Customer Complaints
客戶怨訴

1.0 Purpose 目的

To establish the handling procedure for complaints regarding SCI products.

建立旭富製藥科技股份有限公司(SCI)所有關於產品之怨訴處理程序。

2.0 Scope 範圍

The complaint procedure is applicable to all complaints in oral or written.

本程序適用於處理所有口訴及書面之怨訴。

3.0 Definition 定義

3.1 Classification 分類

3.1.1 Quality related 品質相關

3.1.1.1 Critical 嚴重

The condition will serious affect the quality of product or regulatory compliance.

嚴重影響產品品質或法規符合性。

3.1.1.2 Major 中度

The condition will affect the quality of the product or regulatory compliance.

影響產品品質或法規符合性。

3.1.1.3 Minor 輕微

The condition may not affect the quality of the product or regulatory compliance.

可能不會影響產品品質或法規符合性。

3.1.1.4 Others 其它

There is insufficient information to classify it as minor or major or critical

無足夠的資訊去分類為輕微、中度或嚴重。

3.1.2 Non-quality related 非品質相關

4.0 Responsibility 職責

4.1 Business department (BA) 業務

The main complaint receiver. Log in customer complaint and forward to QA investigation. Continuously communicate with customer till both customer and SCI agree case can be closed. Keep all correspondences.

接收並記錄客戶怨訴。將怨訴轉交品保部門展開調查。持續與客戶溝通，直至雙方同意該怨訴結案。保留所有該怨訴相關之內外聯繫檔案。

4.2 Quality Assurance (QA) 品保

4.2.1 QA justify complaint classification and conduct investigation for all quality related complaints, submit investigation report; communicate with customers when necessary; follow up on corrective actions till related deviation and influences are resolved; maintain all investigation documents.

QA 判定客訴分類及主導所有品質相關之怨訴調查並提出調查報告；必要時與客戶之聯絡；追蹤相關矯正措施至相關偏差或影響被矯正或消除；怨訴相關檔案之保管。

4.2.2 Conduct investigation for the complaints other than quality related cases, follow up corrective actions.

負責主導非品質相關怨訴之調查，跟催矯正措施。

4.2.3 Customer complaints can be categorized by root cause. Do trend analysis.

客訴報告依發生客訴的原因，將客訴分類統計以觀察趨勢。

4.3 Related department 相關部門

Cooperate with BA/QA to solve complaint.

配合 BA/QA 處理相關客訴。

5.0 General statement or supplementary explanation 一般敘述或補充說明

5.1 In GMP meeting, it is necessary to report, discuss and evaluate the correction follow up and the effectiveness of CAPA.

於 GMP 會議中，需報告與討論評估相關矯正追蹤進度與其矯正預防行動之有效性。

6.0 Procedure 程序

6.1 BA shall fill out Form FQA079 and forward to QA. Then, BA or QA will send FQA882 to customer within two working day after QA fill out FQA882.
業務將接獲的怨訴記錄於 FQA079，並送交 QA。然後，QA 填寫 FQA882 後在二個工作天內由 BA 或 QA 將 FQA882 寄給客戶。

6.2 The customer complaint record (FQA079) shall include the following information:
客戶怨訴記錄(FQA079)應包含這以下的資料:

6.2.1 Product name/code 產品名稱/編號

6.2.2 Lot number 批號

6.2.3 Complainant name/company 怨訴人及公司名稱

6.2.4 Complaint nature (include attachment when applicable)
怨訴事項 (若有附件時附上)

6.2.5 Complainant telephone number plus country and area code
怨訴客戶電話號碼，含國碼和區碼

6.2.6 Date received 怨訴日期

6.2.7 Nature of complaint (must be in details) 怨訴的性質(需要詳細)

6.2.8 Classification: 分類
Quality related 品質相關
Quality impact degree 品質相關之影響程度
Necessity to do investigation 是否需要調查
Related investigation department 參與調查之部門

6.2.9 Accountable department 責任部門

6.2.10 Informing complainant. Summarize the communication and action informing with complaint and related response.
客訴通知。總結怨訴及回覆之連繫和行動資訊。

6.2.11 Case close date 回覆結案日期。

6.2.12 QA filing date 品保歸檔日期。

6.3 QA justify the necessary of investigation. If Yes, QA to initiate a deviation investigation per SOP SCI-003. If No, QA shall state the reason in form FQA079.
QA 評判調查之必要性。若需調查，QA 依 SOP SCI-003 啟動偏差調查。若不需調

