



## Draft Document

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# Guidance on the Control of Products and Services Obtained from Suppliers

AUTHORING GROUP

**Quality Management Systems Working Group**

Date

# Preface

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# 48 Introduction

49 This IMDRF guidance document is intended for medical device manufacturers and it is expected that  
50 the reader is familiar with regulatory quality management system requirements within the medical  
51 devices sector. This guidance document may also be useful to regulatory authorities, auditing  
52 organisations and suppliers. This guidance document is intended for educational purposes and it is  
53 not intended to be used to assess or audit compliance with regulatory requirements.

54

55 Existing regulatory requirements, such as Sections 4.1.5 and 7.4 of ISO13485:2016, require  
56 organizations to control products and services obtained from suppliers. These requirements call for  
57 the type and extent of controls to be established and documented within the organization's quality  
58 management system. Control could be defined and documented in the form of contractual  
59 arrangements, quality plans or other types of documents.

60

61 Several medical device quality management system regulations have their requirements harmonized  
62 around ISO 13485. Therefore, familiarity with its requirements and definitions is recommended for the  
63 application of this guidance. Furthermore, ISO/TC 210 have published a practical guidance on the  
64 development, implementation and maintenance of quality management systems in accordance with  
65 ISO 13485.

66

67 This is a revision of the document GHTF SG3 (Quality Management System - Medical Devices -  
68 Guidance on the Control of Products and Services Obtained from Suppliers - December 2008) to  
69 reflect the current state of the art and experience gained from use of the initial version.

# 70 **Scope**

71 This document provides regulatory guidance for manufacturers on the control of products and  
72 services obtained from suppliers, throughout the life cycle of medical devices.

73 Note: This guidance applies to all medical devices, including IVD medical devices and combination  
74 products (if regulated as medical devices).

75 This guidance is applicable to manufacturers of medical devices, irrespective of their size, and can be  
76 used by other interested parties providing a service or product such as importers and distributors.

77

# 78 **References**

## 79 **3.1. IMDRF/GHTF Documents**

- 80 • GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD)
- 81 Medical Device'
- 82 • GHTF/SG1/N55:2009 Definitions of the Terms Manufacturer, Authorized Representative,
- 83 Distributor and Importer

## 84 **3.2. Standards**

- 85 • ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for
- 86 regulatory purposes
- 87 • ISO 14971:2019 Medical Devices – Application of risk management to medical devices
- 88 • ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary

# 89 Definitions

90 Within the context of this guidance document, the terms used follow the definitions below. It should be  
91 taken into consideration that some terms definitions might have different definitions in different  
92 jurisdictions

## 93 **4.1. Purchased Product (ISO 13485: 2016, 3.16)**

94 product provided by a party outside the organization's quality management system

95

96 Note 1 to entry: The provision of product does not necessarily infer a commercial or financial  
97 arrangement.

## 98 **4.2. Provider/Supplier (ISO 9000:2015, 3.2.5)**

99 organization (3.2.1) that provides a product (3.7.6) or a service (3.7.7)

100

101 EXAMPLE Producer, distributor, retailer or vendor of a product or a service.

102

103 Note 1 to entry: A provider can be internal or external to the organization.

104

105 Note 2 to entry: In a contractual situation, a provider is sometimes called "contractor".

## 106 **4.3. External Provider/External Supplier (ISO 9000:2015, 3.2.6)**

107 provider (3.2.5) that is that is outside the organization's quality management system (3.2.1)

108

109 EXAMPLE Producer, distributor, retailer or vendor of a product (3.7.6) or a service (3.7.7)

## 110 **4.4. Service (ISO 9000:2015, 3.7.7)**

111 output (3.7.5) of an organization (3.2.1) with at least one activity necessarily performed between the  
112 organization and the customer (3.2.4)

113

114 Note 1 to entry: The dominant elements of a service are generally intangible.

115

116 Note 2 to entry: Service often involves activities at the interface with the customer to establish  
117 customer requirements (3.6.4) as well as upon delivery of the service and can involve a continuing  
118 relationship such as banks, accountancies or public organizations, e.g. schools or hospitals.

119

120 Note 3 to entry: Provision of a service can involve, for example, the following: — an activity  
121 performed on a customer-supplied tangible product (3.7.6) (e.g. a car to be repaired); — an activity  
122 performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a  
123 tax return); — the delivery of an intangible product (e.g. the delivery of information (3.8.2) in the  
124 context of knowledge transmission); — the creation of ambience for the customer (e.g. in hotels and  
125 restaurants);

126

127 Note 4 to entry: A service is generally experienced by the customer.

#### 128 **4.5. Product (ISO 9000:2015, 3.7.6):**

129 output (3.7.5) of an organization (3.2.1) that can be produced without any transaction taking place  
130 between the organization and the customer (3.2.4)

131

132 Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place  
133 between provider (3.2.5) and customer, but can often involve this service (3.7.7) element upon its  
134 delivery to the customer.

135

136 Note 2 to entry: The dominant element of a product is that it is generally tangible.

137

138 Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (3.10.1) (e.g. tyres).  
139 Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft  
140 drinks). Hardware and processed materials are often referred to as goods. Software consists of  
141 information (3.8.2) regardless of delivery medium (e.g. computer programme, mobile phone app,  
142 instruction manual, dictionary content, musical composition copyright, driver's license).

#### 143 **4.6. Process (ISO 9000:2015, 3.4.1)**

144 process set of interrelated or interacting activities that use inputs to deliver an intended result

145

146 Note 1 to entry: Whether the "intended result" of a process is called output (3.7.5), product (3.7.6) or  
147 service (3.7.7) depends on the context of the reference.

148

149 Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a  
150 process are generally the inputs to other processes.

151

152 Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to  
153 as a process.

154

155 Note 4 to entry: Processes in an organization (3.2.1) are generally planned and carried out under  
156 controlled conditions to add value.

157

158 Note 5 to entry: A process where the conformity (3.6.11) of the resulting output cannot be readily or  
159 economically validated is frequently referred to as a "special process".

160

161 Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management  
 162 system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives,  
 163 Part 1. The original definition has been modified to prevent circularity between process and output,  
 164 and Notes 1 to 5 to entry have been added

#### 165 **4.7. Objective evidence (ISO 9000:2015, 3.8.3)**

166 objective evidence data (3.8.1) supporting the existence or verity of something

167

168 Note 1 to entry: Objective evidence can be obtained through observation, measurement (3.11.4), test  
 169 (3.11.8), or by other means.

170

171 Note 2 to entry: Objective evidence for the purpose of audit (3.13.1) generally consists of records  
 172 (3.8.10), statements of fact or other information (3.8.2) which are relevant to the audit criteria (3.13.7)  
 173 and verifiable.

