

INSTRUCTION

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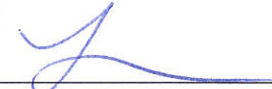


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1 PURPOSE

This SOP specifies Kibion’s procedure for handling of customer complaints. The purpose of this SOP is to assure that all customer complaints are handled fast and effective and lead to suitable corrective and preventive actions.

The procedure defines responsibility and authority to initiate investigations, correction, corrective and preventive actions, initiate recall and market safety actions.

A procedure for complaint handling is necessary to assure that all complaints are documented, analyzed (root cause) and controlled in an effective and correct way. The control can either be a correction, corrective action or preventive action.

Complaints handling is necessary to assure product safety and performance as well as customer satisfaction. Complaints are also a crucial input to Kibion’s system for post market surveillance and routine for vigilance.

Note: Adverse reactions and specific situations are handled by SOP 10 5023 (**ref.1**).

2 SCOPE

This SOP only describes the handling of complaints registered by Kibion.

If a complaint is registered outside of Kibion (e.g. one of Kibion’s third part manufacturer), Kibion will participate in the investigation but the locally valid SOP for complaints will govern the procedure.

IRIS specific procedures exist at the Bremen site due to the direct contact with end users. The cases are handled via Service & Maintenance but are controlled at the Production meetings.

3 RESPONSIBILITY

It is the responsibility of all Kibion employees to report any customer complaint to QA department (in this routine called QA). All complaints shall be registered in the Complaint form (see **Ref 2 & Ref 3**).

QA is responsible for handling complaints. This responsibility includes register the complaint, assure sufficient information about the complaint is documented, analyze the root-cause, trigger risk management, and decide/implement suitable actions.

The activities in the complaint procedure do not have to be performed by QA (the analysis is often performed by external suppliers), but shall be monitored by and reported to QA. Thus, QA is responsible for follow-up the status of all complaints.

QA is responsible for vigilance and reporting to the competent authority.

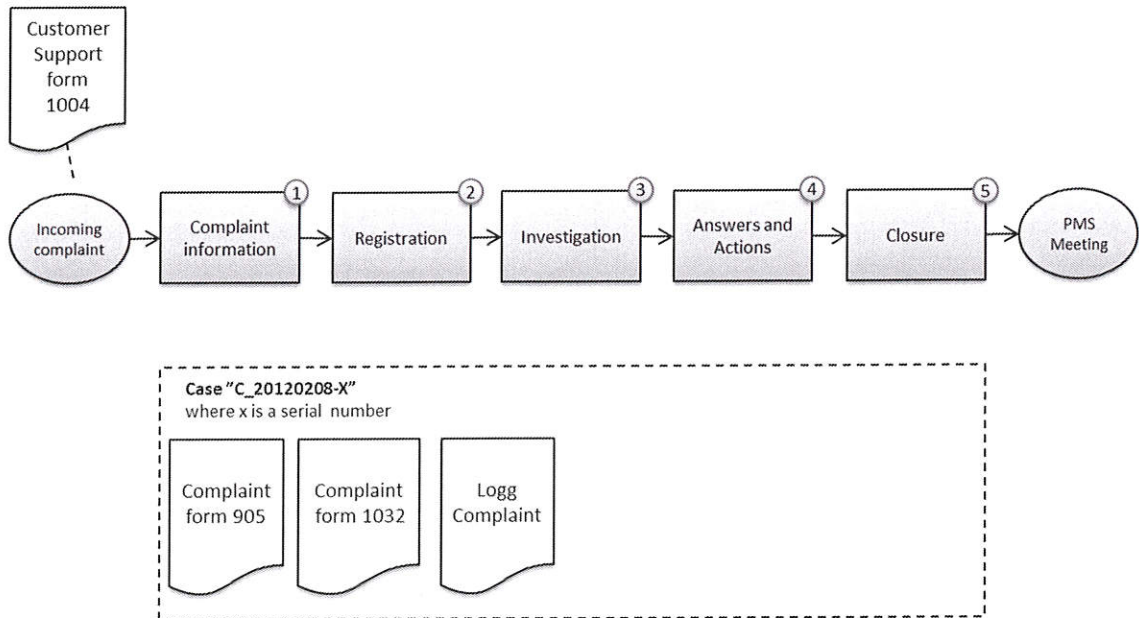
QA is overall responsible for complaint handling within Kibion and also responsible for implementing and maintaining this SOP.

