

# Quality guide for Ypsomed suppliers – V05

Quality Control, Ypsomed  
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## Foreword

Ypsomed is the leading developer and manufacturer of injection and infusion systems for self-medication and a proven diabetes specialist with over 35 years of experience. As an innovation and technology leader, Ypsomed is the trusted partner of pharmaceutical and biotech companies for pens and autoinjectors for the administration of liquid medications.

It is headquartered in Burgdorf, Switzerland, has a global network of production sites, and employs over 2000 people worldwide. As Ypsomed operates in the medical technology environment and maintains partnerships with numerous successful pharmaceutical and biotechnology companies, the company is subject to strict legal requirements designed to protect product users. In order to meet these requirements, Ypsomed complies Regulation (EU) 2017/745 (MDR), the principles of Good Manufacturing Practice (GMP), and has a certified quality management system in accordance with ISO 13485.

This quality guide is intended to enable suppliers with little previous experience in the field of medical technology to familiarize themselves with issues in this industry and to assist them in meeting the relevant requirements.

In addition to any contractual agreements, the quality guide for suppliers contains:

- Brief instructions and detailed descriptions of particularly complex topics
- Ypsomed's expectations regarding hygiene and cleanliness, the documentation practices to be applied, and audit rights

## Contents

<b>1</b>	<b>Quality and legal requirements in the medical sector</b> .....	4
1.1	Quality .....	4
1.2	Legal requirements / GMP .....	4
1.3	Certificates .....	4
1.4	Labeling .....	5
<b>2</b>	<b>Documentation requirements</b> .....	6
<b>3</b>	<b>Line clearance</b> .....	7
<b>4</b>	<b>Handling of complaints/notices of defects</b> .....	8
4.1	Principles .....	8
4.2	Documentation .....	8
<b>5</b>	<b>Hygiene and cleanliness</b> .....	9
5.1	General .....	9
5.2	Expectations regarding environmental conditions .....	9
5.3	Wounds .....	9
<b>6</b>	<b>Process validation/equipment qualification</b> .....	11
6.1	Definitions .....	11
6.2	Procedure/Overview .....	11
6.2.1	Design Qualification (DQ) .....	11
6.2.2	Installation Qualification (IQ) .....	12
6.2.3	Operational Qualification (OQ) .....	12
6.2.4	Performance Qualification PQ .....	13
<b>7</b>	<b>Audit rights</b> .....	13

# 1 Quality and legal requirements in the field of medical technology

## 1.1 Quality

In addition to meeting the specified requirements, the term **"quality" for a medical device** implies that it is suitable for its intended use. This means that:

- the intended function is guaranteed throughout its entire service life.
- the labeling and instructions for use are correct.
- there is no loss of quality due to storage or transportation.
- the product is safe for patients, users, or third parties.
- the risk posed by the product is minimized and acceptable in relation to its benefits.

The quality of medical devices is regulated by law and continuously monitored because:

- it can directly affect human health.
- patients cannot reliably detect hidden defects.
- legislators aim to protect patient safety.

The quality of the product and its documentation must be guaranteed.

- a high-quality product meets customer requirements.
- complete documentation makes it possible to verify product quality at any time.

## 1.2 Legal requirements / GMP

Due to the strict regulatory requirements to which Ypsomed is subject, compliance with all legal requirements is mandatory. Proof of conformity with these legal requirements can be provided, among other means, by applying and complying with relevant standards that are recognized internationally as state of the art, as well as by applying the principles of Good Manufacturing Practice (GMP).

## 1.3 Certificates

The content requirements are defined in the technical or purchasing specifications and, where applicable, in the quality assurance agreement (QAA). A certificate of conformity (COC) or certificate of analysis (COA) is usually required. The content and structure of the document are based on the current DIN EN 10204 standard.

As a minimum, the following information must be included on the certificate:

- Quantity
- Reference to the order/order number
- Batch number (supplier)
- Date of manufacture

Overdeliveries (physical delivery quantity in relation to certified goods) are generally considered more critical than underdeliveries, as they involve goods that have not been inspected. Such events prevent Ypsomed from accepting or using the goods.