#### 174 **4.8. Medical Device (GHTF/SG1/N55:2009, 5.1)**

175 instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software,  
 176 material or other similar or related article, intended by the manufacturer to be used, alone or in  
 177 combination, for human beings, for one or more of the specific medical purpose(s) of:

178

- 179 — diagnosis, prevention, monitoring, treatment or alleviation of disease;
- 180 — diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- 181 — investigation, replacement, modification, or support of the anatomy or of a  
 182 physiological process;
- 183 — supporting or sustaining life;
- 184 — control of conception;
- 185 — disinfection of medical devices;
- 186 — providing information by means of *in vitro* examination of specimens derived from  
 187 the human body;

188

189 and does not achieve its primary intended action by pharmacological, immunological or metabolic  
 190 means, in or on the human body, but which may be assisted in its intended function by such means

191

192 Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but  
 193 not in others include:

194

- 195 — disinfection substances;
- 196 — aids for persons with disabilities;
- 197 — devices incorporating animal and/or human tissues;
- 198 — devices for *in vitro* fertilization or assisted reproduction technologies.

199

#### 200 **4.9. Manufacturer (GHTF/SG1/N071 2012, 5.1)**

201 natural or legal person with responsibility for design and/or manufacture of a medical device with the  
 202 intention of making the medical device available for use, under his name; whether or not such a  
 203 medical device is designed and/or manufactured by that person himself or on his behalf by another  
 204 person(s).

205

206 Note 1 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance  
 207 with all applicable regulatory requirements for the medical device in the countries or jurisdictions  
 208 where it is intended to be made available or sold, unless this responsibility is specifically imposed on  
 209 another person by the Regulatory Authority (RA) within that jurisdiction.

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Note 2 to entry: The manufacturer’s responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: ‘Design and/or manufacture’, as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

237 **4.10. Outsource (ISO 9000:2015, 3.4.6)**

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make an arrangement where an *organization outside of the organization’s quality management system* (3.2.1) performs part of an organization’s function or *process* (3.4.1).

Note 1 to entry: An external organization is outside the scope of the *management system* (3.5.3), although the outsourced function or process is within the scope.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

247 **4.11. Risk (ISO 14971:2019, 3.18)**

248

combination of the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that *harm* (3.3)

249

# General Principles

250 These general principles, found throughout this guidance document, are fundamental for the control  
251 of suppliers by manufacturers.

252 The appropriate control of suppliers is essential element/necessary to ensure medical device safety  
253 and performance. Therefore, manufacturers should establish and implement a robust purchasing  
254 process including supplier control and management. The intent of the purchasing process is to ensure  
255 that purchased, subcontracted, or otherwise received products and/or services conform to specified  
256 requirements. The manufacturer is expected to establish and maintain documented procedures for  
257 planning and performing purchasing activities (including pre and post-market activities) and to keep  
258 the necessary records.

259 Regulatory authorities and third parties may inspect/audit a manufacturer to confirm that objective  
260 evidence of control over products and services from suppliers is present, or readily available, at the  
261 manufacturer's site.

262 There may be many different types of suppliers and different terms are used for these organisations  
263 (subcontractors, suppliers, providers, outsourced contractors, etc...).

264 All suppliers (irrespective of whether they are external or internal to the manufacturer's organization)  
265 need to be subject to the control of the manufacturer. The level/extent of the controls applied needs  
266 to be proportional to the risks associated with the product and/or service being supplied. The control  
267 activities consist of a balance of supplier controls (e. g. supplier evaluation and approval) and  
268 inspection/verification activities (e.g. incoming goods verification, pre-production verification activities).  
269 While these activities may be carried out, on behalf of the manufacturer, by an independent party, the  
270 manufacturer retains the ultimate responsibility for all functions within their own quality management  
271 system including the purchasing process (i.e. the ultimate responsibility cannot be relinquished or  
272 delegated).

273 When the supplier is part of the same organization but operates under a separate quality  
274 management system, they are to be controlled in a similar way as external suppliers.

275 When a medical device manufacturer chooses to utilize suppliers, the manufacturer needs to ensure  
276 control over any product or service obtained from such suppliers as defined within the quality  
277 management system (QMS). The controls may extend further if a supplier subcontracts work.

278 A supplier or provider is an organisation that provides a product or a service, examples include (but  
279 not limited to):

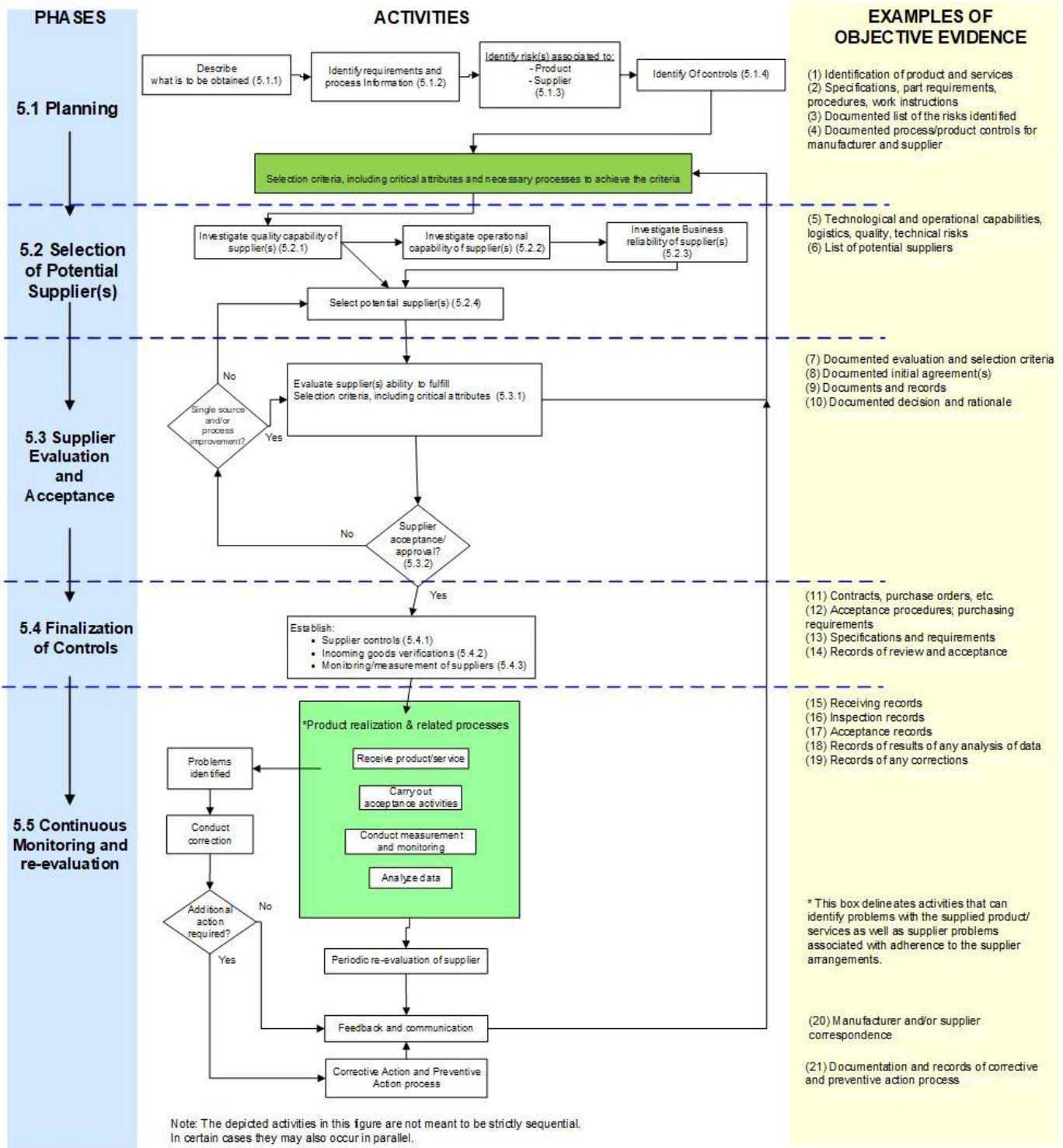
280 - Service providers: e.g. regulatory, marketing, consulting, R&D, Product development, CRO, pest  
281 control, sterilisation, packaging, coating, storage/distribution/transport, medical device installation and  
282 servicing.

