

Risk Assessment Workshop

風險評估實作練習

題目：依法規主管機關之要求，請對貴公司之“倉儲設施或系統”提供一個全面性的風險評估

引導：

- 步驟一：就貴公司貨物進出倉儲的標準流程建構出一個流程圖 (process map)，此流程圖須包含個連結站與傳輸途徑
- 步驟二：將步驟一中所建立之各流程填入附件一之“失效模式”(FMEA) 表中
- 步驟三：與組員進行大腦激盪來執行風險辨識 (risk identification)，在步驟二中所列出的每一個流程下紀錄出所有可能的風險來源
- 步驟四：與組員進行具科學邏輯的風險分析 (risk analysis)，依照附錄二之評分表將步驟三中所列出之所有風險做進一步的評分 (Severity 嚴重性，Probability 發生率；Detectability 可偵測性)

注意：照附錄二之評分表可依各組之實際案例狀況做更改

- 步驟五：參照附錄三對步驟三和步驟四所表列之各風險進行風險評價 (risk evaluation)來計算出 RPN 值
- 步驟六：對步驟五所評價出之中和高風險層級之風險源提供風險控制 (risk control) 計畫 (remediation action)
- 步驟七：對已經控制之風險源重新進行風險分析和風險評價，重複步驟六與步驟七直到風險源之風險層級降至低等級

附錄一

[illegible]

附錄一

[illegible]

附錄一

[illegible]

附錄一

[illegible]

附錄一

[illegible]

附錄二

Score	Risk Severity
1	No or negligible harm/ quality alert
3	Loss of product activity/ drug appearance or package damage
6	Injury to patient/ batch loss
9	Death or extremely serious injury to patient/ product recall or regulatory action
Score	Risk Probability
1	Not observed, extremely unlikely to occur/ proactive control
3	Not anticipated, but possible/ passive control
5	Failure observed occasionally, likely to occur/ no control/ passive control with harsh environmental effect
7	Very likely to occur, almost certain/ no control with harsh environmental effect
Score	Risk Detectability
1	Almost certain- Failure detected in every instance (i.e. automatic detection)
3	Very likely detection (i.e. checked by multiple personnel)
5	Moderate chance of detection (i.e. detected by one personnel)
7	Essentially Undetectable

附錄三

	1	3	5	7
1	1	3	5	7
3	3	9	15	21
5	5	15	25	35
6	6	18	30	42
7	7	21	35	49
9	9	27	45	63
15	15	45	75	105
18	18	54	90	126
21	21	63	105	147
27	27	81	135	189
30	30	90	150	210
42	42	126	210	294
45	45	135	225	315
63	63	189	315	441

Risk Level	RPN Range
Low	$RPN < 30$
Medium	$30 \leq RPN < 90$
High	$90 \leq RPN$