TS-QMA

Technical Specification:

Quality Assurance Requirements for the Supply of Medical Devices and Medicinal Products to the Bundeswehr

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TS-QMA document history

Version	Remarks
1 August 2019	TS-QMA compiled
8 August 2019	Minor change to layout
21 April 2020	Incorporation of legal amendments
7 May 2020	Incorporation of Regulation (EU) 2020/561

Table of contents

Terms and definitions

The following sources apply for establishing terms and definitions:

- Medical Devices Act, for as long as it still applies to in vitro diagnostics (note: will likely only apply until 25 May 2022)
- EU Medical Devices Adaptation Act (Section 1, Medical Device Law Implementation Act)
- Regulation (EU) 2017/745
- Regulation (EU) 2017/746
- EU Guide to Good Manufacturing Practice (GMP), as amended

Term	Definition
Government quality assurance	The process by which responsible national purchasing organisations (e.g. procurement agencies) establish confidence that the contractual requirements relating to quality are met.*) In national (German) contracts, it is possible to reach an additional contractual agreement on government quality assurance in the form of quality inspection in accordance with Section 12 of the normally applicable General Terms and Conditions for Supply and Service Contracts – Part B (*Verdingungsordnung für Leistungen – Teil B*).
Customer	A government and/or NATO organisation that concludes with a contractor a contract laying down the product and quality requirements.
Contractor	An organisation (company) that, within the scope of a contract, supplies the customer with products.
BfArM	Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*) – Personnel at the Federal Institute for Drugs and Medical Devices includes doctors, pharmacists, chemists, biologists, legal experts, engineers, technical assistants and administrative staff. Their work focuses on marketing authorisation, improving the safety of medicinal products, conducting risk analyses and assessments for medicinal products and medical devices as well as monitoring the legal trade in narcotics and precursor chemicals.
CAPA	Corrective and preventive action
DIMDI	German Institute for Medical Documentation and Information (*Deutsches Institut für medizinische Dokumentation und Information*)
GQAR	Government quality assurance representative (also quality controller, if applicable)
Good manufacturing practice (GMP)	Good manufacturing practice (GMP) is the part of quality assurance which ensures that products are consistently produced and checked to the quality standards appropriate to their intended use in accordance with the marketing authorisation, the authorisation for clinical trials and/or product specification.
Good distribution practice (GDP)	Good distribution practice is the part of quality assurance which ensures that the quality of medicinal products is maintained throughout all stages of the supply chain, from the site of manufacture to the pharmacy or person authorised or entitled to supply medicinal products to the public.
NATO	North Atlantic Treaty Organisation
PEI	Paul Ehrlich Institute – The Paul Ehrlich Institute (the Federal Institute for Vaccines and Biomedicines) is a higher federal authority that reports to the Federal Ministry of Health. It is responsible for the research, assessment, and marketing authorisation of biomedicines for human use and immunological veterinary medicinal products. Its remit also includes the authorisation of clinical trials and pharmacovigilance, i.e. documenting and evaluating potential adverse effects.
Other products	Products that are not medical devices/accessories or medicinal products

TS-QMA	Bundessprachenamt - SMD 10
Sub-suppliers / subcontractors	Sub-suppliers or subcontractors supply the contractor with products and/or services.
Administrative assistant	External employee of the customer who provides assistance with government quality assurance
ZLG	Central Authority of the German Federal States for Health Protection Related to Medicinal Products and Medical Devices (*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*)

Scope

The Technical Specification for the Supply of Medical Devices and Medicinal Products to the Bundeswehr (TS-QMA) is a document that the Bundeswehr contractually agrees on with contractors/suppliers in addition to the relevant national and EU regulations when medical devices, other products or medicinal products are purchased.

Under certain circumstances, medical devices/medicinal products can also be procured/integrated as a partial consignment in Bundeswehr weapon systems contracts. In these special cases, the TS-QMA can be agreed on in addition to the usual contractually agreed quality assurance.

Bundeswehr contractors may pass this document on to suppliers as a contractual requirement.

To give the contractors time to adjust to the new provisions and because of the COVID-19 pandemic, the section “Contractual Quality Assurance Requirements” in the TS-QMA applies as a binding guideline until 25 May 2021. After this date, i.e. as of 26 May 2021, it must be complied with in full. All other provisions in the TS-QMA, such as audit rights, apply with immediate effect as a contractually agreed requirement.