283 - Manufacturing contractors: e.g. parts/raw materials/components suppliers or organisations  
284 producing the semi-finished/finished device or part of the manufacturing process, on behalf of the  
285 legal manufacturer.

286 The process of establishing controls for products and services obtained from suppliers typically  
287 comprises six phases, which include:

- 288 • Planning
- 289 • Selection of potential supplier(s)
- 290 • Supplier evaluation and acceptance
- 291 • Establishment of control and change management

- 292 • Delivery, measurement and monitoring, including control of changes
- 293 • Feedback and communication, including Corrective Action and Preventive Action process
- 294 Management of changes is fundamental and needs to be considered for each of the phases.
- 295



298

## 299 **5.1. Planning**

300 Throughout the life cycle of a new or existing medical device, manufacturers may need products or  
 301 services from a supplier. Therefore, the manufacturer's QMS should include, where deemed  
 302 necessary, planned controls on these items, such as materials, parts, components, sterilisation,  
 303 training, testing, regulatory services, quality services or document archiving (see 5.1.1 for additional  
 304 examples)

305 When establishing controls for product and/or services from suppliers, it is essential to start with the  
 306 planning phase. The outcome of this activity might include design and development plans, quality  
 307 plans, purchasing plans, and other documents as stipulated by the manufacturer's QMS. The  
 308 manufacturer should consider the objectives, risks, requirements, processes and resources, ensuring  
 309 that effective controls are implemented and regulatory obligations are satisfied. Depending on various  
 310 inputs and considerations (e.g., costs, availability, sustainability, location) the manufacturer may  
 311 decide to manufacture the given product and/or to perform the activities in house).

312 It is essential that the criteria established ensure that the selection of suppliers meets measurable  
 313 quality objectives along with other factors like corporate, commercial, ethical, political, environmental  
 314 aspects, and the supplier's ability to consistently deliver on time.

315 Planning lays the groundwork for determining the appropriate level of control over products and  
 316 services obtained from suppliers. These plans are generally documented and approved, as part of the  
 317 manufacturer's QMS.

318 Planning provides the direction for establishing the extent of controls for product and services  
 319 obtained from suppliers. These plans are typically documented and approved, as part of the QMS.

### 320 **5.1.1. Identification of the product or service to be obtained from supplier(s)**

321 During the planning phase, the products and/or services in scope (from suppliers) should be  
 322 identified. The products may include materials, components and subassemblies being incorporated  
 323 into the manufactured devices and/or materials used in product realization and/or impacting product,  
 324 work environment or other QMS activities.

325 These are examples of products/services<sup>1</sup>:

326 Parts and components of the final medical device made either to manufacturer's specifications or  
 327 purchased "off-the-shelf":

- 328 • Mechanical components (screws, washers, helicoils, tubing, valves, pumps, etc.)
- 329 • Electronic components (resistors, capacitors, power supplies, detector arrays, circuit board
- 330 assemblies, etc.)
- 331 • Computer hardware (laptops, recorders, etc.)
- 332 • Commercial software (operating systems, databases, etc.)
- 333 • Software for specified uses (radiation therapy planning software, planning software for hip
- 334 implants, including Artificial intelligence (AI), etc.)
- 335 • Other: glucose test strips, reagents, enzymes, etc.

336

337 Services obtained from suppliers:

- 338 • Design of product and/or label
- 339 • Document archiving
- 340 • Quality and/or regulatory services (pre-clinical evaluation, clinical evaluation, pre/post-market
- 341 activities)

---

<sup>1</sup> The examples listed may be classified differently according to local regulatory requirements

- 342 • Packaging
- 343 • Sterilisation
- 344 • Environmental monitoring (e.g. microbial and particle counts for clean rooms, temperature
- 345 monitoring and/or mapping)
- 346 • Testing
- 347 • Calibration
- 348 • Process validation
- 349 • Transport / storage
- 350 • Representatives of the manufacturer for regulatory purposes (e.g. EU Authorised
- 351 representative, Australian Sponsor, etc....)

352

353 Entire/complete medical device obtained from supplier:

- 354 • Any final medical device made on behalf of the manufacturer under manufacturer's
- 355 specification
- 356 • Supplied medical device used as component in manufacturer's medical device (X-ray tubes,
- 357 ECG cables, medical batteries, patient monitors)

358

### 359 **5.1.2. Identification of specific product/service requirements and the required**

### 360 **process knowledge**

361 Appropriate personnel and stakeholders (such as subject matter experts) should be engaged in all the

362 appropriate steps of the process, starting with the planning phase. Trained personnel should

363 document the specific product/service features required and identify the processes necessary to

364 deliver these products/services in a manner that meets required criteria. The areas where these

365 personnel may assist could include:

- 366 ➤ Identifying the product and service requirements/specifications and/or master samples for
- 367 parts, materials, process, software, environment, testing, etc, identifying critical attributes of
- 368 the products, and detailed selection criteria to be met by the required services
- 369 ➤ QMS process requirements, such as procedures/work instructions for adverse event
- 370 reporting, QMS auditing, post market data, design, manufacturing, calibration, maintenance,
- 371 verification activities, etc.
- 372 ➤ Regulatory requirements relative to the markets the business is planning to access
- 373 ➤ Business capabilities to assess the need of external vs internal services including expertise
- 374 and business bandwidth/capacity
- 375 ➤ Project management of the planning, development and implementation phase of the medical
- 376 device
- 377 ➤ Other applicable requirements, such as environmental protection, Occupational Health and
- 378 Safety, Good Laboratory Practices, embargoes, ethical considerations, commercial and/or
- 379 corporate requirements, etc...