#### **1.4 Labeling**

The content requirements are defined in the technical or purchasing specifications and, if applicable, in the quality assurance agreement (QAA).

Generally, the following information must be indicated on the label as a minimum:

- Order number
- Material number
- Batch number
- Quantity





The label must be visible on every container or outer carton. Double labeling is mandatory for cleanroom goods (double packaging).



### 3 Line clearance

The purpose of performing line clearance is to prevent the mixing of batches and to ensure complete traceability.

Line clearance is the process of clearing the workplace of all previously produced products, used documents, equipment, and any other materials that will no longer be used for the next series to be processed. For certain processing steps, additional cleaning or decontamination of work surfaces and equipment may be required.

Line clearance – notes	
	What needs to be done (checked)?
	No materials from the last order.
	No unnecessary operating materials from the last order.
	No documents, labels, forms, etc. from the last order.
	Machine or workstation thoroughly cleaned.
<b>IMPORTANT: check and document.</b>	

The execution of line clearance must be verified and documented. The preferred and most reliable way to document this is in the working records or as digital evidence in the ERP system. In this case, traceability must be ensured through an individual employee login (e.g., code, badge, or similar).

## 4 Processing of complaints/notices of defects

### 4.1 Principles

- Complaints can be a tool for a company's success.
- Complaints must always be processed immediately. Ypsomed expects an initial response within 24 hours and a 3D report within 72 hours, or as defined in existing contracts.
- Complaints must be handled by qualified personnel.
- Complaints must be handled to the best of our knowledge and belief (honest description of the situation, serious analysis of the cause(s), appropriate corrective measures, and conclusive proof of effectiveness).
- Continued communication with Ypsomed is required, for example after the next batch has been delivered, to confirm whether the supplier's improvement measures have led to the desired result at Ypsomed.
- Return deliveries, e.g., for sorting or reworking, a return delivery order must be used. Redelivery must be made via a new order. If rework or supplementary processes are applied to a batch that has already been delivered, this must be clearly and unambiguously identifiable, e.g. by a new batch number or a numerical addition (e.g., \_1; #1, ...).
- Transport damage: responsibility and liability are defined in accordance with the applicable delivery agreements (Incoterms)

### 4.2 Documentation

The 8D report is a suitable method of documenting the causes and corrective measures taken in the event of a complaint. The 8D problem-solving methodology originates from the automotive industry and supports complaint handling through a systematic approach. The eight steps of the 8D methodology must be completed sequentially and documented in a clear and comprehensible manner.

Discipline Keyword		Description
1	Problem-solving team	<ul style="list-style-type: none"> <li>■ Who takes care of it?</li> <li>■ Teamwork to find solutions.</li> </ul>
2	Problem description	<ul style="list-style-type: none"> <li>■ Where is the problem?</li> <li>■ Is it a recurring deviation?</li> <li>■ What do I want to achieve (goal)?</li> </ul>
3	Define immediate measures	<ul style="list-style-type: none"> <li>■ What needs to be done immediately to prevent deviation from occurring in the next batch?</li> </ul>
4	Root cause analysis	<ul style="list-style-type: none"> <li>■ What is the cause?</li> <li>■ Why was it not detected?</li> </ul>
5	Planning corrective measures	<ul style="list-style-type: none"> <li>■ How can deviations be avoided in the future?</li> <li>■ Effective improvement measures.</li> <li>■ Training employees is usually not a solution, as the problem often occurs beforehand.</li> </ul>
6	Introduction of measures	<ul style="list-style-type: none"> <li>■ Does it need to be documented in detail?</li> <li>■ Qualify and validate?</li> </ul>
7	Preventing errors from recurring	<ul style="list-style-type: none"> <li>■ Are the measures sensible and effective?</li> <li>■ Have we achieved our goal?</li> </ul>
8	Success control and conclusion	<ul style="list-style-type: none"> <li>■ Document success based on subsequent batches produced.</li> <li>■ Success control / proof of effectiveness</li> </ul>

## 5 Hygiene and cleanliness

### 5.1 General

Hygiene and cleanliness throughout the entire company are fundamental requirements for manufacturing high-quality products.

