prior to shipping product.

A. **Quality Control Plan** - The supplier must submit a detailed QCP describing how all process, quality and inspection steps will be executed and monitored throughout the process. The QCP is a map of the systems, tools, gages and equipment used to control the quality of the part, minimizing process and

product variation. All Critical, Major, and process control characteristics must be identified on the QCP. The QCP must be utilized and updated with Plexus approvals before release and to reflect changes over the life of the product.

B. Measurement System Analysis (MSA) - All measuring strategies for Critical, Major, and process control characteristics must be studied with a MSA. See below for acceptance criteria per Medtronic requirements.

MSA Acceptance Criteria defined by Medtronic:

Gage R&R – (Percent of Tolerance Ratio)[1]:

- %P/T <25% - Measurement system is acceptable
- %P/T >25% - ratio maybe acceptable with sufficient mitigation and/or rationale.
- See 10082325DOC *Variables Test Method Validation* for options on addressing %P/T of >25%.

Destructive Variable Reproducibility Study[2]:

- Samples shall be from one continuous unimodal distribution
- %Tolerance for Reproducibility ≤ 25% and the StDev Ratio is less than or equal to the critical value shown in Table 5 below

Table 5: Critical Value table for StDev Ratio

# of Operators	Critical Value
2	2.56
3	2.92
4	3.10

Attribute Agreement Analysis[3]:

- Number of presentations to be commensurate with Confidence and Reliability Levels

Table 6: Standard Examples of Confidence and Reliability Levels and the Required Minimum Numbers of Presentations

Feature Level Quality Impact	Feature Criticality	Confidence % / Reliability%	Minimum Presentations of Rejectable Samples	Minimum Presentations of Acceptable Samples
Critical	Very High	95 / 98	149	149
Major	High	95 / 95	59	59
Minor	Moderate	95 / 90	29	29
Negligible	Low	95 / 85	19	19

- Accuracy on acceptable units higher than 10% may be used with explanation in the report.
- No rejectable units may be accepted (C=0).
- Multiple defect criteria may be combined with rationale.

C. First Article Inspection Report - The supplier will perform a first article inspection including a measurement and acceptance of every characteristic, requirement and/or drawing note. This will be documented and submitted on a report for a minimum of 5 pieces. All dimensions must be within print tolerance. The FAIR must be complete and include the requirements as listed in the Plexus Supplier Quality Manual DCS 10503. In addition, the FAIR must include the following: test facility name and location; date; test method and equipment used; person who collected or approved the data and signature.

D. Material Certification - must include a list/BOM of all raw materials used with associated raw material certification or test data. If product is designated to comply with RoHS, REACH or similar material substance requirement, the appropriate certificate must also be included.

E. **Capability Studies** - During the qualification run(s), the supplier will sample (using sample size identified in the table above) from an appropriate number of pieces that represent the distribution of the process. Using these samples, the supplier will perform a capability study on all Critical, Major, and Minor characteristics, and any supplier selected process control characteristics. The supplier's submission to Plexus will include: control charts; calculated values for X-bar and Sigma; charts showing the data distribution; Pp and Ppk values; all associated data; and reference to the software and revision used for the data analysis. The results must meet the Ppk requirements defined in the table above. This is not required if the characteristic is 100% ongoing inspected.
Note:
- Processes are not always double sided or normally distributed. In these cases a comparative measure and representation of Process Capability shall be recommended by the supplier and approved by Plexus.
- The supplier shall provide rationale if using sample size or number of lots less than the minimum (e.g. homogeneous materials where sample size may be 1 per lot, only a single lot will be purchased for the lifetime of the product, etc.)

F. **Validation for Special Processes using an IQ, OQ and PQ methodology** - The supplier is required to validate all processes that produce any Critical or Major characteristics where 100% ongoing inspection will not be performed. The validation shall include a Process Characterization study as needed in order to establish the process window prior to OQ. All protocols require Plexus approval prior to execution. The execution of the validation shall result in an approved result with appropriate ongoing process controls. Documentation of such must be represented in the Quality Control Plan. Please see the Appendix A for additional definition of process validation.

