IMDR QMS WG
Comment Form

Date: Deadline 6 July 2026	Document: **Guidance on the Control of Products and Services Obtained from Suppliers**

Name/Organization	Line number	Section	Comments	Proposed change	Resolution
GMTA	75-76	Scope	The scope appropriately identifies manufacturers as the primary audience and indicates that the guidance may also be used by other interested parties, such as importers and distributors. To avoid unintended interpretation that importers or distributors are expected to apply manufacturer-level supplier controls, please consider clarifying that use by these parties should be limited to activities applicable to their role and responsibilities under the relevant jurisdiction.	Please consider revising this part as follows: “This guidance is applicable to manufacturers of medical devices, irrespective of their size, and can be used by other interested parties providing a service or product, such as importers and distributors, as applicable to their role and responsibilities under the relevant regulatory framework.”	
GMTA	249	4 (Definitions)	The term 'critical attribute' is used extensively throughout the document as the central driver of risk assessment and control decisions (appearing in Sections 5.1, 5.2, 5.3, 5.4, and 5.5), yet it is not defined in Section 4. This may create ambiguity in interpretation and application across different manufacturers and regulatory jurisdictions.	Add the following definition to Section 4: 'Critical Attribute: A characteristic of a supplied product or service that, if outside its specified range or absent, could adversely affect the safety, performance, or quality of the final medical device or its realization processes.'	
GMTA	280	General Principles	The example list includes “marketing” as a service provider. This term is broad and may be interpreted to include general commercial marketing services that do not affect how the product is designed, manufactured, or any other aspect that could affect the quality of the product. To avoid overextending supplier-control expectations to purely commercial activities, we recommend removing “marketing” from the example list. This would improve clarity and maintain alignment with the risk-based approach described in the guidance, where the type and extent of supplier controls should be proportional to the risks associated with the supplied product or service. “Consulting” is similarly very broad and for purchasing controls should be narrowed to “QMS relevant” consulting. Not all consulting needs to be governed by the Purchasing Controls portion of the QMS.	Service providers: e.g. regulatory, ~~marketing,~~ consulting (QMS relevant), R&D, Product development, CRO, pest control, sterilisation, packaging, coating, storage/distribution/transport, medical device installation and servicing.	

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GMTA	333-34	5.1.1	AI algorithms and SaaS cloud platforms are listed as examples of purchased products in Section 5.1.1 but receive no further guidance. These suppliers present unique control challenges that may be incompatible with the traditional supplier control model: (a) continuous silent updates without change notification; (b) restricted audit access due to IP or contractual limitations; (c) algorithm opacity limiting transparency; (d) cross-border data residency creating regulatory compliance complexity. Without specific guidance, manufacturers face significant uncertainty in applying this document to AI/software suppliers.	Add a dedicated subsection for Software and AI Suppliers addressing: (a) definition of critical attributes for software/AI outputs (e.g., algorithm performance metrics, sensitivity/specificity thresholds, bias validation); (b) acceptable alternative audit evidence (SOC 2 Type II, ISO/IEC 27001, third-party algorithm audits); (c) contractual requirements for algorithm update notifications to the manufacturer before deployment. Cross-reference IMDRF N66 (SaMD) for consistency.	
GMTA	373-374	5.1.2	The bullet refers to “business capabilities” and “business bandwidth/capacity.” These terms are broad and may be interpreted as general commercial or internal resourcing considerations rather than factors directly relevant to identifying product/service requirements or required process knowledge. Since Section 5.2 separately addresses supplier business, operational, and technological capability during supplier selection, we recommend revising this bullet to focus on the manufacturer’s internal expertise, resources, and capacity only where relevant to determining whether the product or service should be performed internally or obtained from an external supplier. This proposed revision would improve clarity and avoid duplication between the planning and supplier-selection sections.	~~Business capabilities to a~~ Assessment of the ~~need of external vs~~ manufacturer’s internal expertise, resources, and capacity to determine whether the product or service should be obtained internally or from an external supplier, and to inform the type and extent of supplier controls, as applicable ~~internal services including expertise and business bandwidth/capacity~~	