### 5.2 Expectations regarding environmental conditions

Absolute cleanliness is expected for the product and packaging. Specifications are provided in the technical or purchasing specifications.

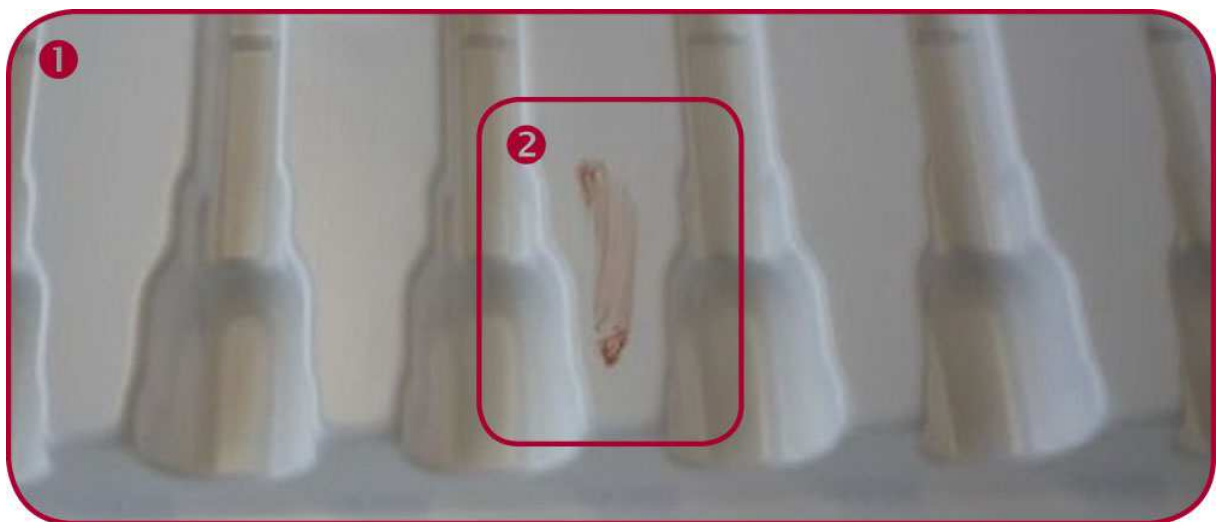
If manufacturing or packaging is defined as taking place under controlled conditions or environments (e.g. in a cleanroom), it is expected that a consistent zoning and clothing concept will be established and that pest control measures will be introduced, monitored, and evaluated.

- No grease, oil, or other residues
- No foreign particles
- No hair
- etc.

These expectations can be met through simple measures (e.g., wearing work clothes that are changed regularly, and wearing headgear).

### 5.3 Wounds

Such a condition is unacceptable to customers and is considered an absolute exclusion criterion by Ypsomed.



- ① Workpiece carriers for finished components    ② Dried blood

What to do in case of injuries or wounds?

1	Stop work immediately	
2	Wound treatment	Disinfect the wound and cover it with a waterproof bandage
3	Workplace	Clean the workplace and disinfect if necessary
4	Supervisor	Inform supervisor
5	Dispose of material	Sort out and dispose of contaminated material
6	Change workstation	The affected employee may need to temporarily change workplace
7	Documentation	The incident must be documented

## 6 Process validation / equipment qualification

According to the applicable QM standards, all processes used for the manufacture of products and the provision of services must be validated if their results cannot be verified by subsequent checks (e.g., 100 % inspection).