Crisis situations

In crisis situations, legal or other requirements can change very quickly. The contractor must take this into account in such cases. Because of the COVID-19 pandemic, for example, the European Commission made a legal proposal to defer the application of some of the provisions of Regulation (EU) 2017/745 by one year. This was legally implemented with EU Regulation 2020/561.

Purpose

TS-QMA defines minimum quality requirements that, according to the customer (Bundeswehr), must be observed by economic operators, distributors or manufacturers over the entire supply chain. In addition, contractual agreements are made on rights of access, rights of inspection, and auditing rights. The proper application of the requirements contained in the TS-QMA creates trust in the contractor’s ability to deliver products that meet the customer’s contractual requirements.

Government quality assurance and quality control

The public contracting authority generally does not have a quality control inspection carried out unless one is stipulated in the contract.

Nevertheless, all products are subject to the contractual right to government quality assurance. The customer may, to an appropriate extent, verify that the quality assurance requirements are met, e.g. in the context of an on-site meeting or an audit.

The customer can only make use of this right if:

- they have received warranty claims or incident reports;
- the contractor has informed the responsible authorities (or the customer) about product risks;
- the CE marking was awarded on the basis of a type examination and, by way of exception, there is no quality management system in accordance with DIN EN ISO 13485;
- product samples have to be taken for quality control purposes and examination in Bundeswehr testing facilities;
- the customer/purchaser wishes to conduct a potential analysis or a supplier appraisal (requires mutual agreement);
- representatives of the Bundeswehr as a customer wish to obtain product information on site;
- representatives of the Bundeswehr as a customer wish to present risk assessments from a client perspective on site;
- a quality control inspection as a form of a contractually defined quality assurance has been agreed.

Rights of access and rights of support

The Bundeswehr agrees with the contractor the rights of access and rights of support defined here, even if they will rarely be used in practice. The customer's representatives may wish to verify the contractual quality assurance on site, e.g. in the event of a supplier appraisal, government quality assurance, etc.

Customer representatives may be:

- Bundeswehr personnel, e.g. pharmacists, physicians, soldiers, project managers, purchasing officers, quality controllers/personnel of the Centre for Technical Quality Management,
- administrative assistants.

The customer must ensure that its representatives are professionally competent, including in matters of:

- evaluating processes in the field of quality assurance (not product assessment);
- technical assessments from the perspective of the customer/Bundeswehr as a client.

No information that the customer receives from the contractor may be forwarded to third parties unless there are reporting channels to be observed, such as a duty to report to responsible authorities or, for example, to affected NATO countries if a government quality assurance process has been agreed on in the form of international quality control.

The contractor guarantees the following rights of access and support for the customer's representatives:

1. right of access to all facilities in which the contractually agreed work is carried out;
2. provision of information relating to the fulfilment of the requirements specified in the contract;
3. unrestricted ability to check whether the requirements specified in the TS-QMA are being met;
4. unlimited scope to verify that the sub-supplier is meeting the requirements specified in the TS-QMA (the contractor will be notified before checks take place);
5. support for participation as an observer in order to evaluate from a client perspective how the contractor or subcontractor assesses, verifies, validates, tests, inspects or releases products;
6. provision of office space with lockable doors;
7. access to information and communication facilities;
8. submission of contractor documents necessary to confirm that the product meets the contractual requirements;
9. issuing of contractor documents necessary to confirm that the product meets the contractual requirements;
10. access to inspect the risk management documents and the CAPA process.;
11. access to inspect the Technical Documentation for Medical Devices.

Point of contact for customer representatives

Point of contact for quality assurance

The contractor's highest level of management appoints from the management organisation a management representative for government quality assurance matters, who, irrespective of their other tasks, has the necessary organisational authority and freedom to solve quality issues. The management representative reports directly to the top level of management. In small companies, the managing director may assume this function.

Among other things, the management representative has the responsibility and the authority to ensure that the processes required for the quality management system are in place, implemented and maintained. This also includes cooperation with the GQAR and/or the customer on matters concerning quality. The management representative must have the necessary competence in matters of quality management.