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4 PROCESS DESCRIPTION



5 PROCESS DEFINITIONS

A problem detected internally and not reported by any customer i.e. distributor, end user), is not considered to be a complaint. These problems shall instead be handled as a deviation (see **Ref 4**).

Problems at the customer are usually reported as customer support cases and are handled by the Customer support form (see **Ref 5**). If identified as a complaint it should be registered and handled through the Complaint Form (see **Ref 2 & Ref 3**).

A complaint is within Kibion defined as a deviation perceived or detected by a customer (i.e. distributor, end user).

Anyone within Kibion can receive a complaint from customers (distributors or end users).

All complaints shall be reported in the Complaint form, which shall be used for the compiled *complaint information* (shall include information about the customer, the actual complaint, actions and decisions in the entire complain procedure).

The complaint form shall be sent to QA for *registration*. QA registers the complaint in the complaint file and dedicates a case number.

QA reviews the information about the complaint, asses if the complaint refers to an incident/ near incident, and initiates an *investigation* of the root cause.

Depending on the investigation result, an *answer* is given to the customer and suitable *actions* are implemented.

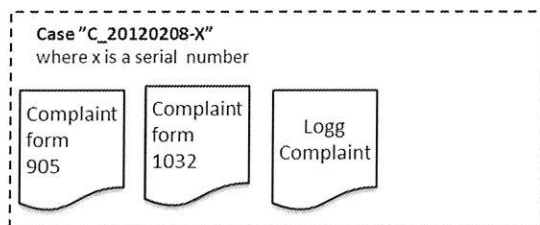
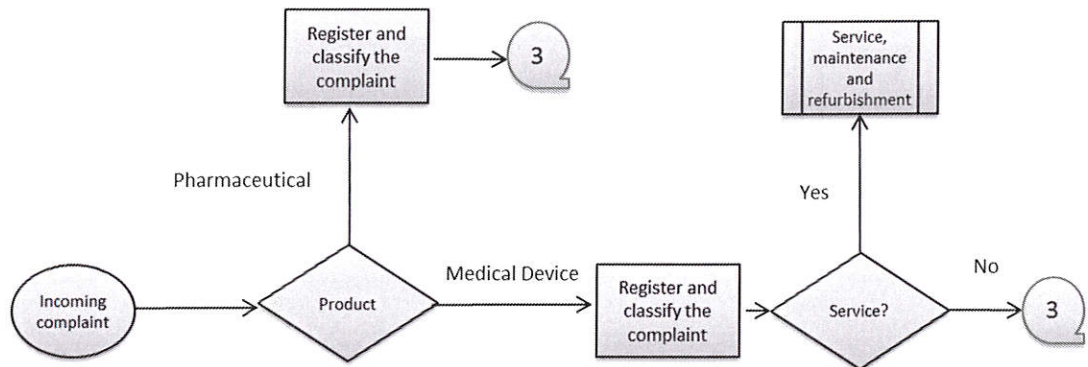
All complaints are closed internally. After closure they are reported with the regards of where implemented actions and trends to the Post Market Surveillance meeting.

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5.1 Complaint information (part 1) and registration (part 2)



5.1.1 Complaint information

All complaints shall be documented in the complaint form (see **Ref 2 & Ref 3**).

If the complaint is reported by a distributor, the complaint form should be sent to the distributor who completes *Part one* of the complaint form (Complaint information).