### 380 **5.1.3. Identification of risk(s) associated with products/services supplied**

381 During the planning activities, the manufacturer should identify the risks associated with the product

382 or services to be obtained from suppliers.

383 For this purpose, the manufacturer may utilize the concepts and requirements of ISO 14971:2019

384 Medical devices — Application of risk management to medical devices, ISO/TR 24971 – Guidance on

385 the application of ISO 14971 and GHTF/IMDRF Documents on Risk Management Principles and

386 Activities Within a Quality Management System,

387

388 In the process of identifying risks, consideration may be given to the following:

389 1. Identify the critical attributes (i.e. the characteristics of the product/service that, if changed could  
390 change the product in a way that could potentially impact the manufactured product or QMS) of the  
391 supplied product/service.

392 2. Identify the processes necessary to produce/deliver the product/service.

393 3. Identify any relevant regulatory requirements (these may relate to the product/service directly or  
394 impact the product, product realisation or QMS indirectly (e.g. environmental protection and  
395 Occupational Health and Safety requirements)

396

397 The following questions can help in the identification of the risks:

398 - Risks intrinsic to the device/type of product:

399 • Is the part custom built or off-the-shelf?

400 • How complex is the part to manufacture?

401 • What is the criticality of the part? For example, considering a Design Failure Mode & Effects  
402 Analysis (DFMEA)

403 • Which are the hazards and characteristics of the part/component related to safety and  
404 performance?

405 - Risks associated with the supplier:

406 • Does the supplier currently manufacture parts for medical device regulated industry or is this  
407 their first?

408 • Is an alternative supplier (or second supplier) identified?

409 • Has the supplier third party certification and undergoes audits?

410

411 Information about potential suppliers (such as technical, financial, continuity of supply, etc.) should be  
412 used to determine additional potential risks (such as business risks).

413 It should be noted that a potential type of supplier is to be considered in planning, not a specific  
414 supplier (specific suppliers are considered as part of evaluation and approval process).

415 Quality-related risks should be given precedence before other risks are considered. Other risks the  
416 manufacturer may wish to consider would include business risks such as:

417 • Financial viability of the supplier

418 • Continuity of supply (e.g., with respect to geopolitical risks, extreme weather events, disease  
419 outbreaks)

420 • Liability

421 • Amount of work awarded to supplier in view of supplier's overall capacity

422 • Capital investment

423 • Single source suppliers

424 • Supplier company legal status (e.g. licensing)

425 • Corporate considerations

426

#### 427 **5.1.4. Risk assessment and identification of controls**

428 The identified risk(s) should be evaluated to determine the type and extent of control(s) required. The  
429 extent of verification activities shall be based on the supplier evaluation results and proportionate to  
430 the associated risks of the product or service obtained from the supplier

431 During the planning phase, it is essential for the manufacturer to identify the high-level potential risks  
432 and eventual controls to ensure that they are thoroughly captured during the subsequent phases (for  
433 further details on controls, see section 5.4 Finalization of controls).

434

435 The manufacturer should:

- 436 1. Identify what needs to be monitored/measured to ensure the supplied product/service  
437 maintains its critical attributes (as identified in 5.1.4)
- 438 2. Identify the hazards that could potentially have negative impact on the critical attributes of  
439 product/service
- 440 3. Identify the eventual controls that will mitigate the risks of the hazards negatively impacting  
441 the critical attributes of product/service
- 442 4. Identify any additional training needs.

443 The controls between supplier and manufacturer should be balanced to mitigate the identified risk.  
444 Examples of controls can include:

445 (i) For the supplier:

- 446 • Control of external supplier's production or supply chain, including supplier audits
- 447 • Key Performance Indicators
- 448 • Response times

449

450 (ii) For the manufacturer control of supplied products:

451

- 452 • 100% incoming product verification
- 453 • Reduced (<100%) incoming product verification
- 454 • Incoming goods confirmation of product/supplier on receipt (reliance on supplier's controls)

455

456 (iii) For the manufacturer's control of supplied services:

457

- 458 • Witnessing/evaluation of the service provided by competent personnel.
- 459 • Reliance on external certification

460

461

#### 462 **5.2. Selection of potential suppliers**

463 When selecting potential suppliers, the manufacturer should thoroughly evaluate their business and  
464 operational capabilities, including technological competence, to ensure that the supplier can deliver  
465 the necessary quality, safety, performance and reliability of the products and services. These  
466 evaluations should also include projected growth as well as disaster-planning.

### 467 **5.2.1. Supplier quality capability**

468 The manufacturer should determine the critical attributes of the product/service to be supplied as well  
 469 as product realisation/service criteria to be met (see Section 5.3.1). When selecting potential  
 470 suppliers of products/services, the manufacturer needs to investigate the supplier's ability to fulfil  
 471 these pre-determined product/product realization/service criteria. Only suppliers capable of meeting  
 472 these pre-determined criteria for safety, quality, performance and reliability should be considered  
 473 further. In cases where these criteria are not fully met, prior to moving to the next potential supplier,  
 474 the manufacturer can consider an implementation of planned supplier education/training/development  
 475 that addresses the identified shortcomings. Alternatively, the manufacturer may (where possible)  
 476 decide to implement measures that mitigate the risks of a supplier not fulfilling the selection criteria.

477 For suppliers whose quality capabilities have been confirmed by the manufacturer to meet the defined  
 478 quality objectives, the manufacturer should consider the supplier's operational and business  
 479 capabilities.

### 480 **5.2.2. Supplier operational and technological capability**

481 The operational capability should be investigated to determine whether the supplier is able and willing  
 482 to adapt and respond to performance indicators required by the manufacturer, such as lead times, on-  
 483 time delivery, response time, etc. The scope of the investigation may include the supplier's past  
 484 performance, experience, expertise, and human resources.

485 Investigation of the supplier's technological capability should include the assessment of the supplier's  
 486 ability to meet the manufacturer's product and/or service specifications. Things to consider may  
 487 include the adequacy of manufacturing processes or equipment, information technology, system  
 488 infrastructure, engineering resources, etc.

### 489 **5.2.3. Supplier business reliability**

490 The potential supplier's business capabilities, such as business conduct, practices, reputation and  
 491 financial viability, should be considered by the manufacturer as these could impact the manufacturer's  
 492 ability to deliver safe and effective devices. The outcome of these considerations, coupled with an  
 493 analysis of the potential risks of the product/service provided, should drive the manufacturer's  
 494 decisions about the type and extent of controls of products/services provided by the suppliers

### 495 **5.2.4 Selection of potential supplier**

496 The manufacturer should select potential suppliers according to predefined criteria and the results of  
 497 capability investigations.