Customer's audit

If the customer is entitled to carry out government quality assurance inspections then the customer may, via representatives, also carry out supplier audits, i.e. client audits from the contractors' perspective. The audit can be made up of different kinds of audits to form an overall audit, e.g. a system audit, a process audit, a CAPA audit, etc. An audit may also be necessary in the event of a mutually requested supplier appraisal.

In each individual case, the customer and the contractor agree on how the audit is conducted.

Contractual quality assurance requirements

- Medical devices / in vitro diagnostic devices, including accessories
- Other products
- Medicinal products, including accessories
- Legal requirements

The following applies to medical devices (including in vitro diagnostic devices)

Note: According to Article 16 of Regulation (EU) 2017/745 (applicable from 26 May 2020) and Article 16 of Regulation (EU) 2017/746 (applicable from 26 May 2022), distributors, importers or other persons may be considered manufacturers. All economic operators (manufacturers, distributors, importers, authorised representatives) are assigned new legal tasks. Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, must also be observed.

General requirements for distributors and manufacturers

- All products must bear a CE marking valid for medical devices (or in vitro diagnostic devices).
- An EU (previously EC) certificate of conformity / declaration of conformity is included with the delivery.
- All legal quality assurance requirements must be fulfilled.
- If the installation / operation of medical devices has already been contractually agreed, the legal requirements of the Ordinance on Operators of Medical Devices must be observed, e.g. with regard to manufacturer's instructions on medical devices, entries in the medical devices log book, inventory as well as requirements concerning maintenance / metrological checks.

  Note: The Ordinance on Operators of Medical Devices will be adapted by a new EU Medical Devices Adaptation Ordinance (MPEUAnpV) at some point in the future.

Quality assurance requirements for importers, authorised representatives

- The legal requirements apply.

Contractual quality assurance requirements for distributors

- Distributors must verify that an EU (previously EC) certificate of conformity / declaration of conformity is available for the medical device in question and that the device bears a CE marking.

- Distributors must verify that the manufacturers of medical devices have carried out quality assurance measures that at least comply with the TS-QMA requirements. Products for which no adequate quality assurance has been performed must not be delivered to the Bundeswehr.
- The storage and transport conditions for medical devices must comply with the manufacturer's requirements.
- For products with a limited shelf life, the distributor must check the expiry date. The remaining shelf life must be determined and communicated to the customer before delivery.
- Prior to delivery of medical devices, distributors must verify that the device in question is not subject to any risk information or product recalls. In addition to such information provided by the manufacturer, relevant information from the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute must also be taken into account. Devices subject to recalls or risk information must not be delivered to the Bundeswehr.
- Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available must immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. They must keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where applicable, the manufacturer's authorised representative and the importer informed of such monitoring and provide them with all relevant information upon request.
- Upon request by the customer, distributors must provide any information and documentation which is available to them and which is necessary to prove conformity of a device.
- Distributors must assess their suppliers / manufacturers in terms of quality. This assessment must be clearly reflected in the future selection of all procurement sources.
- If the distributor is aware that the purpose of the medical device as intended by the manufacturer is inconsistent with its actual use by the Bundeswehr, the distributor must notify the customer and initiate measures as necessary.

Contractual quality assurance requirements for manufacturers

The Bundeswehr requires manufacturers of medical devices to have a quality management system according to DIN EN ISO 13485 in place and to apply it to medical devices of the Bundeswehr.

Legal requirements governing quality assurance and risk management must always be observed. From May 2020 and May 2022, new minimum legal requirements of the following regulations (EU) will apply:

- Regulation (EU) 2017/745, to be bindingly and fully applied from 26 May 2020; however, a new Regulation (EU) 2020/561 amending Regulation (EU) 2017/745 on medical devices as regards the date of application of some of its provisions must additionally be observed;
- Regulation (EU) 2017/746, to be bindingly and fully applied from 26 May 2022.

Manufacturers must monitor, as far as possible, their products supplied to the Bundeswehr. They must check compliance with the intended purpose. In some exceptional cases (which must be evident from the contract), medical devices are used in Bundeswehr aircraft, ships, tanks and tents under different global climatic conditions:

- vibrations, e.g. when installed in tanks;
- salt spray resistance when used in the Navy;
- altitude, e.g. when used in aircraft – at the risk of decreasing dielectric strength of electronic components.

With the participation of notified bodies, the contractor must initiate hardening measures as necessary to ensure safe operation – safety for patients, users and third parties. Once hardening measures are complete, the intended purpose of the device must be updated.