查，QA 應說明原因記錄於 FQA079。

Conduct deviation investigation based on but not limit to followings
偏差可依下列但不局限於下列方向展開調查:

6.3.1 Equipment cleaning and use log 設備清洗與使用記錄

6.3.2 Component, container, closure, and labeling records
成份，包裝容器，封蓋和產品標籤記錄

6.3.3 Batch production and control records 批次生產和管制記錄

6.3.4 Batch packaging records 批次包裝記錄

6.3.5 Laboratory records 實驗室記錄

6.3.6 Distribution records 配銷記錄

6.3.7 Operator interview 作業員訪談

6.3.8 Clean rooms management and use log 潔淨室管理及使用記錄

6.3.9 Raw materials 原料

6.3.10 QC/IPC retained samples 品管/製程品管留樣

6.4 Use Form FQA078 “Customer complaint investigation report” to summarize the investigation for response with customer.
使用表格 FQA078 客訴調查報告回覆客戶。

6.4.1 Description 重點描述事件內容

6.4.2 Influenced batches/lots 影響批次

6.4.3 Investigation finding 調查結果

6.4.4 Conclusion 調查結論

6.4.5 Corrective actions taken and due date 矯正行動及期限

6.4.6 Corrective actions follow up 跟催矯正行動

6.4.7 Reviewed and confirmed by related department 相關部門審閱及確認

6.4.8 Disposition of complaint lot and influenced lot
客訴批次及受影響批次處理方式

6.5 Due date for minor / other complaint investigation and CAPA plan verification is within 30 working days and for major / critical complaint investigation and CAPA plan verification is within 14 working days. If it cannot be completed in time, update completion target date shall be explained.
次要及其它客訴調查與矯正預防行動計劃確認應於 30 個工作天內完成，重大或關

鍵性客訴調查與矯正預防行動計劃確認應於 14 個工作天內完成，若無法及時完成，應更新完成預訂日應做說明。

BA shall inform customer within a week to invite customer's comment and reason. If the report is not acceptable, QA do re-evaluation and clarification with one month. If none comment response received after a month, SCI shall assume the investigation report is accepted. QA can decide to close the case.

BA 應於一周內將報告轉予客戶。並取得客戶的意見和理由。若報告不被接受，QA 需於 1 個月內重新評估並釐清. 若一個月後仍未見回覆，SCI 應認定其接受調查報告，QA 可決定將客訴予以結案。

6.6 Customer complaint number assignment 客訴編碼

For example 例如: ccn-2013-001

The prefix number is always "ccn-". The first to fourth digits stand on year. The fifth digit is always "-". The sixth to eighth are sequential code. The example means the first customer complaint happened in 2013.

字首為 "ccn-"，第一碼至第四碼代表年份，第五碼為"-",第六碼到第八碼為流水號。例句表示為 2013 年發生之第一件客訴。

6.7 When a customer complaint is received, record information in customer complaint list (FQA863) immediately.

QA 於收到客訴時，應立即填寫怨訴資訊於客訴清單(FQA863)。

6.8 When customer complaint is closed by QA, record shall be sent to BA immediately. And BA will send complaint record to customer within one week.

QA 將客訴結案後，應將記錄立即寄給 BA。BA 將會於一個禮拜內將此份客訴紀錄寄給客戶。

6.9 All written records shall be retained according to SOP SCI-120.

記錄保存期限，依 SOP SCI-120 規範。

7.0 Related documents 相關文件

7.1 21 CFR 211.198, 21 (Complaint files).

7.2 ICH Q7 (GMP for Active pharmaceutical ingredients)

7.3 SOP SCI-120 Controlled documents and safe-guarding

SOP SCI-003 Non-conformance, Incident, Deviation Report and Investigation

不一致事項 事件 偏差報告及調查

SOP SCI-404 Corrective action and preventive action (CAPA)

7.4 Form: FQA078 Customer complaint investigation report

FQA079 Customer complaint record

FQA863 Customer complaint list

FQA882 Notification on Complaint Confirmation

FPD042 Deviation Report Correction Corrective Action and Preventive Action

7.5 Attachment 1: Flow chart of customer complaint procedure

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