Risk Management

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仁愛綜合醫院，大里院區

Presented by:

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陳憲章－醫療業簡歷

現職－

- 美國CTI科技管理顧問集團公司首席顧問
- 中華六標準差應用協會理事長
- 美國食品藥物管理局(FDA)醫療品質系統法規設定及執行諮詢委員(QSR-Quality System Regulation) 之風險評估/管理指導顧問(Risk Analysis / Management)
- 美國威斯康新大學(university of Wisconsin-Madison)兼任教授。主授：如何將失效模式與應變計劃(FMEA)應用在醫療器材研發及藥物研發上
- 美國喬治華盛頓大學(George Washington University-Washington, D.C.)兼任教授。主授：FMEA運用在醫療管理上，以防止失誤發生。
- 美國德頓大學(university of Dayton)"產學合作中心" (Center for Excellence)顧問，諮詢及輔導項目－Six Sigma及FMEA。

陳憲章－醫療業簡歷

現職－

- 美國Johnson & Johnson 長年約聘顧問，諮詢及輔導項目－Six Sigma，FMEA及Product Launch。
- 美國Beck Dickson公司長年約聘顧問，諮詢及輔導項目－FMEA，Risk Analysis / Management 及Design Control。
- 美國禮立藥廠(Eli LiLi Company)長年約聘顧問，諮詢及輔導項目－FMEA，Risk Analysis / Management 及Design Control。
- 美國Mayo Clinic醫院集團專案約聘顧問，諮詢及輔導項目－Productivity Quality Improvment，Cost Reduction。
- 美國Mentor公司(外科美容)專案約聘顧問，諮詢及輔導項目－醫療Quality Improvment。
- 美國奇異醫療器材事業部(GE-Medical)專案約聘顧問，諮詢及輔導項目－FMEA，Risk Reduction，Product Development，及Six Sigma。
- 德國西門子醫療器材事業部(Siemens-Medical)專案約聘顧問，諮詢及輔導項目－FMEA及Six Sigma。

陳憲章－醫療業簡歷

在醫療相關業界之傑出成就及過去經歷－

- 美國律師公會專案約聘顧問。諮詢及輔導項目－如何在法庭中判讀FMEA(專家證言的應用)，以釐清法律責任。
- 美國AAMI(Association of Advanced Medical Instrament)協會指導顧問及培訓資深講師。主授：FMEA及風險管理。
- 美國MD&M(Medical Device Design & Manfacturing)協會指導顧問。指導項目：FMEA、風險管理及如何協調醫院與醫事人員正確使用醫療器材。
- 美國病理學會專案約聘顧問。諮詢及輔導項目－如何使用FMEA來減少誤判擴會，進而減少醫事糾紛。
- 諮詢輔導美歐主要醫療、藥物、器材等公司及醫療單位近50家，培訓相關專業醫生、護士、管理及行政人員超過2,000人。

陳憲章－醫療業簡歷

在Six Sigma方面之傑出成就－

- 多次應邀赴GE管理學院，對高階管理人員主授FMEA，Control Plan等課程。
- 諮詢及輔導Motorola總公司編寫FMEA訓練手冊，並培訓Motorola種子教官
- 諮詢GE總公司編寫Six Sigma訓練手冊。
- 諮詢、輔導並培訓GE－Motor 事業部內的Six Sigma種子教官。
- SAE及SME的FMEA訓練手冊主編人及指導人。
- 培訓具國際水準的黑帶資格合格人員(BB)183人、綠帶資格合格人員(GB)431人、黑帶大師資格合格人員(MBB) 6人，另有其他黑、綠帶結業人員，但非認證人員數百人。

Risk Management

- ❖Identify the Hazard
- ❖Estimate the Harm/Damage
- ❖Assess the Risks
- ❖Establish the Mitigation
- ❖Evaluate the Residual Risks
- ❖Control the Situation

Risk

- Everything has a risk of continuously performing to the way we want, or at least expect
- The challenge is how much a risk we are facing in a normal condition, as well as an abnormal condition.
- Since there is always a risk, what can we do about it – in terms of mitigation to reduce the risk to an acceptable & tolerable level.
- Control, and Control Points
- Risk Management (RM)
- Crisis Management (CM)
- CM is not equal to RM

Type of Risk

Product Risk -

A. Risk to the general public
B. Risk to the end product user and 3rd parties
C. Risk to the organization
D. Risk to the "process" itself

Process/Operation Risk -

A. Internal Risk – Immediate Impact & Downstream Impact
B. External Risk – Couldn't stop & correct internally, therefore there is an external risk; likely on the product & product user

Risk Impacts – Harm & Damage

Harm/Damage to the general public, end product user, 3rd party, organization, & "process" itself.

Thinking about S-I-P-O-C concepts.
Who is the customer?
Who is the supplies?

