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4. Critical supplier details



A critical supplier delivers materials (raw or processed), components (including hardware and software), or services, that may influence the safety and performance of the product.

The following is a non-exhaustive list of examples of critical suppliers:

- suppliers of certain types of raw materials, including; medicinal substances, active ingredients, and material of animal, microbial or recombinant origin.
- suppliers of sterilisation services.
- suppliers of design and development activities for manufacturers holding, or applying for, a full quality assurance Conformity Assessment certificate.
- suppliers that carry out all stages of production and supply on behalf of the manufacturer.

The TGA may list some, or all, of the identified critical suppliers on a Conformity Assessment certificate(s).

Note: In the context of a QMS inspection 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. The manufacturer should determine the type and extent of controls to be applied to outsourced processes or purchased products from the risk management that is applied throughout product realisation. (See clauses 7.1, 4.1, and 7.4.1 of ISO13485:2003).

Copy this section for each critical supplier:

Supplier's name	
Supplier's physical address	
TGA Client ID (if available)	
Scope (i.e. stages performed at this site or services provided for which device[s])	