If it is not suitable/possible to let the distributor fill in the form, the employee within Kibion who received the complaint shall complete applicable parts of part one of the complaint form.

- 1) Please note the information may already have been received through the Customer Support Case.
- 2) Please note that IRIS Specific procedures exit at Site Bremen. All cases originated from customer are handled within the Service and Maintenance process. Classification is reviewed at the weekly product meetings. QA updates the register log for service Maintenance cases in Bremen

5.1.2 Registration/review/evaluation

All complaints regarding Pharmaceuticals are to be sent to a dedicated e-mail address (complaints@kibion.com) within Kibion. QA is responsible for continuously control of incoming e-mail.

All questions and problems related to the Medical Device products should be sent to support@kibion.com. Complaints will be handled by QA.

QA is responsible for register the complaint in the complaint log and provides the complaint with a registration number (C_YYYYMMDD-X, where x is a serial number).

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5.1.3 Complaint classification

QA reviews the information and classifies the complaint according to the reported deviation/failure. The procedure for Risk Management can be used to identify the problem severity and impact (**Ref 6**).

5.1.3.1 Medical Devices

Category	Examples
Instrument failure (old)	An old instrument that has went broken, for example a broken GM tube.
Instrument failure (new)	A completely new instrument that does not work on opening.
Product failure	A broken BreathCard
Product function	Product does not act as intended
Packaging	A problem/deviation concerning the packaging (for example broken package or missing components).
Delivery	<u>Incorrect delivery:</u> <ul style="list-style-type: none"> • wrong product • wrong quantity • incorrect terms of delivery • incorrect handling during transportation (temperature, moist etc.)

5.1.3.2 Pharmaceuticals

Category	Examples
System (kit)	An assembled kit that does not function correctly, which for example give false positive result.
Vials & Packaging	<u>A problem/deviation concerning the packaging:</u> <ul style="list-style-type: none"> • broken package or components in kit • missing tablets or components in kit • mislabelled product
Reagent	A broken tablet or capsule.
Delivery	<u>Incorrect delivery:</u> <ul style="list-style-type: none"> • wrong product • wrong quantity • incorrect terms of delivery • incorrect handling during transportation (temperature, moist etc.)

Please note that a complaint related to medicine for human use is classified as having a medical impact it will be handled in accordance with the procedure for recall (**Ref 6**).

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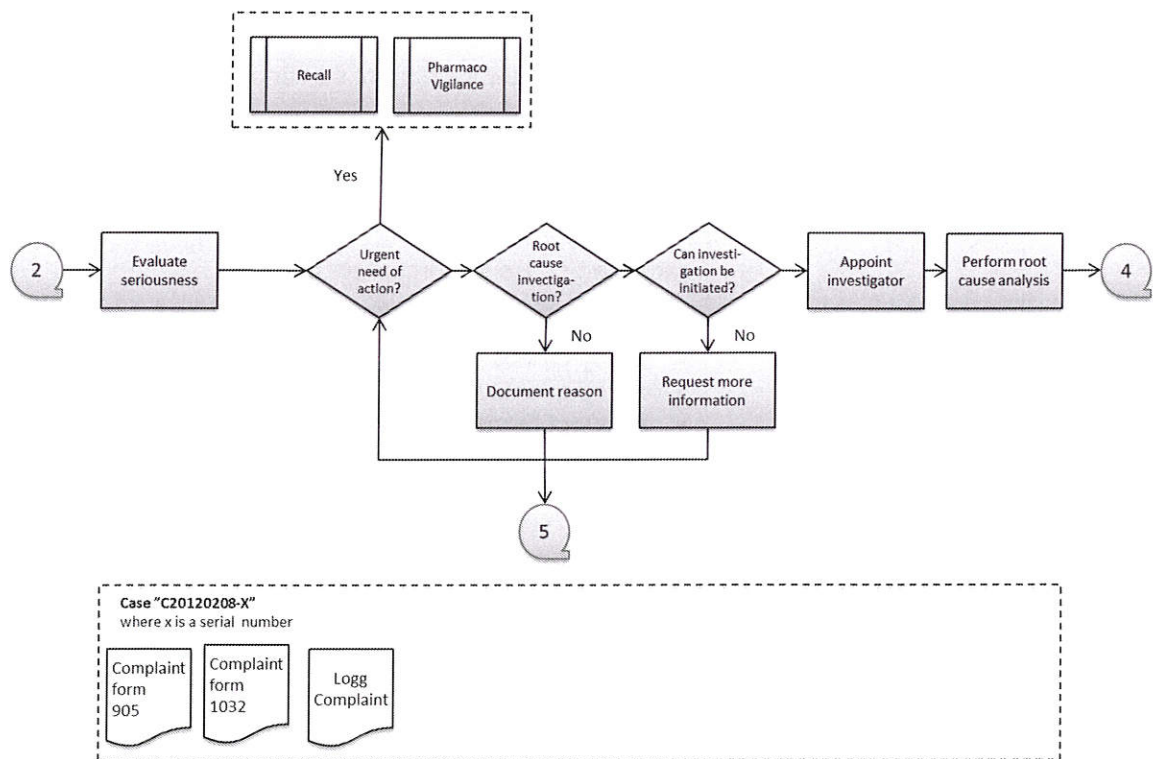
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5.1.4 Event evaluation