For class 1, 1* and 2a medical devices or in vitro diagnostic devices with low risk levels, exceptions are permitted if the manufacturer performs a type examination as a prerequisite for CE marking. Minimum quality assurance requirements are listed in the table below. The Bundeswehr accepts quality management systems according to 21 CFR 820.

Minimum quality assurance requirements for manufacturers	
Medical devices	
Class 3 and 2b medical device, invasive	• DIN EN ISO 13485 • DIN EN ISO 14971 • DIN EN ISO 10993

Class 3 medical device and active medical devices	• DIN EN ISO 13485 • DIN EN ISO 14971
Class 2 b medical device	• DIN EN ISO 13485
Class 2a, 1* and 1 medical device	As a minimum requirement: • DIN EN ISO 13485. In exceptional cases: • e.g. for small enterprises: CE marking based on type examination In exceptional cases, the customer will tolerate quality assurance based on legal requirements as a minimum. In such cases, the contractor must take quality assurance measures to ensure the safety of patients, users and third parties. Harmonised standards must be applied where appropriate from a regulatory perspective. The customer is entitled to visit the contractor's premises to observe how quality assurance measures are implemented.
In vitro diagnostic devices	
In vitro diagnostic devices	• DIN EN ISO 13485 • In high risk cases: DIN EN ISO 13485 and DIN EN ISO 14971
In vitro diagnostic devices where a type examination was the basis of the CE marking	• In exceptional cases, the customer will tolerate quality assurance based on legal requirements as a minimum. The contractor must take quality assurance measures to ensure the safety of patients, users and third parties. Harmonised standards must be applied where appropriate from a regulatory perspective. The customer is entitled to visit the contractor's premises to observe how quality assurance measures are implemented.

The following applies to other products

General requirements for distributors and manufacturers

- Customer requirements must be identified, fulfilled and documented by the contractor.
- If required by EU legal norms (e.g. EU PPE Regulation), other products must bear a valid CE marking and be accompanied by an EU / EC declaration of conformity or EU / EC certificate of conformity (type examination) for each applicable EU legal rule. Additionally, distributors must check EU / EC declarations of conformity and EU / EC certificates of conformity for correctness.
- All legal quality assurance requirements must be fulfilled.
- Quality assurance must at least meet the requirements of DIN EN ISO 9001 (or DIN EN 9120 as an additional option for distributors).
- Other products must be delivered in an appropriate, clean condition.
- Contractors must agree with suppliers on quality assurance commensurate with the risk involved.
- Storage and transport conditions must at least comply with the manufacturer's requirements where such requirements exist.
- All other products must be permanently marked at the manufacturing site, on the other product itself or, in exceptional cases, only on the packaging in order to ensure identifiability / traceability throughout the entire supply chain. The marking must reflect the configuration status of the other product in question.
- Contractors must keep a list of all incoming complaints and select suppliers only on the basis of past positive experience / quality capabilities.
- Other products with quality deficiencies must not be delivered to the Bundeswehr.

Quality assurance requirements for importers, authorised representatives

- The legal requirements apply.

The following applies to medicinal products (including veterinary medicinal products)

General requirements

- Only approved medicinal products may be distributed.
- Legal requirements must be observed, including:
    - Medicinal Products Act and Ordinances relating to the Medicinal Products Act;

- Regulations (EU) 2019/4 and 2019/6 as soon as in force;
- Regulation (EU) 2019/5;
- EU Guide to Good Manufacturing Practice (GMP);
- "Good Distribution Practice" according to EC Guideline 2013/C 343/01.

Requirements for distributors (medicinal products for human and/or veterinary use)

- Distributors are subject to the requirements of "Good Distribution Practice" according to EC Guideline 2013/C 343/01.
- In their contracts with suppliers, distributors must ensure:

  1. that subcontractors and subsuppliers implement the requirements of the EU GMP Guide and ensure that this requirement is forwarded to the production plant. This also applies to countries outside the EU.
  2. that distributors can, upon request, inspect the manufacturing site to verify proper implementation of all legal requirements.
- Distributors must also ensure legal reporting channels throughout the entire supply chain.