G. **Validation for Test Methods using IQ and OQ methodology** - The supplier is required to validate all test methods used in the process validation. The Test Method Validation shall result in an approved result before execution of OQ and PQ process validation. Please see the Appendix A for additional definition of process validation.

H. **Packaging and Labeling Documentation** - The supplier is required to evaluate, define, and document the packaging specifications and submit the specifications for approval to Plexus. The specifications shall be adequately defined to assure consistency in packaging methods and protection during the shipping and handling.

If the above qualification criteria is met, utilizing the defined processes, the supplier will be granted a SMPQ approval from Plexus and the product will be released for production builds. If any of the above criteria are not met during the SMPQ approval builds, the supplier must notify Plexus and use the data to make the appropriate tool, sampling, measurement system and/or process corrections in order to re-execute the qualification successfully before concessions to this plan can be made. Any concessions made will require an alternative strategy with approval by the supplier and Plexus with an updated QCP. This most commonly will include a 100% sampling of the measurement or use of a Poke Yoke device.

ALL SHIPMENTS

The following are the quality requirements for all shipments of purchased parts qualified per this Q-code. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below. The following steps and deliverables are required of the supplier:

A. **Approved for Production** – the supplier must use the approved process (as defined in the qualification runs above) to manufacture and supply the part.

B. **Critical and Major Characteristics Verification and Report** – The supplier will monitor all Critical and Major characteristics per the sampling plan defined in the approved QCP. Measurements must be completed with the approved gage per the MSA study and QCP. Inspection data shall be provided to Plexus with each shipment.

C. **Certificate of Compliance** – Must be titled as such and include a statement of compliance to all applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as drawing, PO, customer specifications, Plexus G9000-3, NFS, IPC specifications, UL, etc.). It also must include the following information for traceability:
   - Name of Supplier (if different than the actual Manufacturer/OEM/OCM)
   - Plexus part number ordered on the Plexus PO
   - EC level or Revision level as specified on the Plexus PO for the Plexus part number ordered
   - Quantity Shipped
   - Plexus PO number
   - Name of Manufacturer/OEM/OCM
   - Manufacturer's/OEM's/OCM's Part Number
   - The Manufacturer/OEM/OCM Lot numbers **or** Date Codes (both are preferred) for each shipment
   - Location or place of manufacture
   - If the product has a shelf life, the manufacturer or cure date, batch number, the shelf life and expiration date must be included (note: the remaining shelf life must be greater than 50% of the stated shelf life). Any special handling and/or storage requirements must also be included
   - Name and title of supplier representative certifying the product, with signature and date

D. **Material Certification**

All cartons, required documentation, labels, packaging and packing slips must have the Supplier Name, Plexus part number, EC level or revision (if applicable), lot number or date code(s), quantity, and P.O. number listed on them.

The above listed required documentation must be submitted with each shipment. Shipments received without the completion and proper execution of these quality requirements is considered non-conforming and Plexus reserves the right to return to the supplier at the supplier's expense.

Product Change Notification

Product or Process change notification requests (PCNs) shall be submitted to pcns@plexus.com, please reference the details of our PCN policy and requirements in the Plexus Supplier Quality Manual DCS 10503.

Appendix A

1. **Process Validation Overview**
   The following is an overview of process validation using the IQ, OQ, PQ methodology.

   1.1 Installation Qualification (IQ)
   Installation Qualification is the verification that the supplier has installed equipment/tooling related to the specific component being qualified as per manufacturer specification. Within the supplier's Process Validation report consider the need to include the following:
   - Equipment/tooling is described, including equipment software and version, if applicable

- Equipment/tooling is installed as per guidance from equipment supplier e.g. utility connections, safety features as per drawings/manuals
- Calibration, preventative maintenance and cleaning schedules
- Any environmental conditions as applicable (temperature, humidity, cleanroom class etc.) are documented

1.2 Operational Qualification (OQ)

Operational Qualification is the verification that the supplier is capable of producing product which meets specifications at the process control limits. A Process Characterization study may be necessary prior to OQ in order to establish the process window. Within the supplier's Process Validation report consider the need to include the following:

- Process control limits/ranges are listed for key process parameters
- OQ consists of one or more production runs at process control limits
- Acceptable Measurement System Analysis
- Evidence that product meets acceptance criteria when processed at the OQ limits
- Where OQ is not required – provide justification (e.g. locked inputs)

1.3 Performance Qualification (PQ)

Performance Qualification is the verification that the supplier is capable of consistently producing product which meets specifications under normal operating conditions. Within the supplier's Process Validation report consider the need to include the following:

- Process operated at nominal operating conditions, within the limits defined in OQ above
- PQ consists of multiple production runs in order to be representative
- Evidence that product meets acceptance criteria when processed at the nominal conditions
- Evidence that capability requirements are met
- Process instruction log with validated parameters and limits listed or other similar control document forms basis of monitoring in order to maintain state of validation

2. Validation Documentation for the IQ, OQ, and PQ methodology

A specific format of the validation documents is not required, but consistency, completeness and accuracy in the documentation are required.

3. Validation Protocols

A protocol is a written plan that describes how to conduct qualification/validation activities, the set process or methods, and define acceptance criteria. All protocols must be reviewed and approved for technical content and regulatory compliance by the supplier and Plexus prior to execution.

All protocols shall be controlled and contain the following information:

- Title Page
- History and Document Revision Control
- Table of Contents
- Approval Record: An approval sheet with name, signature, and date of each Validation Team member must be part of the Protocol.
- Personnel Identification Form: If anywhere within validation package a person uses initials only to sign a document (such as test records), a table or form that provides initials and signature cross-reference for each person using their initials needs to be included.
- Purpose: Provide a clear, concise statement describing the intent of the Qualification.
- Scope: Identifies the process/system to be Qualified.
- Assumptions/Strategies: State any assumptions or strategies that pertain to the qualification.
- General Description of Process or System: Description of the process/system, equipment location within the facility and the site location where the validation activities will occur.

- References: List the applicable regulatory standards, equipment manuals and specifications, procedures, software versions, and other documents that are needed to plan the Qualification.
- Definition
- Personnel/Responsibilities: Record title/function of any internal or external personnel required to complete the Qualification tasks.
- Test and Acceptance Criteria: List the requirements of the items to be verified, including pass/fail criteria, to conclude that the results of the given protocol are acceptable. Test and Acceptance criteria shall be traceable to a customer, industry requirements or manufacturer specifications as applicable. Otherwise engineering characterization or DOE studies should be conducted to make the determination.
- Procedure: Details qualification activities based on product/process requirements:
  - Determine what to verify/measure
  - Determine how to verify/measure
  - Determine how many to verify/measure
  - Define acceptance/rejection criteria
  - Define required documentation for collecting and reporting data

***Note**: Once the validation team approves the protocol, the protocol can only be revised in a controlled manner.*

4. **Validation Sampling Plan**
   Refer to Table 1 for sampling plans. When using 100 % ongoing inspection the 5 piece sample plan will be used for the FAIR and this data will be acceptable to use for the PQ data and no OQ characterization data will be required unless specified by Plexus.

5. **Validation Report**
   At the conclusion of executing any formal protocol a validation report is required. The validation report is an overview of the respective protocol and actual validation activities.

   A validation report shall contain the following:

   - Purpose
   - Scope
   - General Description of System/Process
   - Training and the verification of training records
   - References (if required)
   - Review of Discrepancies (if required)
   - Acceptance Criteria
   - Gage R&R or Verification of Measurement System with data
   - Capability Statistics and Study with data
   - Verification/inspection data
   - Conclusions, include validation activities results summary
   - Rationale for acceptance and conclusions (if required)
   - Statement Authorizing Release of the System/Process
   - Approval signatures

   Validation reports for each respective validation protocol stage must be reviewed and approved prior to beginning the execution of the next step.

REVISION HISTORY

REV	RELEASE DATE	ORIGINATOR	DESCRIPTION OF CHANGE(S)	REASON FOR CHANGE(S)
A	29 JAN 2021	Joyce Conn	New - Initial Release	N/A