### 6.1 Definitions

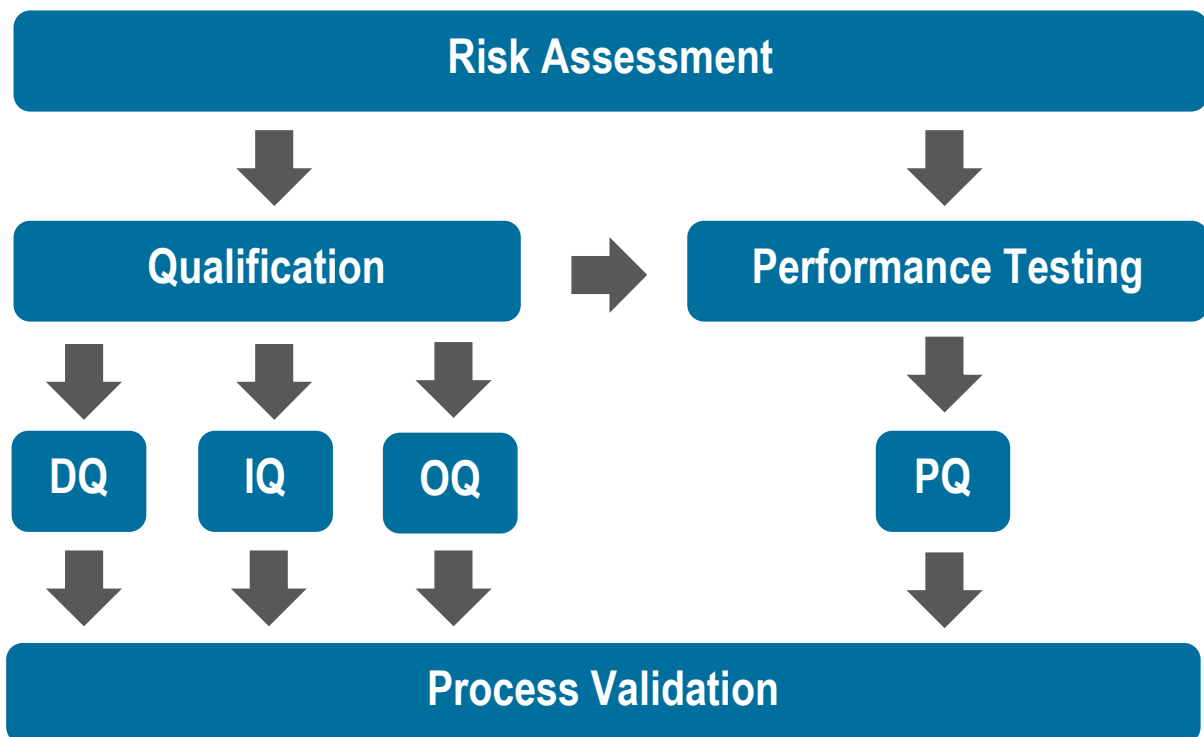
#### Qualification

- is **system-related**.
- is a proof of suitability for rooms, systems, and devices.

#### Validate

- is **process-related**.
- is proof that a specific manufacturing process continuously produces a product that meets predefined specifications and quality characteristics with a high degree of assurance.

### 6.2 Process/Overview



Overview of the end-to-end process used to systematically assess and approve new equipment or a manufacturing process. The process follows a step-by-step approach – from the initial risk assessment through Design Qualification (DQ), Installation Qualification (IQ), and Operational Qualification (OQ), up to Performance Qualification (PQ), which demonstrates that production runs reliably under real operating conditions and meets the required quality standards. Each phase is based on the previous one, ensuring that process and quality work together reliably before series production can be started. The individual phases are described in detail in the following chapters.

### **6.2.1 Design Qualification (DQ)**

Design Qualification represents the interface between the user requirements specification on the one hand and the functional specification (part of the contract) on the other. The DQ documents that all standards and guidelines applicable to the machine or system, all GMP regulations, company-specific requirements, and, above all, the specifications defined in the user requirements specification have been incorporated into the planning of the machine or system and are implemented accordingly.