498 The processes established by the manufacturer for the selection of the potential suppliers should be  
 499 properly documented:

- 500       ➤ The manufacturer's assessment of the supplier's resources (e.g. facilities, personnel,  
501       infrastructure), current product/service portfolio
- 502       ➤ Documentation and records provided by the supplier, such as environmental control records,  
503       equipment maintenance programs, calibration records, qualification records of appropriate  
504       personnel, process validation records, capacity planning, certificates, etc.
- 505       ➤ Documentation of potential suppliers
- 506       ➤ Fulfillment of the predefined criteria and decision rationale

507

## 508 **5.3. Supplier evaluation and acceptance**

509 This section provides guidance on the process by which the manufacturer evaluates that the selected  
510 potential supplier is capable of supplying product or service in accordance with the manufacturer's  
511 requirements.

512 The evaluation assures that the selection criteria (see 5.1) are met by the suppliers. The extent of  
513 evaluation and acceptance activity performed should be in proportion to the identified risk (see 5.1.3)  
514 of the procured product, and/or services, impacting the safety and effectiveness/performance of the  
515 final product, product realization processes or QMS.

516

517 Generally, the process of supplier evaluation consists of the following:

- 518 • Communication with potential supplier and refinement of the requirements
- 519 • Evaluation of the potential supplier's ability to meet selection criteria
- 520 • Acceptance/Approval of the supplier

521

### 522 **5.3.1. Evaluation of potential supplier's ability to meet selection criteria**

523 Prior to the evaluation of the supplier, the manufacturer should ensure adequate information / data in  
524 relation to quality, operational, technological and business capabilities (see 5.2.1-5.2.3) is available  
525 for consideration. This can be obtained through communication with the potential suppliers (e.g.  
526 through supplier questionnaires or direct contact). The data should be measurable and aimed at  
527 providing necessary evidence to establish that the selection criteria can be met by the potential  
528 supplier.

529 The manufacturer is responsible for communicating the selection criteria to the potential suppliers. In  
530 addition the manufacturer may request data and/or a product samples (e.g. first article, first lot,  
531 prototypes) from the potential supplier in order to evaluate their ability to fulfill the specified  
532 requirements.

533 The manufacturer needs to evaluate potential suppliers based on their ability to meet the defined  
534 selection criteria

535 The evaluation should ensure that:

- 536 a. Adequate data is gathered to demonstrate that the selection criteria have been met. This  
537 comes from a number of sources, e.g. the communications with the supplier, literature,  
538 manufacturer's data.
- 539 b. Data is evaluated to determine whether the potential supplier is capable of fulfilling the  
540 selection criteria. Commensurate with the degree of risk, the data may include evaluation of  
541 first article(s), first lot(s) or prototype(s), auditing of the potential supplier and subcontractors,  
542 data from other organizations, or any combination of thereof. Where appropriate, valid  
543 statistical techniques should be employed. Certification may play a role in evaluating  
544 suppliers but manufacturers should be cautioned against relying solely on certification as  
545 evidence that suppliers have the capability to provide quality products or services.
- 546 c. The evaluation is performed together with the consideration about the necessary controls that  
547 the manufacturer needs to implement (See 5.4)

548

549 Whenever selection criteria cannot be fully met by the potential supplier, other control measures  
550 mitigating the risks of this circumstance need to be implemented. The supplier cannot be fully  
551 approved until all selection criteria are met and all necessary controls are in place. If the gaps are not  
552 addressed through mitigating controls, the manufacturer / organisation need to consider finding an  
553 alternate supplier that is capable of meeting the selection criteria.

554 Based on the collected data and its review additional selection criteria, to be confirmed in the supplier  
555 evaluation, may be identified. These need to be documented (including the risk-based rationales for  
556 their selection) and be controlled under the QMS (including an assessment of impact on  
557 product/service, product/service realisation processes and QMS (see clause 4.1.4).

558 The principles listed above apply to the evaluation of both external and internal suppliers.

559 Examples of supplier data collection and evaluation (used alone or in combination) include:

- 560 – Desktop/ reviews: These involve off-site review of documents and records providing  
561 evidence of supplier meeting the selection criteria.
- 562 – Audits (carried out on-site and/or remote approaches): These are conducted on-site at the  
563 supplier's location(s) and involve review of documents and records demonstrating supplier's  
564 fulfilment of selection criteria as well as verifying the adequacy, suitability and effectiveness of  
565 the supplier's QMS arrangements. When the supplier is using a subcontractor in relation to  
566 the product/service provided to the manufacturer, the audit involves a review of the controls  
567 exerted by the supplier over this third-party subcontractor.
- 568 – Product testing. This involves the testing of product(s) provided by the supplier to establish  
569 the products (and, by inference, the supplier) are able to meet the product/process selection  
570 criteria.
- 571 – Review of relevant data provided by affiliated parties (e.g. corporate partners) to which  
572 products/services are already provided by the supplier.

573 The relevant information gathered and compiled should be communicated throughout and should be  
574 considered by the manufacturer as well as the supplier. Records of communications need to be  
575 maintained.

576 In planning for evaluation of suppliers of products/services, the manufacturer should plan for  
577 contingency arrangements (e.g. back-up suppliers) which might arise, for example, as a result of  
578 geopolitical events, weather-related incidents, or supply chain disruptions. The evaluation of such  
579 suppliers needs to include the assessment of their capability to meet the selection criteria. It is  
580 recommended that this activity is done proactively.

581 In cases where there is only one supplier available (i.e. single-source supplier) the selection criteria  
582 need to be met without concessions. However, the manufacturer can implement control actions (see  
583 Section 5.4), which compensate for any gaps in supplier control.

584

### 585 **5.3.2. Supplier acceptance / approval**

586 No supplier can be fully approved until all selection criteria have been met and all necessary controls  
587 are in place. It is good practice for the selection criteria and relevant controls to be reviewed and  
588 acknowledged or approved by the supplier. Records of these activities should be maintained.