QA performs an event evaluation to decide if the problem requires urgent corrective action at the field and if the complaint regards an incident or near incident which shall be reported to the competent authority.

QA also assess if the complaint should be considered to be a service case i.e. if the complaint regards an old instrument, where the problem is caused by wear and tear and/or neglected maintenance.

5.2 Investigation (part 3)



Based on the complaint information, QA decides if an investigation shall be initialized. If no investigation shall be performed, a justification (reason for not performing an investigation) shall be documented.

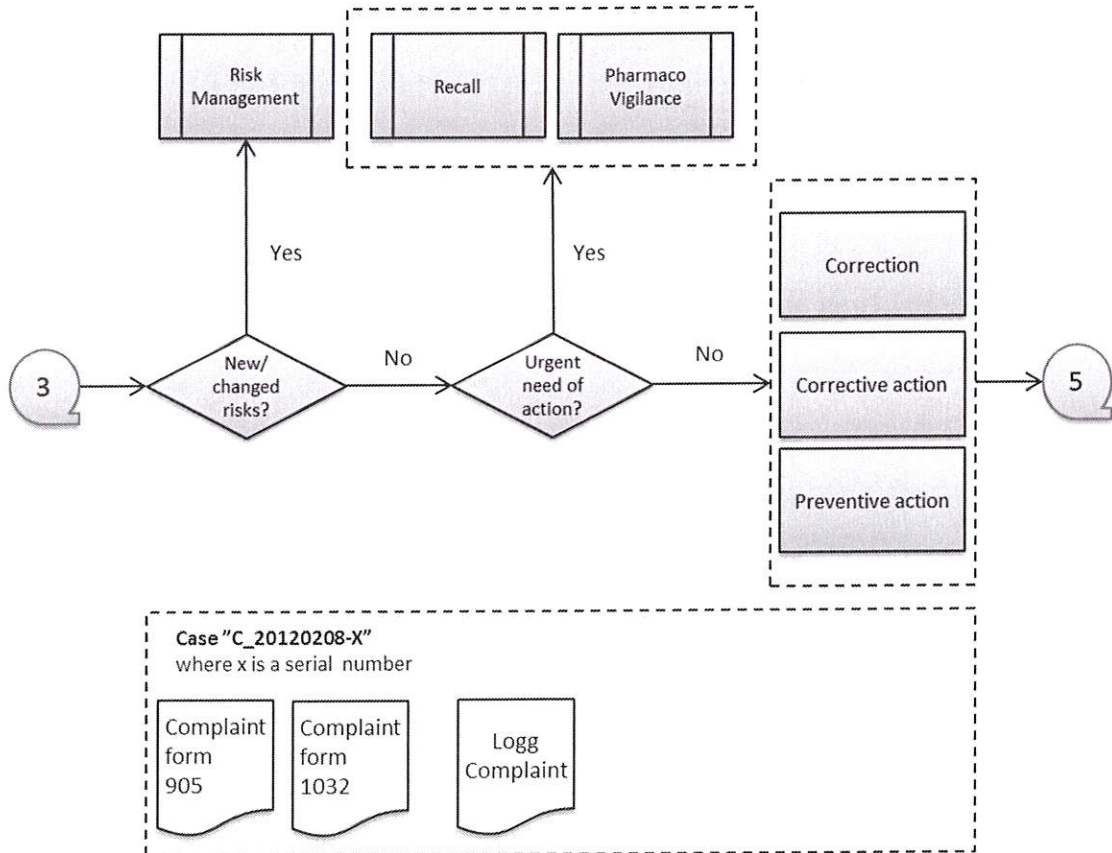
QA reviews the provided information and assess if the information is sufficient for initialize an investigation of the root cause to the complaint. QA also decides who shall be responsible for performing the investigation.

