111年化粧品GMP研討會(二)

授課主題：

內部稽核 (含偏差、變更管制)

黃　國　良

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經歷: **SGS KN** 產品經理
現職: 諮詢顧問, 講師, 稽核員
資格：

1. 國際 **QSA ISO 9000** 主導稽核員
2. 國際 **IRCA ISO 9000** 主導稽核員課程講師
3. 化妝品 **ISO22716**主導稽核員 + 訓練講師
4. 國際 **ICH Q7**藥品 **API** 主導稽核員(深圳考試通過)
5. **WHO GDP** 主導稽核員(台灣考試通過)
6. 化妝品 **ISO22716**(泰國考試通過)
7. 連鎖賣場稽核員
8. 醫療器材 **ISO13485** (韓國考試通過)
9. 一般實驗室 **ISO17025** (台灣考試通過)

主題有:

稽核

變更作業

偏差作業

參考資料

1. ISO22716
2. CNS22716
3. ICH
4. 衛福部官網資料

INTERNATIONAL STANDARD

ISO 22716

First edition
2007-11-15

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

Cosmétiques — Bonnes Pratiques de Fabrication (BPF) — Lignes directrices relatives aux Bonnes Pratiques de Fabrication

Introduction

These guidelines are intended to provide guidance regarding Good Manufacturing Practices for cosmetic products. These guidelines have been prepared for consideration by the cosmetic industry and take into account the specific needs of this sector. These guidelines offer organizational and practical advice on the management of the human, technical and administrative factors affecting product quality.

These guidelines have been written to allow them to be used following the flow of products from receipt to shipment. Additionally, in order to clarify the way this document reaches its objectives, a 'principle' is added to each major section.

Good Manufacturing Practices constitute ~~the practical development of the quality assurance concept through~~ the description of the plant activities that are based on sound scientific judgement and risk assessments. The objective of these GMP guidelines is to define the activities that enable you to obtain a product that meets defined characteristics.

Documentation is an integral part of Good Manufacturing Practices.

重大概念

are based on sound scientific judgement and risk assessments.

基於堅實的科學判斷及風險評估

Good Manufacturing Practices constitute the practical development of the quality assurance concept through the description of the plant activities that are based on sound scientific judgement and risk assessments. The objective of these GMP guidelines is to define the activities that enable you to obtain a product that meets defined characteristics.

ICH HARMONISED TRIPARTITE GUIDELINE QUALITY RISK MANAGEMENT Q9

- Basic risk management facilitation methods (flowcharts, check sheets etc.);
- Failure Mode Effects Analysis (FMEA);
- Failure Mode, Effects and Criticality Analysis (FMECA);
- Fault Tree Analysis (FTA);
- Hazard Analysis and Critical Control Points (HACCP);
- Hazard Operability Analysis (HAZOP);
- Preliminary Hazard Analysis (PHA);
- Risk ranking and filtering;
- Supporting statistical tools.

法規名稱：化粧品優良製造準則 EN

發布日期：民國 108 年 08 月 13 日

法規類別：行政 ＞ 衛生福利部 ＞ 食品藥物管理目

所有條文 | 編章節 | 條號查詢 | 條文檢索 | 沿革

第 一 章 總則

第 1 條

1 本準則依化粧品衛生安全管理法（以下簡稱本法）第八條第四項規定訂定之。

2 本準則之訂定，其內容依國際標準組織化粧品優良製造規範（ISO 22716：Cosmetics－Goodmanufacturingpractices（GMP）－Guidelinesongoodmanufacturing practices）之規定。

回上

關於:稽核1, 2, 3

關於:內部稽核

16 Internal audit

16.1 Principle

An internal audit is a tool which is designed to monitor the implementation and the status of these cosmetic Good Manufacturing Practices and, if necessary, to propose corrective actions.

16.2 Approach

16.2.1 Specially designated competent personnel should conduct internal audits in an independent and detailed manner, regularly or on demand.