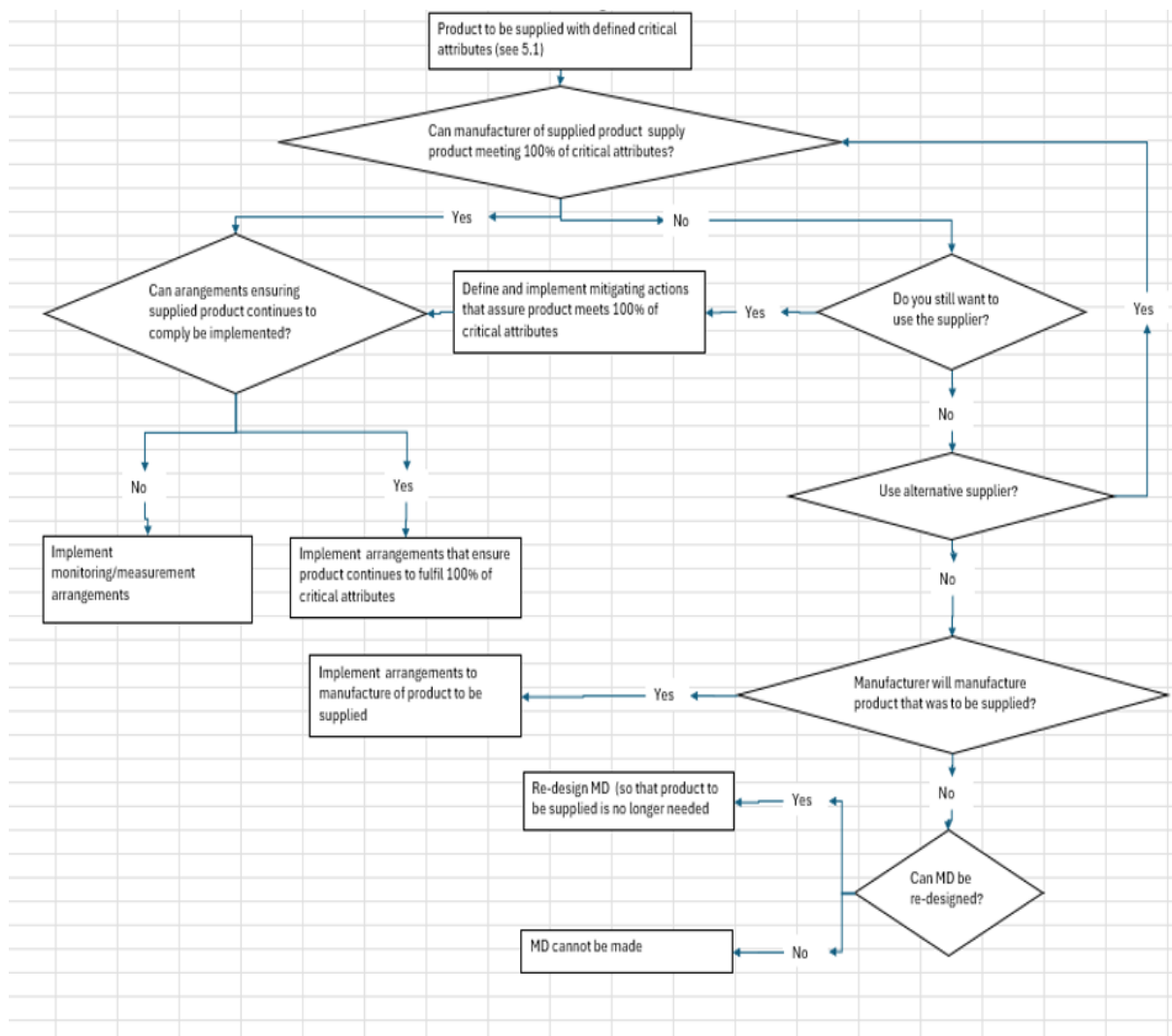
589 Formal record of the manufacturer's acceptance / approval of the supplier (by an authorised person)  
590 needs to be clearly documented, defining the details of the supplier, date and expiry of the  
591 acceptance / approval, scope of the acceptance / approval, and any restrictions. Only approved  
592 suppliers can be used.

593 If a potential supplier is found to be acceptable then the manufacturer needs to document the  
594 acceptance/approval decision in a manner required by the manufacturer's QMS (e.g. by inclusion of  
595 the supplier into a documented Approved suppliers list). Additionally, the records of the results of the  
596 evaluations need to be retained.

597 **5.4. Finalization of controls**

598 Only products and or services that meet the determined selection criteria (see 5.1) can be used in the  
 599 medical device realization. The manufacturer needs to achieve this through the establishment,  
 600 implementation and maintenance of appropriate QMS controls that assure that only products/services  
 601 that meet the critical attributes are supplied and verified. Risks, identified in planning (see 5.1) and  
 602 during supplier selection and evaluation (see 5.3), are considered and assessed to determine the type  
 603 and extent of control(s) required. The arrangements need to ensure that products/services are  
 604 supplied by suppliers only after the suppliers had been evaluated and approved and all the necessary  
 605 controls had been established, implemented and are maintained. Clear lines of responsibilities need  
 606 to be defined by the manufacturer and where relevant be agreed upon by the supplier.

607 An example of a typical thought process in these activities is shown in the Figure below.



608 Typically, the controls relating to supplied products consist of various combinations of supplier  
 609 controls, incoming goods verifications and monitoring/measurements.

610 **5.4.1. Supplier controls**

611 These controls usually established that:

- 612 • The product meets the critical attributes (e.g. through initial testing, review of specifications,  
 613 etc)

- 614       • The supplier is able to produce the product in the same form consistently (e.g. under a robust  
615           QMS, using adequate processes that are validated or the outcome of which is  
616           measured/monitored)
- 617       • The supplier maintains a suitable, adequate and effective QMS that ensures appropriate  
618           change control and notification as well as appropriate action when nonconformities arise.

619 The manufacturer/organisation usually achieves this through documented agreements with the  
620 supplier, on-site or off-site audits, review of relevant documentation (e.g. testing reports, certifications)  
621 or through some other activities (e.g. monitoring/measurement, training, etc).

622 Supplier controls over the suppliers need to be implemented irrespective of whether the supplier is  
623 external (e.g. subcontractor) or internal (e.g. Global corporate partner) supplier to the manufacturer.  
624

#### 625 **5.4.2. Incoming goods verifications**

626 When the supplier controls do not assure all product critical attributes will always be met, the  
627 manufacturer often decides to measure/monitor on incoming goods verification. The extent of this  
628 activity depends on the risk assessment and is subject to any relevant regulatory requirements.  
629 Where the risks are deemed as high, 100% testing or statistically-based testing (e.g. see ISO2859  
630 series of standards) may be selected. This is often implemented even when the supplier controls are  
631 considered as robust. Where the risks are considered low, reduction in the sampling size or in  
632 frequency of testing can also be considered.

633

#### 634 **5.4.3. Monitoring/measurement of suppliers**

635 Control over suppliers who provide product and/or services is often achieved through reliance on  
636 accredited certification of the activity and/or by direct (e.g. witnessing of the activity being performed)  
637 or indirect (e.g. review of protocols and reports) monitoring/measurement. The extent and frequency  
638 of these controls is dictated by the risks of the activities being carried out.

639 When the risk dictates, defined controls around second or further-tier suppliers may be needed.

### 640 **5.5. Continuous monitoring and re-evaluation**

641 Once approved, the suppliers of products/services need to be monitored by the organisation to  
642 ensure the products/services continue to be supplied in compliance with the selection criteria and in  
643 accordance with the agreed arrangements.