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5.3 Answer and action (part 4)



The result of the investigation including root cause shall be documented in the complaint form (or referred to). It shall also be reported if/what corrective and preventive actions that are planned, ongoing or completed.

Based on the investigation, QA shall decide if the complaint regards a new or already known problem and, if possible, categorize the action (based on the root cause) into:

- Routines not followed, training needed
- Routines not appropriate: Issue change request
- No actions, complaint can be closed

If the complaint regards HeliCap or Diabact UBT; QA shall, based on the root cause, also decide if the complaint is medicinal, pharmaceutical or technical.

- Medicinal (i.e. adverse reactions, lack of efficacy or clinical response)
- Pharmaceutical (i.e. change in color, odor, appearance, quality, safety and effectiveness)
- Technical (i.e. incorrect handling during, transport, storage or use)

If the complaint regards an incident or near incident, QA/RA shall promptly decide which actions that are to be performed at the field (recall, field safety notice etc.). See **Ref 7**, **Ref 8** and **Ref 9**.

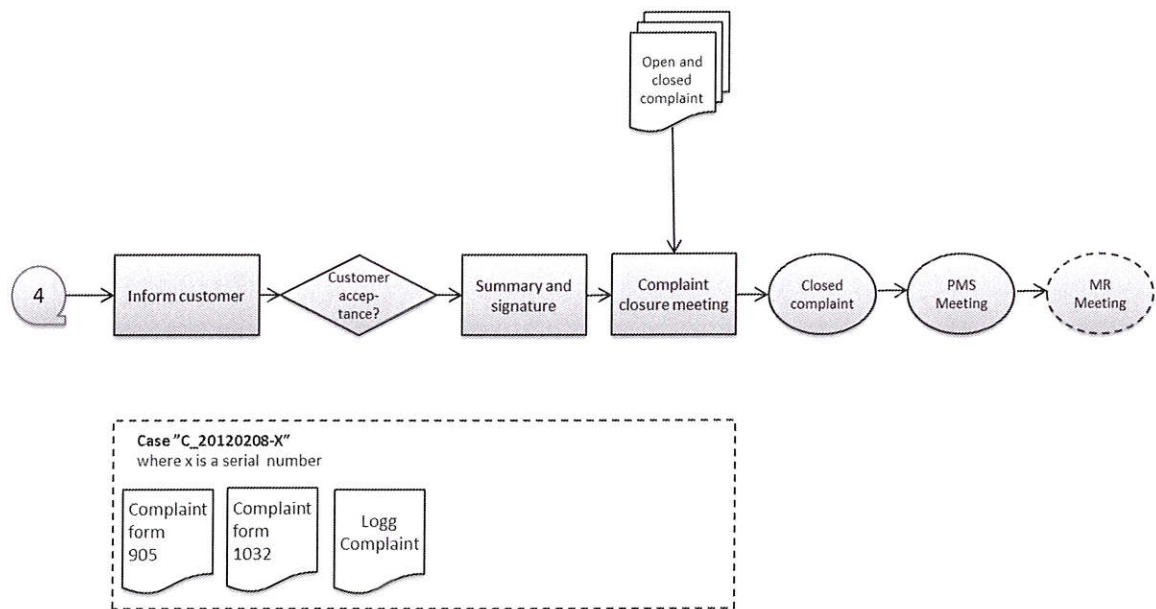
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5.3.1 Risk management

