



COMPLAIN AND COMPLEMENT FEEDBACK

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References	Abbreviations
P-05-01 Nonconformities R-05-03 Incident register	LSG = Life Science Group Ltd

Life Science Group Ltd (LSG) is committed to providing a high level of quality product and services. We welcome comment from our customers and suppliers, both positive and negative. Occasionally things will go wrong and it is by listening to the feedback from stakeholders that the Company can learn and go on to improve and enhance the products and services that we supply.

At LSG we have a strong focus on customer service and Quality. Clear communication allows us to understand individual needs and challenges and to adapt to meet changes in requirements. Our Complaints, Complements and Feedback policy provides valuable information to enable the Company to promote and recognise good service, to correct and rectify faults as they occur, to capture the need for change to enable the Company to grow and develop and provide highly effective levels of service.

Jennifer Murray
Managing Director

1. Purpose

The purpose of this document is to outline for all stakeholders the LSG policy for handling customer feedback including complaints about the services and provided by the Company.

The aim is to make it easier for stakeholders to provide feedback including complaints and easier for LSG to deal effectively and efficiently with feedback received. The focus is to provide a customer focussed experience of providing feedback, including complaints, to the Company. Stakeholders will be kept informed and advised as to how their feedback will be handled

2. Definitions

Compliments are expressions of praise for quality of service or actions completed. It is usually made in recognition of an action which was over and above what was expected of the standards of service.

Complements should be recorded and reported to the Management Team.

Comments or Suggestions are remarks about how a service may be improved.

All comments should be acknowledged within five working days. As a general rule a comment or suggestion should be passed to the Management Team for consideration and discussion. The appropriate Manager will write to advise what, if anything, will happen as a result of their feedback.

A concern is a difficulty or problem which is current and needs to be resolved.

As a guide a concern is a problem or difficulty that can be resolved very quickly and successfully by the frontline team or service, rather than escalated to a manager. This should be acknowledged by the team member and the individual who has raised the concern should be informed of the process to escalate to a Non-Conformance or Complaint should the concern reoccur.

The difference between concerns and complaints is very slight in some cases and it is important to discuss with the customer how they wish the matter resolved and by whom.

Non-Conformance or Complaints may be generally defined as expressions of dissatisfaction which require a response.

All Non-conformances or Complaints should be acknowledged within 24 hours of receipt and process set out in P-05-01.

All Non-conformances or Complaints should be responded to within 14 days although at times the response may take longer due to outside factors such as external quality testing, timelines for supply chain etc. The Complainant must be informed in writing of the contact details of the person handling the non-conformance or complaint. The Complainant must also be kept informed of the progress of the Non-conformance or Complaint and, if required, a monthly update should be provided.

All complaints, suggestions, concerns and nonconformities should be recorded in Incident Register (R-05-03) run by QM.

3. Company Aims and Objectives

- All feedback from our stakeholders is seen as positive and valuable, ensuring that service users are protected from poor standards of service.
- To ensure that all stakeholders are treated with politeness, transparency and respect, they have their concerns listened to and are taken seriously.
- To ensure that all concerns and complaints are handled swiftly and efficiently.
- To ensure that all feedback is handled fairly and consistently.
- The LSG Customer Complaints, Complements and Feedback procedure is regularly monitored and reviewed to ensure that it is easy to use and accessible
- To ensure the effective monitoring of the system and identifying opportunities for improvement from representations and complaints.
- To ensure that all Staff have access to guidance and training to effectively manage concerns, including an awareness of identifying creative solutions at whatever stage.

4. Providing Feedback

We welcome any feedback, either positive or negative in order that we may improve our products and services. In order to provide feedback you may:

Phone us	Send an e-mail	Send a letter
+44 (0) 1234 889180	quality@lifesciencegroup.co.uk info@lifesciencegroup.co.uk	The Managing Director, Life Science Group Ltd., The Science Centre, 1 Blaydon Road, Sandy, Bedfordshire, SG19 1RZ

5. Information that would help us to deal with your feedback

In order to respond to your feedback, please provide as much of the following information as possible when you contact us:

Title & Name

Company Name if appropriate

Postcode

Telephone Number (including dialing code)

Email Address

Customer account number (if known)

LSG reference number (if known)

Type of feedback:

Compliment

Complaint (first complaint or a follow up to a reply you were not satisfied with)

Comment

A clear description of the feedback.

6. Process flow

Step 1: Intake
<p>Initial Triage</p> <p>Valid comment?</p> <p>Potentially reportable?</p>
Step 2: Investigation
<p>Level I: Conducting the initial investigation</p> <ul style="list-style-type: none"> • Complete Summary statement • Confirm the complaint. Is the alleged deficiency actually a deficiency? • Do you have enough information to investigate the complaint? Make earnest attempts to get the information you need. • Review reported errors against product information <p>It may be possible to close the complaint after an initial investigation into assignable cause. The following actions should be taken:</p> <ul style="list-style-type: none"> • It should be determined if there is an open CAPA for this issue. • Does the current complaint suggest that a closed CAPA action was ineffective? • Check if the issue is already being investigated • Document clearly retaining all supporting documentation within the file • Pass for Management Review or further investigation <p>Level II: Investigation of probable cause</p> <p>Following the initial Level I investigation, it is necessary to investigate the probable cause:</p> <ul style="list-style-type: none"> • Has a new (previously unreported) issue occurred? • Is the failure within the limits established based on labelling, intended use, and risk files? • Is the failure a known issue but falls outside a risk threshold? • Document clearly retaining all supporting documentation. • Record if issue is to be closed at Level II and give reasoning • Pass for Management Review <p>Level III: Investigation of root cause</p> <p>If the Level II investigation reveals that there is a new failure the next step will be a review of the risk management and a CAPA. Points to consider:</p> <ul style="list-style-type: none"> • Is a product recall required? • Has the issue failed current predefined specifications or limits • Has there been a violation of applicable regulation or product specification • Investigation by Management Team

Step 3: Closing

Closure occurs in conjunction with investigation level (Step 2) as long as the applicable parallel processes are completed.

Before closing a complaint, the following documentation should be completed where applicable:

- Vigilance reporting
- Risk Management file updates
- CAPA – is it possible to close issue at this point referencing the work of opened CAPA?

Communicating the outcome of issues

It is important to communicate fully the outcome of any issue raised both internally and externally.

Internally

- **CAPA:** Complaint trending is used for determining effectiveness and must be defined by the product, failure code(s)
- **Statistical monitoring:** In addition to trending, it is important to monitor times from complaint receipt to investigation to closure and reporting

Externally:

- **Vigilance reporting:** Submit a vigilance report to regulatory authorities on the complaint investigation closure.
- **Recall/customer communication:** This should include a summary of the investigation and CAPA, plus link a recall to complaints affected by the failure.

Parallel Processes

Risk Management

Vigilance Reporting

Requirement for immediate field action

7. Document history:

Created / reviewed	Version	Main changes	Responsible
16.03.2016	01	First version (10574)	Katy Applegarth
15.07.2020	01 (under new reference)	Updated to the latest SOP format Process review – clear distinction between NC and INC. Updated process owner. Change SOP number from 10574 to G-05-01	Michal Kisiel
07 Dec 2022	02	Minor update to contact details	Jenny Murray