Critical Suppliers

QSR, ISO 13485:2003, and ISO 13485:2016 require (implicitly or explicitly) that device manufacturers establish the type and extent of control for each product and its supplier. Some device manufacturers develop a system to classify the product and the supplier and apply controls based on the classification. The system could be complex with multiple levels and a variety of control activities. Other device manufacturers could develop a method for each individual product and its supplier

Determining Critical Suppliers
However, there is a simple classification system that performs well, is easy to maintain, and satisfies the regulatory requirements. Classify each product (including services) as critical or not. A supplier that provides one or more critical products is a critical supplier.

Two GHTF guidance documents provide useful information.

SG4 N33 R16[1] says, "A *critical supplier* is a supplier delivering materials, components, or services that may influence the safety and performance of the product."

SG4 N84 R13[2] says that *Critical Supplier* means a supplier delivering materials, components, or services that may influence the safety and performance of the product. There is a note that says, "In the context of audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician, or others, or could cause a significant degradation in performance. This can include suppliers of services which are needed for compliance with QMS or regulatory requirements, *e.g.*, internal audit contractors or EU Authorized Representatives."

Another source is §820.30(d) on design output which requires that "Design output procedures … shall ensure that those design outputs that are essential for the proper functioning of the device are identified". QSR doesn't define essential design outputs or provide a method to determine them.

To develop an approach, start with some working definitions.

Essential Design Output means any design output that directly affects the device safety, effectiveness, or ability to meet a labeled performance specification.

Safety means freedom from unacceptable risk [ISO 14971:2007, 2.24]
Note: If the output were absent, the risk would go up, *i.e.*, a risk control measure.

Effectiveness means the ability of the device to satisfy its intended use.

[1] Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers Part 3: Regulatory Audit Report
[2] Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers Part 5: Audits of manufacturer control of suppliers

Labeled performance specification means the requirements for device performance included in the labeling.

> Note: Failure to meet a labeled performance specification would require evaluation under Corrections and Removals and a potential recall.

One common technique in design control uses a trace matrix to help ensure design output matches design input. ISO 13485:2016 clause 7.3.2.e requires the device manufacturer to document the methods to ensure traceability of design and development outputs to design and development inputs.

Use the trace matrix to classify each design output as contributing to safety, effectiveness, or a labeled design output. If a design output contributes to one or more these, then it is critical. Trace it any purchased product, which then becomes critical. Trace the critical product to the supplier, who then becomes a critical supplier.

Notice that SG4 N84 R13 adds suppliers of services needed for compliance with QMS or regulatory requirements.

In short, a critical supplier provides either a critical product (based on essential design output) or a service needed to meet QMS or regulatory requirements. Note that these services may also be outsourced processes that require additional control under ISO 13485:2016 clause 4.1.5.

Controls

QSR requires procedures to ensure that received products and services conform to specified requirements. The method is often implemented as part of Receiving Acceptance Activities in §820.80(b). The requirement is to inspect, test, or otherwise verify incoming product as conforming to specified requirements.

Where the inspection or test utilizes sampling plans, adjust the AQL. For example, if non-critical products have a 1.0% AQL, then critical products might use 0.65% or 0.40%.

The device manufacturer must monitor and re-evaluate the supplier's performance in meeting requirements for the purchased product. One method is to increase the re-evaluation frequency for critical suppliers. For example, if non-critical suppliers were re-evaluated every 12 months, then critical suppliers might be evaluated every 6 months.

Note that the monitoring activities could produce a signal, such as too many late deliveries or switch to Tightened Inspection, that could require corrective action and re-evaluation.