644 Typically, monitoring and measurement inputs include:

- 645       • Inspecting/verifying/testing incoming products/services to confirm compliance with critical  
646           attributes
- 647       • Confirmation of testing being performed by the supplier or their contractor
- 648       • In-process and finished good monitoring and measurement during product realisation
- 649       • Supplier audits
- 650       • Review of nonconformities raised in relation to the quality of supplied products/services
- 651       • Review of business, technological and operational performance, according to principles  
652           described in 5.2.

653 These activities can identify problems with the supplied product/service as well as supplier problems  
654 associated with adherence to the supplier arrangements.

655 The organisation needs to plan and perform periodic supplier re-evaluations, regardless of whether  
 656 problems have been identified. The purpose of this re-evaluation is to assess the supplier's continued  
 657 ability (process and output) to meet specified critical product/service attributes. Monitoring and  
 658 measurement data, obtained from the inputs listed above, needs to be trended and analysed using  
 659 valid statistical techniques, whenever relevant.

660 The length of the monitoring intervals influences how early problems can be detected. Earlier  
 661 detection means the organization can take preventive actions rather than solely reactive ones.

662 This output should be assessed used in supplier re-evaluation. In addition, re-evaluation needs to:

- 663 • Review the continued adequacy of supplier selection criteria
- 664 • Review the currency of the information which formed the basis of the supplier's initial or  
 665 previous approval
- 666 • Identify new requirements and changes impacting the delivered product/service (e.g. new  
 667 regulatory requirements)
- 668 • Review of the effectiveness of the implemented supplier controls (e.g. supplier audit program,  
 669 supplier agreements)

670 The frequency of supplier re-evaluation is typically based on the organisation's assessment of the  
 671 risks associated with the supplier and supplied product/service.

672 It is expected that the organisation will communicate with the supplier in relation to the monitoring and  
 673 re-evaluation activities. The frequency of these communications need to be defined and based on  
 674 risk. Feedback should be both positive and negative.

675 The manufacturer should ensure that there are effective lines of communication (including up to date  
 676 contact points) for both parties to discuss problems/complaints or other matters. It is important that  
 677 trust be developed between parties so that any problems can be resolved quickly in a cooperative  
 678 way.

679 Arrangements need to be established, implemented, and maintained to ensure that the supplier  
 680 communicates relevant problems identified in relation to the supplied product/service to the  
 681 organisation. Conversely, problems and nonconformities identified by the organisation, during  
 682 monitoring and measurement, need to be communicated to the supplier. Evidence of corresponding  
 683 corrections and corrective actions implemented by the supplier (or their subcontractor, as required)  
 684 need to be communicated back to the organisation.

685 Depending on the nature of the procured product and/or service obtained from a supplier, portions of  
 686 the activities that are to be performed under CAPA may be delegated by the manufacturer to the  
 687 supplier. The combined CAPA related activities of both the manufacturer and the supplier need to  
 688 satisfy the requirements of applicable regulations and standards.

689 The arrangements need to ensure that the manufacturer and supplier inform each other, in a timely  
 690 manner, of changes that could impact the product quality, product realisation processes, or QMS. It is  
 691 expected that appropriate steps will be taken to establish, implement, and maintain these changes.  
 692 Changes could include improvements, CAPAs, new or revised regulatory requirements, and business  
 693 or operational needs. While some of the CAPA activities may be delegated to a supplier, the overall  
 694 responsibility for these activities resides with the manufacturer.

## 695 **5.6. General QMS requirements**

696 In implementing the supplier control arrangements, the manufacturer needs to ensure that the  
 697 following QMS principles are adhered to:

- 698 • Documented requirements are established, implemented, and maintained (See Clause 4.2.4).
- 699 • Responsibilities and authorities are defined and assigned to relevant personnel (See Clause  
 700 5.5.1).
- 701 • Personnel performing tasks are competent on the basis of appropriate education, training,  
 702 skills, and experience (See Clause 6.2).
- 703 • Records demonstrating compliance with requirements are maintained (See Clause 4.2.5).

- 704 • Activities are performed in an appropriate work environment using approved equipment (See  
705 Clause 6.3-6.4).
- 706 • Appropriate resources need to be allocated (Clause 6.1).
- 707 • Changes are evaluated for their impact on the product/services, the product realisation  
708 processes, and QMS (Clause 4.1.4).
- 709 • Processes are monitored for their functionality (Clause 4.1) and appropriate actions are taken  
710 for improvement (Clause 8.5).

## 711 **5.7. Examples**

712 The examples below illustrate possible options for a manufacturer to established appropriate control  
713 for products and/or services obtained from suppliers.

### 714 **5.7.1. Worked Example 1: Sterile Product**

#### 715 Planning

716 The organisation determines, during design and development activities, that the risk of supplying non-  
717 sterile product is high due to the significant potential for patient harm. Therefore, it decides that the  
718 medical device needs to be sterilised.

719 The organisation establishes that a gamma irradiation sterilisation process needs to be used, as  
720 alternative methods, such as sterilisation by ethylene oxide exposure, are not compatible with the  
721 materials of construction.

#### 722 Critical Attributes of Product

723 The product needs to be sterile by gamma irradiation.

724 The product needs to meet its defined safety and performance requirements.

#### 725 Critical Attributes of Process

726 The sterilisation process needs to comply with ISO 11137.

- 727 • Process validation - the sterilisation process will require
  - 728 ○ A gamma radiation source.
  - 729 ○ Determination of minimum and maximum irradiation doses (e.g. minimum dose  
730 verification and maximum dose studies).
  - 731 ○ Dose mapping.
  - 732 ○ Dose audit.
  - 733 ○ Ability to perform product bioburden determinations and sterility testing in compliance  
734 with ISO 11737 standards.
- 735 • Routine sterilisation will require
  - 736 ○ Ability to deliver doses within the specified range.
  - 737 ○ Ability to qualify and maintain steriliser and source.
  - 738 ○ Ability to store products after sterilisation.

#### 739 Identify Type of Supplier

740 The manufacturer determines that they cannot perform these activities themselves.

741 The manufacturer identifies that they require a gamma irradiation sterilisation service provider to meet  
742 the critical process attributes.

#### 743 Selection of Specific Service Providers

744 The manufacturer identifies Supplier A and Supplier B as having a gamma source and being able to  
745 sterilise goods.

746 The manufacturer contacts Supplier A and Supplier B to perform sterilisation on the manufacturer's  
747 behalf with the following outcome:

748 Supplier A

- 749 • Can perform routine irradiation.
- 750 • Can perform dose verification, dose audits, and dose mapping.
- 751 • Cannot perform microbiological (bioburden and sterility) testing.
- 752 • Is able to store products after sterilisation.
- 753 • Can perform irradiation in timely manner.
- 754 • Is more costly than Supplier B.