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GMTA	378-379	5.1.2	The bullet includes “ethical considerations, commercial and/or corporate requirements” as examples of other applicable requirements. These terms are broad, introduce ambiguity, and may be interpreted to include general business or corporate expectations that are not directly relevant to supplier-control planning. To improve clarity and avoid overextending QMS supplier-control expectations, we recommend revising these examples to focus on applicable regulatory and other requirements only where they may affect the supplied product/service, product realization, regulatory compliance, QMS effectiveness, continuity of supply, safety, or performance. This proposed revision would maintain alignment with the risk-based approach described in the guidance and avoid ambiguity regarding purely commercial or corporate considerations.	➢ Other applicable requirements, such us environmental protection, Occupational Health and Safety, Good Laboratory Practices, embargoes, ~~ethical considerations, commercial and/or corporate requirements, etc…~~ and other applicable legal, regulatory, or organizational requirements where they may affect the supplied product/service, product realization, regulatory compliance, QMS effectiveness, continuity of supply, safety, or performance.	
GMTA	394-395	5.1.3	Please replace “Occupational Health and Safety Requirements” as an example of relevant regulatory practices. These requirements are typically managed through other processes (e.g., supplier qualification, selection, and monitoring) rather than being defined as product or product realization requirements. Consider adding language to address requirements that may indirectly impact product realization or QMS effectiveness.	3. Identify any relevant regulatory requirements (these may relate to the product/service directly or impact the product, product realization or QMS indirectly (e.g., environmental protection and ~~Occupational Health and Safety requirements~~ other applicable legal and regulatory requirements that may indirectly impact product realization or QMS effectiveness).	

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GMTA	406-407	5.1.3	The question, “Does the supplier currently manufacture parts for the medical device regulated industry or is this their first?” may unintentionally imply that prior experience in the medical device industry is expected or preferred. While supplier experience may be relevant to risk identification, prior medical device experience should not be treated as a prerequisite or proxy for supplier capability. Many components or services may be appropriately sourced from suppliers outside the medical device sector, including off-the-shelf electronic components, commercial software, hardware, or other products/services that can be adequately controlled through specifications, verification, validation, supplier qualification, and other risk-based controls. To avoid unintended bias and improve alignment with the risk-based approach, please consider revising the approach to focus on assessing supplier capabilities to meet the manufacturer’s specified requirements and applicable controls, rather than prior industry-specific experience.	~~Does the supplier currently manufacture parts for medical device regulated industry or is this their first?~~ Has the supplier demonstrated the capability, experience, and controls necessary to meet the manufacturer’s specified requirements and applicable quality, safety, performance, regulatory, and QMS-related expectations for the supplied product or service?	
GMTA	447-448	5.1.4	Please clarify that “Key Performance Indicators” and “Response Times” should be quality or risk-based when used as examples of supplier controls. These terms may be interpreted broadly as general business metrics if not clearly linked to supplier-control objectives. However, Key Performance Indicators and Response Times can be appropriate supplier controls where they are tied to the supplier’s ability to meet specified requirements, maintain critical attributes, communicate changes, respond to nonconformities, support corrective and preventative action activities, or ensure continuity of supply.	(i) For the supplier: • Control of external supplier's production or supply chain, including supplier audits • Quality or risk-relevant Key Performance Indicators • Response Time where relevant to product/service conformity, change notification, nonconformity handling, CAPA, continuity of supply, or QMS effectiveness	

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GMTA	465-466	5.2	The sentence states that supplier evaluations should include “projected growth as well as disaster-planning.” “Projected growth” is broad and may be interpreted as requiring manufacturers to evaluate a supplier’s general business growth strategy, which may not be directly relevant to supplier-control activities or product/service conformity. To improve clarity and avoid overextending QMS supplier-control expectations to general business planning, we recommend removing “projected growth.” Disaster or business-continuity planning may remain relevant where it affects the supplier’s ability to consistently provide products or services that meet specified quality, safety, performance, reliability, availability, or QMS-related requirements.	When selecting potential suppliers, the manufacturer should thoroughly evaluate their business and operational capabilities, including technological competence, to ensure that the supplier can deliver the necessary quality, safety, performance and reliability of the products and services. These evaluations should also include ~~projected growth as well as~~ disaster planning or business continuity of supply or the supplier’s ability to meet specified requirements.	
GMTA	481-483	5.2.2	Please revise the sentence to incorporate language for performance indicators that “may impact the quality, availability, or control of the product or service.” This clarification improves usability and ensures the focus remains on quality-related activities that directly affect the product or service provided.	The operational capability should be investigated to determine whether the supplier is able and willing to adapt and respond to performance indicators required by the manufacturer~~, such as~~ that may impact the quality, availability, or control of the product or service ~~(e.g., lead times, on-time delivery, response time, etc.)~~	
GMTA	504	5.2.4	The example list includes “capacity planning” as documentation or records provided by the supplier. This term may be interpreted broadly as requiring general business-planning information that is not always relevant to supplier-control activities. However, supplier capacity information may be relevant where it affects the supplier’s ability to meet specified requirements, maintain continuity of supply, or consistently provide products or services that meet quality, safety, performance, reliability, availability, or QMS-related requirements. To that end, to improve clarity and avoid overextending supplier-control expectations to general business records, we recommend qualifying this example.	Documentation and records provided by the supplier, such as environmental control records, equipment maintenance programs, calibration records, qualification records of appropriate personnel, process validation records, ~~capacity planning,~~ or certificates.	

