1. Objective and scope

This document describes the processing of complaints on any issues arising from the services provided by QUAMED.

QUAMED is committed to providing high quality services to the users of its services, including pharmaceutical assessments and audits and the QUAMED’s quality certification program (QCP). Any complaints related to the certification decision related to the QUAMED Quality certification Programme should be treated as a appeal as per SOP-Q-040 (Treatment and handling of an appeal related to QCP)

Although QUAMED’S procedures are run under Quality Management System which includes processes to avoid mistakes, it may happen that the products and services delivered by QUAMED do not have the expected quality. In such a situation, a complaint may be submitted to QUAMED. These complaints allow QUAMED to clarify misunderstands, to correct potential errors, to avoid any dissatisfaction, to further improve products and services, and to establish a long-term relationship of trust with all stakeholders.

It should be noted that Policies P001 and P002 cover the cases of complaints and allegations in case of sexual exploitation or abuse.

2. Responsibilities

The Executive Director (ED) is responsible for:

- Receiving the complaints and sharing it with the operational team members;
- Communicating with the complainant.

The QUAMED Technical Coordinator (QUATC) is responsible for:

- Conducting the investigations,
• Proposing corrective and preventive actions,
• Recording and archiving the complaint files.

The QUAMED Quality and Compliance Coordinator (QCC) is responsible for:
• Oversighting the process from the start until the complaint process is closed,
• Approving the results of the investigations and the CAPA,
• Monitoring the implementation of corrective and preventive actions,
• Reporting to ED on trend analysis for the management review.

3. Definitions and abbreviations

**Complaint**: a report made by an external party of a non-conformity or divergence between expected quality and the results for a product/service received. Complaints may be of different nature and may be related to the conduct of an expert or an auditor during an assignment, to the content of deliverables, to the non-issuance of a QCP certificate, to the way QUAMED has managed information or to the way QUAMED has communicated with the complainant.

**Customer**: is either a QUAMED member, a QUAMED database subscriber, a QCP (QUAMED Certification Programme) owner or applicant, a QUAMED staff member or consultant, a service provider, or another stakeholder in relationship with QUAMED.

4. Procedures

4.1. Receipt of complaints

• **Who can submit a complaint?**
  Anyone in a relationship with QUAMED can submit a complaint.

• **How to submit a complaint?**
  The complaint form is made available on the QUAMED website ([www.quamed.org](http://www.quamed.org)). The website contains also ‘information on complaints to stakeholders (SOP-Q-031-A-002 for English version and SOP-Q-031-A-004 for French version) to communicate key information about complaints to QUAMED stakeholders. The complaint form (SOP-Q-031-A-001 for English version and SOP-Q-031-A-003 for French version) should be sent to QUAMED to info@quamed.org. Only written complaints can be accepted. The complainant should complete the sections I and II of the form. It may be also acceptable that the complainant sends the complaint by email, and then the QCC transfers the information in a complaint form.
  To ensure a timely and efficient treatment of complaints, they should be submitted to QUAMED with as many details as possible, and when applicable, the QCP number or the reference of a QUAMED assessment or audit. Complaints can only be submitted within 3
months of the date of delivery of the products/services. After this timeline, the QUAMED is not obliged to accept a complaint, but will do its best to resolve the issue. An acknowledgement of receipt is sent to the complainant by the E.D. within 2 working days following receipt of a complaint.

### 4.2. Processing of complaints

The E.D. informs the relevant QUAMED staff within the operational team, about the complaint details.

The QUATC is responsible for managing the investigating the complaints and make suggestions about the CAPA. If the complaint is out of the scope of the competencies of the QUATC, the QUATC may delegate the investigation to other staff or BoD member or Committees members. The QCC validates the investigation and the CAPA.

In all cases, confidentiality of information shall be kept during processing and communication.

**Investigation**

All complaints are recorded by QUATC in a specific folder in the QUAMED drive (13.1. complaints) and given an identification number by the QUATC on the first page of the complaint form. The identification code is as follows: C-YYYY-XX (C, the year number (e.g. 2022), and an incremental number of this year (e.g. 02). For instance, the second complaint received of the year 2022 will be coded as: C-2022-02.

The QUATC fills the information on the complaint register (SOP-Q-031-A-005) available on the QUAMED drive at 13.1.1

The QUATC will do a thorough investigation to establish:

- the nature of the complaint,
- what the cause of the complaint was,
- who should be involved (auditors, experts, technical committee),
- what is the impact or potential impact of the complaint, etc.

The complainant may be contacted to obtain further details. The QUATC concludes whether the complaint is valid or not valid. All investigations are documented and the conclusions recorded in the complaint form.

**Correction and preventive actions**

Based on the outcomes of the investigation, the QUATC suggests corrective and preventive actions to be taken in managing the complaint. CAPA are recorded in the form SOP-Q-033-A-001 Non conformity & improvement form as per the SOP-Q-033.

**Sign-off**

The investigations findings and conclusion, are approved by the QCC before being implemented. The complaint form is signed electronically the QUATC and the QCC.
4.3. Notification of the complainant
The complainant is informed of the outcomes of the processing by the ED. Each complaint shall be handled as soon as possible, and not later than 10 working days after receipt. In case the complaint will require longer time for the investigation or corrective actions, the complainant will be informed.

If the complaint is found to be not valid, the complainant is informed in writing within 10 working days of the non-validity of the complaint, supported by suitable explanations, and the complaint case is closed.

4.4. Implementation of corrective and preventive actions and follow-up
Refer to SOP-Q-033 (Management of non-conformities, improvements and CAPAs) for further details.
Monitoring of the preventive actions and trend analysis of complaints received are reported in the periodic management review to the ED and the board of Directors, if required.

4.5. Action in case of dissatisfaction
If the complainant does not agree or is dissatisfied with the treatment of a complaint, he/she may express his/her dissatisfaction by written to QUAMED ED. QUAMED operational team will reconsider the case to try to find an amicable agreement. Otherwise, the complainant is given the possibility to submit a written request for re-consideration of the decision(s) (hearing) within two weeks of receiving the decision. The request will be examined by a QUAMED Ad hoc Committee within 2 weeks. This committee will be set-up by the Board of Directors: The composition may be variable, but this ad hoc committee will be composed of people chosen for their competences required by the field of the complaint. The QUAMED president is the chair of this committee.

5. Annexes
SOP-Q-031-A-001 Complaint report form
SOP-Q-031-A-002 Information on complaints to stakeholders
SOP-Q-031-A-003 Fiche de réclamation QUAMED
SOP-Q-031-A-004 Information sur les réclamations pour les parties prenantes
SOP-Q-031-A-005 Complaint register

6. Related documents
SOP-Q-033 (Management of non-conformities, improvements and CAPAs)
SOP-Q-040 Management of appeals)
7. Revision history

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<td>1&lt;sup&gt;st&lt;/sup&gt; version</td>
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<td>2</td>
<td>14 June 2023</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; version with little changes (no changes in annexes)</td>
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