Requirements for manufacturers (medicinal products for human and/or veterinary use)

- Manufacturers must operate and further develop a pharmaceutical quality management system within the company.
- Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and checked to the quality standards appropriate to their intended use in accordance with the marketing authorisation, the authorisation for clinical trials and/or product specification. Manufacturers must ensure this and apply the EU GPM Guide required by law.
- Legal requirements must be observed (e.g. Medicinal Products Act, Ordinances relating to the Medicinal Products Act).

Reporting obligations of contractors

- Contractors must report to the competent authorities all serious incidents and safety-related corrective action associated with medical devices, including accessories / in vitro diagnostic devices, including accessories.
- For medicinal products for human and veterinary use, legal reporting channels must be ensured by contractors.

Additionally, the customer may be notified by email to the address below if considered necessary in view of the risk involved.

AMMPSicherheit@Bundeswehr.org

Standards and laws / regulations

Index		
Standard	Title	Version
2013/C 343/01	Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use; these Guidelines are based on Article 84 and Article 85b(3) of Directive 2001/83/EC and Directive 2011/62/EU.	5 November 2013
AMWHV	Ordinance on the Manufacture of Medicinal Products and Active Agents / Note: contains a binding requirement for the EU GMP Guide	Latest version
Medicinal Products Act, including related ordinances	Act on Marketing Medicinal Products (Medicinal Products Act)	Latest version
DIN EN ISO 10993	Biological evaluation of medical devices (Part 1 - Part xx) / Note: The biological safety of medical devices must be evaluated and ensured on the basis of the DIN EN ISO 10933 series of standards.	Latest version
DIN EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	Latest version
DIN EN ISO 14971	Medical devices – Application of risk management to medical devices	Latest version
DIN EN ISO 9001	Quality management systems – Requirements	Latest version
DIN EN ISO 9120	Quality Management Systems - Requirements for Aviation, Space and Defence Distributors	Latest version
EU Guide to Good Manufacturing Practice (GMP)	Rules governing medicinal products in the European Union: EU Guidelines on Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use	Latest version
EU Medical Devices Adaptation Act (as soon as in force)	Act adapting current medical devices legislation to Regulation (EU) 2017/745 and Regulation (EU) 2017/746	Latest version
Medical Devices Act, including related ordinances	Act on Medical Devices (Medical Devices Act) / Note: major changes to be expected from May 2020 and May 2022	Latest version
Directive 2011/62/EEC	EU Directive amending Directive 2001/83/EC on the Community code relating to medicinal products for	2011

Index		
Standard	Title	Version
	human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products	
Regulation (EU) 2016/425	EU Regulation on personal protective equipment and repealing Council Directive 89/686/EEC	2016
Regulation (EU) 2017/745	EU Regulation on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	Latest version
Regulation (EU) 2017/746	EU Regulation on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	Latest version
Regulation (EU) 2019/4	EU Regulation on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC	Latest version
Regulation (EU) 2019/5	EU Regulation amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use	Latest version
Regulation (EU) 2019/6	EU Regulation on veterinary medicinal products and repealing Directive 2001/82/EC (28 January 2022)	Latest version
Regulation (EU) 2020/561	EU Regulation amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions	Latest version

Sources

Document	Online source(s) (internet links in document)
AQAP standards	http://nso.nato.int/nso/nsdd/listpromulg.html https://www.bundeswehr.de/en/organization/equipment/contract-award/quality-management
DIN EN ISO standards	https://www.beuth.de/en
EU Guide to Good Manufacturing Practice (GMP)	https://ec.europa.eu/health/documents/eudralex/vol-4_en
EU Regulations	https://eur-lex.europa.eu/
Documents of the European Medicines Agency (EMA)	https://www.ema.europa.eu/en
Harmonised EU standards	http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/
Information on Regulations (EU) 2017/745 and 2017/746	https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
German national laws and regulations	https://www.gesetze-im-internet.de/

Change procedure

The “Technical Specification: Quality Assurance Requirements for the Supply of Medical Devices and Medicinal Products to the Bundeswehr” is a new Bundeswehr requirement.

- If any Bundeswehr contractors have suggestions for improvement, they can contact BAAINBw ZtQ1.3 once a year in January via professional associations (military technology, medical technology or pharmaceutical industry) to arrange for an appointment.
- Bundeswehr personnel are asked to contact BAAINBw ZtQ1.3 with any improvements that need to be incorporated.

Email: BAAINBwZtQ1.3@Bundeswehr.org