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GMTA	506	5.2.4	The phrase “Fulfillment of the predefined criteria and decision rationale” is unclear and should be reworded to better describe documentation of the rationale for selecting the potential supplier, including evidence that the supplier can meet the pre-defined selection criteria. Clarifying this language would improve readability and support consistent implementation.	➢ ~~Fulfillment of the predefined criteria and decision rationale~~ Documented rationale for selecting the potential supplier, including the supplier's ability to meet pre-defined selection criteria.	
GMTA	543-45	5.3.1	The draft cautions that manufacturers “should be cautioned against relying solely on certification” but does not provide guidance on acceptable combinations of evidence when on-site audits are not feasible (e.g., due to geopolitical restrictions, supplier Intellectual Property confidentiality constraints, or resource limitations for smaller manufacturers). This leaves manufacturers without clear direction on how to demonstrate compliance in such scenarios.	Add a practical table or worked example to Section 5.3.1 showing acceptable evidence combinations by risk tier. For example: ISO 13485 certificate plus supplier questionnaire, in addition to incoming product testing would be considered acceptable for medium-risk components where on-site audit is not feasible.	
GMTA	574-575	5.3.1	Please revise the sentence, “Records of communications need to be maintained,” to specify the types of communications expected. The current statement is broad and may lead to inconsistent interpretation. Please consider aligning the language that clearly defines the scope and ensures focus on communications directly related to supplier requirements.	The relevant information gathered and compiled should be communicated throughout and should be considered by the manufacturer as well as the supplier. Records ~~of~~ pertaining to the communication of requirements to be fulfilled by the supplier need to be maintained.	
GMTA	581-582	5.3.1	Please revise the sentence, “In cases where there is only one supplier available (i.e., single-source supplier), the selection criteria need to be met without concessions,” to further clarify that quality requirements must not be compromised due to limited supplier availability.	In cases where there is only one supplier available (i.e., single-source supplier) ~~the selection criteria need to be met without concessions. However,~~ the manufacturer ~~can implement control actions (see Section 5.4), which compensate for any gaps in supplier control~~.should ensure the predefined selection criteria are met without quality being waived or reduced.	

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GMTA	590	5.3.2	The reference to “expiry of the supplier acceptance/approval” should be removed, as there is no formal requirement for supplier approval to expire; ongoing monitoring and management is addressed through established business processes. It is unclear how a manufacturer would proactively determine an appropriate expiration date; establishing mechanisms for ongoing monitoring and re-evaluation of suppliers is a more effective approach aligned with current standard/regulation requirements.	Formal record of the manufacturer’s acceptance / approval of the supplier (by an authorised person) needs to be clearly documented, defining the details of the supplier, date ~~and expiry~~ of the acceptance / approval, scope of the acceptance / approval, and any restrictions. Only approved suppliers can be used.	
GMTA	607	5.4	The figure includes the question “Can arrangements ensuring supplied product continues to comply be implemented?” This wording is unclear in its current state and difficult to interpret. Since Section 5.4 explains that controls should ensure products/services meet critical attributes and that necessary controls are established, implemented, and maintained, we recommend revising the figure to use clearer language focused on the supplier’s ability to continue meeting critical attributes and applicable requirements.	In the figure, please revise the question as follows: ~~Can arrangements ensuring supplied product continues to comply be implemented?~~ Can the supplier continue to meet the critical attributes of the supplied product?	
GMTA	607	5.4	Recommend clarifying the use of “100%” in this figure, as the current intent is unclear. Specifically, it is not evident whether “100%” refers to coverage of all critical attributes (i.e., all critical specification requirements are monitored) or to the expectation that all manufactured product undergoes 100% verification of all critical attributes.	Please add a note to the figure or revise the relevant figure text to clarify the intended meaning of “100%.”	
GMTA	655-656	5.5	The phrase “regardless of whether problems have been identified” is broad and could be interpreted inconsistently. To improve clarity, the sentence should specify that periodic supplier re-evaluation is expected even when no issues have been identified with the supplier’s performance. This clarification aligns with the purpose of re-evaluation.	The organisation needs to plan and perform periodic supplier re-evaluations, regardless of whether ~~problems~~ performance issues have been identified at the supplier.	