16.2.2 All observations made during the internal audit should be evaluated and shared with appropriate management.

○○公司		Page: 1 of 1
	年度定期稽核時程表	
SOP-XXX-1		實施日期: YYYY/MM/DD

	1月	2月	3月	4月	5月	6月	7月	8月	9月	10月	11月	12月
○○部			◇3/15	○4/10	◎5/20							
○○部		◇2/15	○3/10	◎4/26								
○○部												
○○部				◇4/15	○5/10	◎6/26						

備註： ◇ 組成稽核小組 ○ 召開工作會議 ◎ 執行稽核	承辦部門/人員 簽名/日期	
	權責主管 簽名/日期	

稽核案號			
稽核主題			
稽核範圍			
受稽核單位		稽核日期	
檢查要項	符合	未符合	備註
稽核小組 簽名/日期			

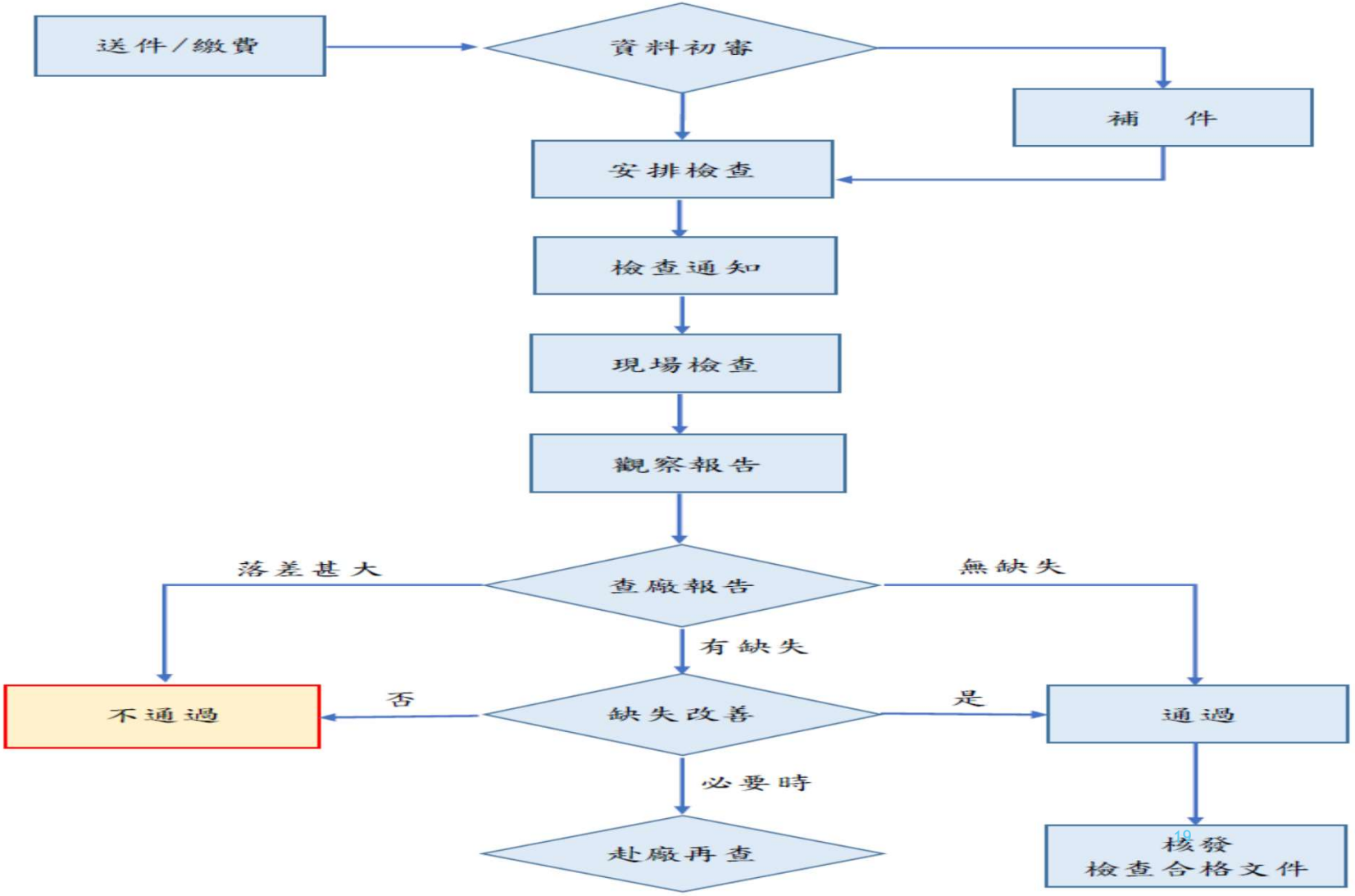
稽核案號			
稽核主題			
稽核範圍			
受稽核單位		稽核日期	
稽核人員			
作業現況			
編號	風險	缺失內容	
結論			
稽核員 簽名/日期		稽核小組組長 簽名/日期	