### **6.2.2 Installation Qualification (IQ)**

Installation Qualification involves the formal acceptance of the system by the Ypsomed supplier. If the equipment used has already been qualified in other validations, relevant parts can be reused for the IQ.

If new equipment or operating resources are used, an initial IQ is mandatory. The following points must be taken into account during installation qualification:

- Technical documentation
- Equipment list / maintenance (list of all equipment used)
- Energy and media supply
- CE conformity or manufacturer's declaration
- Material of parts that come into contact with the product

A measurement system analysis (MSA1 and MSA2) must be performed prior to the start of the OQ phase and must be successfully completed and approved before the OQ phase.

MSA1 is an evaluation that demonstrates whether a measuring device can measure reliably and repeatably without operator influence. This involves checking whether the measuring device always delivers the same result when measuring the same standard multiple times.

MSA2 is an analysis that assesses whether the entire measurement system – including the measuring device, different operators, and various test samples – produces consistent and reliable measurement results. It shows how well the system performs as a whole and to what extent measurements are affected by the device or by operator variability.

### **6.2.3 Operational Qualification (OQ)**

Before the OQ tests can be started, all critical deviations from the installation qualification must be resolved. This is the only way to ensure that the tests are carried out on a correctly installed machine or system.

The OQ provides documented evidence that devices and systems function reliably within defined operating limits.

The following points must be taken into account during operational qualification:

- Work instructions
- Test equipment for qualification
- Checking the environmental conditions
- Functional test plan and approval
- Testing of operating elements
- Testing of control software
- Listing and testing of error messages

In addition to the above points, the following documents must be available, reviewed, and approved by the end of the OQ at the latest:

- Process flow chart, FMEA, production control plans (APQP)
- Qualification documents for the production equipment used (acceptance report, checklist for commissioning, maintenance specifications, etc.)
- Qualification documents for the equipment and tools used (acceptance report, maintenance specifications, etc.)
- Calibration certificates for machines and equipment used, such as tempering furnaces, combustion chambers, etc.
- Quality-relevant process parameters must be identified and their tolerances defined

The aforementioned documents, including the respective results, must be submitted to Ypsomed as part of the process validation documentation.

Upon completion of the OQ, an initial sample test report (ISTR) as well as the MSA1 and MSA2, including the corresponding sample components, must be sent to Ypsomed. This ISTR and the samples are evaluated by the Ypsomed product development team as part of the design verification, and any necessary STI calculations are performed. PQ may only be started once the results have been approved by Ypsomed. Written approval of the successfully completed and passed design verification, and thus approval for the upcoming PQ, is granted by the responsible employee of the product development team.

#### **6.2.4 Performance Qualification (PQ)**

PQ provides documented evidence that the qualified equipment and systems can be used to manufacture products of the specified quality on a continuous basis.

The following points must be taken into account during performance qualification:

- Description of the required performance
- Description of the performance achieved
- Evaluation of the PQ results

The production of the PQ batch(es) should reflect typical events and incidents that occur during routine production. These include material batch changes, production interruptions, and shift changes. Production interruptions should be planned and timed so that they cover the various tasks and work steps required to restart the system (e.g., cooling a temperature-controlled device to room temperature, reheating and restarting the process, removing and cleaning an injection molding tool, or shift changes, etc.).

Written approval for series delivery is granted by the respective Quality Control employee after Ypsomed's internal review and approval of the complete documentation.

## **7 Audit rights**

Suppliers that are classified as critical or important in accordance with Regulation EU 2017/745 (MDR) (these are primarily suppliers that supply Ypsomed with customer-specific materials that are incorporated into end products marketed by Ypsomed) shall ensure that Ypsomed, notified bodies, and the authorities responsible for Ypsomed's end products are granted access to the operating sites relevant to Ypsomed products.

This may include unannounced audits by notified bodies or authorities in accordance with Regulation EU 2017/745 (MDR). The supplier shall ensure that unannounced audits are carried out by notified bodies or authorities and shall grant unrestricted access at any time to the production facilities and to all documentation related to Ypsomed products.