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GMTA	657	5.5	The phrase “needs to” may be interpreted as prescriptive and imply that every listed element is mandatory for every supplier re-evaluation, regardless of supplier risk or the nature of the supplied product/service. To maintain the advisory nature of the guidance and align with the risk-based approach described in this section, we recommend revising the wording to “should include, as applicable.” This preserves the expectation that re-evaluation should assess the supplier’s continued ability to meet specified critical product/service attributes while allowing manufacturers to determine the appropriate scope of re-evaluation based on risk.	In addition, re-evaluation ~~needs to~~ should include, as applicable:	
GMTA	662-669	5.5	We recommend removing the second bullet related to the currency of information for the supplier’s initial or previous approval. Supplier onboarding is a point-in-time activity, after which supplier suitability is maintained through ongoing performance monitoring. Continued evaluation is conducted through performance monitoring processes.	• Review the continued adequacy of supplier selection criteria • ~~Review the currency of the information which formed the basis of the supplier’s initial or previous approval~~ • Identify new requirements and changes impacting the delivered product/service (e.g., new regulatory requirements) • Review of the effectiveness of the implemented supplier controls (e.g., supplier audit program, supplier agreements)	
GMTA	663	5.5	Please rephrase the bullet “Review of the effectiveness of the implemented supplier controls,” as the current wording is unclear and may be interpreted as focusing only on the manufacturer’s control mechanisms rather than the supplier’s performance against those controls. To improve clarity, we recommend revising the bullet to focus on whether implemented supplier controls remain suitable and effective in ensuring the supplied product/service continues to meet specified requirements.	• Review ~~the continued adequacy of supplier selection criteria~~ whether implemented supplier controls remain suitable and effective in ensuring the supplied product/service continues to meet specified requirements, based on supplier performance, monitoring data, and applicable changes.	

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GMTA	689-94	Sec 5.5	The continuous monitoring section does not address supplier ownership changes (mergers, acquisitions, change of controlling entity). Such events can fundamentally alter a supplier's QMS, manufacturing processes, and business reliability without triggering any explicit change notification obligation under current supplier agreements.	Add a provision to Section 5.5 recommending that supplier agreements include contractual obligations for the supplier to notify the manufacturer of material organizational changes, including ownership transfers, facility relocations, and significant workforce restructuring, within a defined timeframe (e.g., 30 days prior or as soon as practicable).	
GMTA	749/754	5.7.1	The Supplier A example includes “Is more costly than Supplier B.” In a worked example focused on supplier controls for a high-risk sterilization process, including cost as a supplier attribute may unintentionally suggest that cost is a determining factor in quality-based supplier selection. Cost may be considered as a secondary business factor only after the manufacturer has determined that the applicable quality, safety, performance, regulatory, and QMS-related requirements and controls can be met. To avoid ambiguity and maintain alignment with the risk-based supplier-control approach, we recommend removing the cost comparison from the supplier attribute list or clarifying that cost is not used to reduce or bypass required supplier controls.	• Can perform routine irradiation. • Can perform dose verification, dose audits, and dose mapping. • Cannot perform microbiological (bioburden and sterility) testing. • Is able to store products after sterilisation. • Can perform irradiation in timely manner. • ~~Is more costly than Supplier B.~~	

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GMTA	756	5.7.1	The Supplier B example includes "Is cheaper than Supplier A." In a worked example focused on supplier controls for a high-risk sterilization process, including cost as a supplier attribute may unintentionally suggest that cost is a determining factor in quality-based supplier selection. Cost may be considered as a secondary business factor only after the manufacturer has determined that applicable quality, safety, performance, regulatory, and QMS-related requirements and controls can be met. To avoid ambiguity and maintain alignment with the risk-based supplier-control approach, we recommend removing the cost comparison from the supplier attribute list or clarifying that cost is not used to reduce or bypass required supplier controls.	• Can perform routine irradiation. • Cannot perform dose verification, dose audits, and dose mapping. • Cannot perform microbiological (bioburden and sterility) testing. • Is able to store products after sterilisation. • Can perform irradiation in timely manner. • ~~Is cheaper than Supplier A.~~	
GMTA	772-773	5.7.1	Please revise the sentence "However, engaging Supplier B and Supplier C services is cheaper than engaging Supplier A "as this example compares suppliers based on cost which should not be a consideration on quality-based decisions. Instead, provide an example that compares other factors when deciding on which supplier to select.	"However, engaging Supplier B and Supplier C services is ~~cheaper~~ more timely than engaging Supplier A."	

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