稽核案號			
受稽核單位		稽核日期	
原缺失編號	缺失內容	改正結果說明	
權責主管簽名/日期			
稽核小組審查意見			
稽核員簽名/日期			
稽核小組組長簽名/日期			

關於:外部稽核

V1-1091020

十三、 符合化粧品優良製造準則檢查流程圖



面對稽核的應對

稽核方:

1.對稽核的標準負責勿過度

2.……

被稽核方:

1.對稽核的標準要了解

2.……

Rehearsal/Practice

關於:變更作業

15 Change control

Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data.

2.7
change control
internal organization and responsibilities relative to any planned change of one or several activities covered by the Good Manufacturing Practices in order to ensure that all the manufactured, packaged, controlled and stored products correspond to the defined acceptance criteria

4.2 變更管制：指為確保所有製造、包裝、管制及儲存之產品符合允收基準，內部組織與權責單位對涉及本準則中一項或多項活動之計劃性變更。

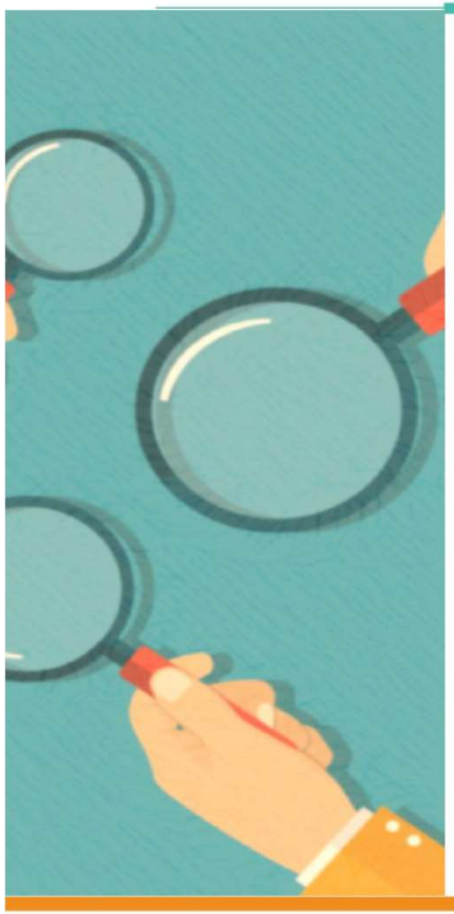
範例
產品配方變更 擴建新生產線 製程參數或步驟變更
倉儲內部管理流程變更
倉庫溫控範圍優化
現有作業程序經評估可滿足需求，無需變更者。

第 十四 章 變更管制

第 74 條

化粧品製造業者對可能影響產品品質之變更，應有充分資料支持並經權責人員同意，始得為之。

變更管制



缺失比例 -1.8 %

查核重點

- 變更管制程序訂定及執行狀態
- 變更評估資料
- 相關紀錄連結、回溯及定期更新

缺失態樣

- 尚未訂定變更管制相關管理程序
- 已執行變更(於評估期)，尚未提出變更申請，未依變更管制相關管理程序執行

衛生福利部 食品藥物管理署 Taiwan Food and Drug Administration

Rehearsal/Practice

關於:偏差作業

2.14
deviation
internal organization and responsibilities relative to the authorization to deviate from specified requirements due to a planned or unplanned and, in any case, temporary situation concerning one or several activities covered by the Good Manufacturing Practices