QA/RA shall as early as possible and throughout the complaint process evaluate if the complaint implies that risk management need to be up-dated i.e. if there could be new or changed risks (**Ref 6**).

5.4 Complaint closure (part 5)



5.4.1 Customer closure

QA shall be responsible for informing the customer that reported the complaint about the result of the investigation and implemented actions.

If the complaint was reported by a distributor, the distributor should be given the opportunity to comment/accept the closure of the complaint.

Please note that IRIS devices; where service has direct contact with the user, are excluded from the above process description.

5.4.2 Kibion closure

QA is responsible for performing the internal closure of the complaint. The decision to close the complaint shall be based on sufficiency of implemented actions and the confirmation of acceptance from the customer. The review and decision to close the complaint is documented by signature of the complaint form.

Kibion closure means that the complaint has been closed and that no for further investigation or action is required.

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5.4.3 Follow-up

QA shall at least two times each year conduct a complaint follow-up, where all received complaints are reviewed. The purpose of the review is to analyze trends among complaints and assure implemented actions have been implemented and effective.

If the review can see or suspect that there is a trend among reported complaint further investigation and actions are needed. The problem is then handled as a CAPA according to **Ref 10**.

The result of the review is reported in to the Post Market Surveillance (PMS) meeting (see **Ref 11**) which is held twice a year prior to Management Review (see **Ref 12**).

6 REFERENCES

Ref No	Doc Type	Doc Id	Doc Name
Ref 1	IN	10 5023	Reporting adverse events on Kibion products
Ref 2	Form	905	Complaint Form - Pharmaceuticals
Ref 3	Form	1032	Complaint Form – Medical Device
Ref 4	IN	10 2827	Deviation
Ref 5	Form	1004	Customer Support
Ref 6	IN	10 2934	Risk Management
Ref 7	IN	10 010	Recall
Ref 8	IN	10 2957	Vigilance Reporting for Medical devices
Ref 9	IN	10 3240	Registration and Maintenance - Pharmaceutical
Ref 10	IN	10 782	CAPA
Ref 11	IN	10 3200	Post Market Surveillance
Ref 12	IN	10 3128	Management review

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7 DOCUMENT INFORMATION

7.1 Definitions

Term	Explanation
PCC	Potentially Critical Complaint
QA	Quality Assurance
RA	Regulatory Affairs
SOP	Standard Operating Procedure

7.2 Submitted for comments

Function	Name
QA	Catarina Högberg

7.3 Changes from previous version

No	Change
1	Added a reference to SOP 10 5023
5.1.2	Updated email address.

7.4 Distribution

7.4.1 Registered electronic copy (pdf with watermark)

Function	Name	Copies
Doc. Handler	DocHandler@kibion.com	1

7.4.2 Registered paper-based copy

Function	Name	Distributed by	Copies
QP, Orifice	Katarina Svensson	Eva Kjaer, Kibion	1
QPPV; TFS	Margareta Svensson	Eva Kjaer; Kibion	1
Kibion	Röda Webben pärm	Eva Kjaer; Kibion	1

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