755 Supplier B

- 756 • Can perform routine irradiation.
- 757 • Cannot perform dose verification, dose audits, and dose mapping.
- 758 • Cannot perform microbiological (bioburden and sterility) testing
- 759 • Is able to store products after sterilisation.
- 760 • Can perform irradiation in timely manner.
- 761 • Is less costly than Supplier A.

762 Based on the provided communications, the manufacturer decides to extend their investigations and  
763 identifies Supplier C.

764 Supplier C

- 765 • Cannot perform routine irradiation.
- 766 • Can perform dose verification, dose audits, and dose mapping.
- 767 • Cannot perform microbiological (bioburden and sterility) testing.
- 768 • Cannot store product after sterilisation.
- 769 • Can perform irradiation studies in a timely manner.

770 The manufacturer determines that the critical product and process attributes will be met when (1)  
771 Supplier B and Supplier C are engaged together, or (2) when Supplier A is engaged with an additional  
772 supplier to perform microbiological testing. However, engaging Supplier B and Supplier C services is  
773 cheaper than engaging Supplier A.

774 The manufacturer decides to engage Supplier B and Supplier C in combination.

775 Evaluation and Controls

776 The manufacturer confirms the availability of Supplier B and Supplier C and implements agreements  
777 and the following controls:

- 778 • Supplier audits need to be carried out commensurate with the suppliers' known ISO 13485,  
779 ISO 11137 and, as relevant, ISO 11737 compliance.
- 780 • The manufacturer's verification of the sterilisation cycle results needs to be commensurate with  
781 the level of assessment performed at audits.

782 Having implemented the necessary evaluation and controls, the manufacturer approves Supplier B  
783 and Supplier C for the required activities, subject to review on an annual basis. The suppliers are  
784 entered into the Approved Supplier List, which is used by the purchasing department when routine  
785 sterilisation of product is required.

786 The manufacturer verifies, on an ongoing basis, the arrangements and monitors the suppliers'  
787 performance.

788 The annual review needs to consider the currency of information on which the basis of supplier was  
789 approved, as well as the monitoring data gathered by the organisation over the review period.

790 **5.7.2. Worked Example 2: Low risk component**

791 Planning

792 The manufacturer determines, in design and development, that an absence or failure of a given  
 793 component used in the medical device is associated with low risk, in that there would be no impact on  
 794 the product safety and performance, or on the product realisation and other QMS processes.

795 The organisation does not intend to manufacture the component themselves.

796 Critical Attributes of Product

797 The given component needs to be identified and confirmed to be manufactured from an approved  
 798 supplier (Supplier A). The component needs to be of the specified size and appearance.

799 Critical Attributes of Process

800 The manufacturing process needs to reliably produce components consistent with their specification.

801 Identify Type of Supplier

802 Component can be purchased from any warehouse store or can be sourced directly from the  
 803 manufacturer of the component.

804 Selection of Specific Service Providers

805 Supplier A supplies only in quantities exceeding the quantities required and is located halfway across  
 806 the world. The component should be sourced from Hardware Store X as only Hardware Store X sell  
 807 the component manufactured by Supplier A (others have components manufactured by other  
 808 suppliers).

809 Evaluation and Controls

810 No controls will be applied to Supplier A and the product distributor Hardware Store X.

811 The component will be bought from Hardware Store X, confirming the component catalogue number  
 812 and that it was manufactured by Supplier A.

813 Incoming goods verifications will confirm the component complies with the component specification by  
 814 measurement and approved master sample by visual inspection. The manufacturer performs a risk  
 815 assessment and determines that verification activities will be performed on 100% of purchased  
 816 components in the first year. If there are less than 2.5% defects in the first year, the manufacturer will  
 817 proceed to perform verification activities on a statistically relevant sample size of components  
 818 thereafter or will verify a randomly selected representative sample of purchased lots.

819 The re-evaluation of the supplier is to be performed annually. The annual review needs to consider  
 820 the currency of information on which the basis of supplier was approved, as well as the incoming  
 821 inspection data gathered and any other nonconformities identified by the organisation over the review  
 822 period.

823

824

825

826 **5.7.3. Worked example: Scorecard supporting standardized risk assessments**

- 827 • Define score card elements:

•	Subcategory A (Score value 1)	Subcategory B (Score value 3)	Subcategory C (Score value 5)
Category I	•	•	•
Category II	•	•	•

Category III	•	•	•
Category IV	•	•	•
Score per level	•	•	•
Total score	•		

- 828 • Identify 3-4 categories that typically characterize the risk, e.g.
- 829 • Type of supplied product/service
- 830 • Criticality of supplied product/service to final MD
- 831 • Number of potential suppliers
- 832 • Impact of final MD to patient/customer safety
- 833 • Define per category 3 subcategories – based on risk, e.g.
- 834 • Criticality of supplied product/service to final MD, e.g.
  - 835 • Low
  - 836 • Medium
  - 837 • High
- 838 • Nature of supplied product/service, e.g.
  - 839 • Packaging material
  - 840 • Raw material, service
  - 841 • Final MD
- 842 • Define score values for each subcategory level – e.g. 1, 3, 5 (according to the
- 843 increasing risk)
- 844 • During the assessment the scores per category are added up to a total score
- 845 value
  - 846 • The range of the total score values depends on how many categories
  - 847 are included in the scorecard (e.g 4 to 20)
- 848 • Subdivide the total score range into groups (e.g. 3)
- 849 • Define for each group, according to the total risk, mandatory supplier selection evaluation criteria,
- 850 e.g

Total Score	4-8	9-12	12-20
Criteria	<ul style="list-style-type: none"> <li>• Supplier quality capability</li> </ul>	<ul style="list-style-type: none"> <li>• QMS certification</li> <li>• Supplier quality capability</li> <li>• Design specification review</li> <li>• ..</li> </ul>	<ul style="list-style-type: none"> <li>• QMS certification</li> <li>• Supplier quality capability</li> <li>•</li> <li>• Design specification review</li> <li>• Technical/operational capability assessment</li> <li>• ..</li> </ul>

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- Example for score card application:
  - Intermediate material
  - Crucial for MD performance
  - used for IVDR CI. C IVD
  - single source supplier

•	Subcategory A (Score value 1)	Subcategory B (Score value 3)	Subcategory C (Score value 5)
Category I (nature)		3	
Category II (risk to final MD)			5
Category III (impact of final MD on patient safety)		3	
Category IV (number of available suppliers)			5
Score per subcategory	0	6	10
Total score	• 16		
Mandatory evaluation criteria:	<ul style="list-style-type: none"> <li>• QMS certification</li> <li>• Supplier quality capability</li> <li>• Design specification review</li> <li>• Technical/operational capability assessment</li> <li>•</li> </ul>		

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