13 Deviations

13.1 Deviations from the specified requirements should be authorized with sufficient data to support the decision.

13.2 Corrective action should be made to prevent recurrence of the deviation.

第 十二 章 偏差處理

第 68 條

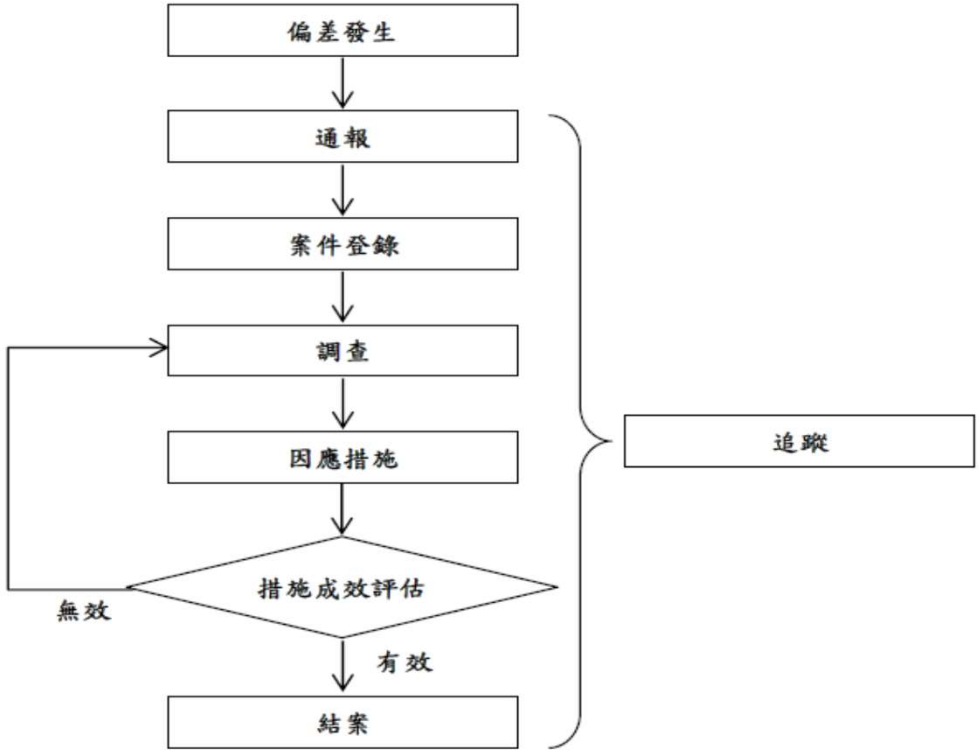
化粧品製造業者發現有偏差情事者，對該偏差之處置，應具充分資料支持，始得為之。

第 69 條

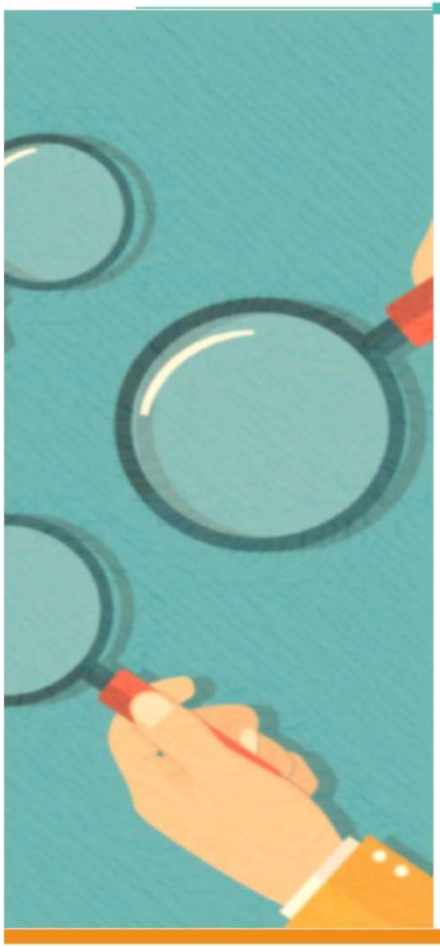
化粧品製造業者應採取偏差矯正措施，防止偏差再次發生。

4.1 偏差：指當一項或多項與 GMP 有關之活動，出現預期、非預期或其他臨時性狀況時，偏離特定要求之情形。

5.1 偏差處理流程圖：



偏差處理



缺失比例 -0.9 %

查核重點

- 偏差處理程序
- 偏差處理紀錄
- 偏差處理結案追蹤

缺失態樣

- 產品OO原料實際下料量與預計量不一致，惟未有相關偏差調查
- 偏差事件逾結案日未追蹤情況
- 後續追蹤顯示，偏差事件未獲改善

Rehearsal/Practice

關於: Q & A

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