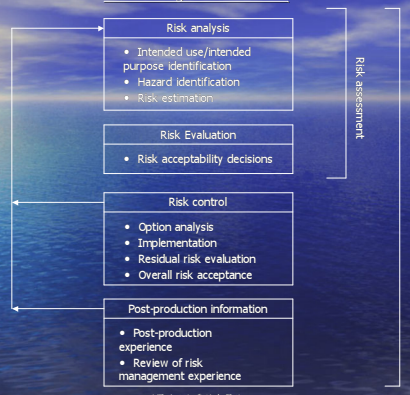
Risk Estimation , Analysis, & Mitigation

Risk Estimation & Analysis

Normal Condition and Failure Condition

- Mechanism — Function Fails
- Condition — Inside —Outside
- Restraint — Constraint — Regulations —Social Values & Practices

Risk Management Process



Three Risk Components Approach

– Cause, Failure, & Effect

A) The probability of a Failure occurring by an identified cause under current control – occurrence
B) How much of the impacts – Severity
C) How early in the life cycle, and how much of the problem can we detect and correct – Detection

Risk = Occurrence x Severity x Detection

The acceptability of a risk to a stakeholder is influenced by these three components, and by the stakeholder's perception of the risk

Two Risk Components Approach

– Hazard & Harm (Damage)

a). The probability of the occurrence of harm (damage), that is, how often the harm may occur.

b). The consequences of that harm (damage), that is, how severe it might be.

Risk = Probability x Severity

- or Matrix of these two

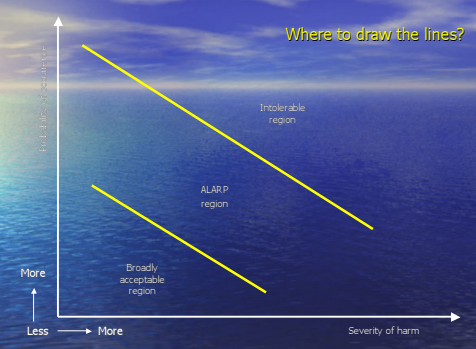
The acceptability of a risk to a stakeholder is influenced by these two components, and by the stakeholder's perception of the risk.

Probability of Occurrence Estimation

- Ask yourself three questions --
  1. Does the hazard occur in the absence of a failure?
  2. Does the hazard occur in a failure?
  3. Does the hazard occur only in a multiple-fault condition?
- Qualitative approach --
  - Level 1: Incredible
  - Level 2: Improbable
  - Level 3: Remote
  - Level 4: Occasional
  - Level 5: Probable
  - Level 6: Frequent
- Quantitative approach -- 1 ~ 10 ranking. May refer to FMEA tables

Severity Estimation

- Must consider immediate, short term, and long term effects
- Qualitative approach --
  - Level 1: Negligible
  - Level 2: Marginal
  - Level 3: Critical
  - Level 4: Serious
  - Level 5: Catastrophic
- Quantitative approach -- 1 ~ 10 ranking, may refer to FMEA tables



Risk Estimation

In estimating the risk for each hazard, the following aspects should be taken into account:

- extent of reliance on the analytical result (contribution to the Mitigation Decision)
- plausibility checks
- availability and use of controls
- quality of assurance measures/techniques applied in the test laboratories
- detectability of deficiencies/errors
- situations of use (e.g. emergency cases)
- professional use/non-professional use
- method of presentation of information

Possible Hazards for Products

- Energy Hazards
- Biological Hazards
- Environmental Hazards
- Hazards resulting from incorrect output of energy and substance
- Hazards related to the use of the Product
- Inappropriate, inadequate or over-complicated user interface (man/machine communication
- Hazards arising from functional failure, maintenance, and aging
- Hazards from the following:
  - batch inhomogeneity, batch-to-batch inconsistency
  - Common interfering factors
  - Carry-over effects
  - Specimen identification errors
  - Stability problems (in storage, in shipping, in use, after first opening of the container)
  - Problems related to taking, preparation and stability of specimens
  - Inadequate specification of prerequisites
  - Inadequate test characteristics

HACCP (Hazard Analysis & Critical Control Points)

- Hazard Analysis -

  The identification of hazards and their initiating causes

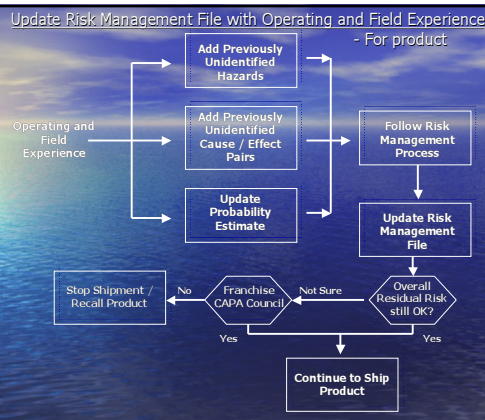
- Critical Control point -

  A point, step, or procedure at which control can be applied and is essential to prevent, eliminate, or reduce a hazard to an acceptable level

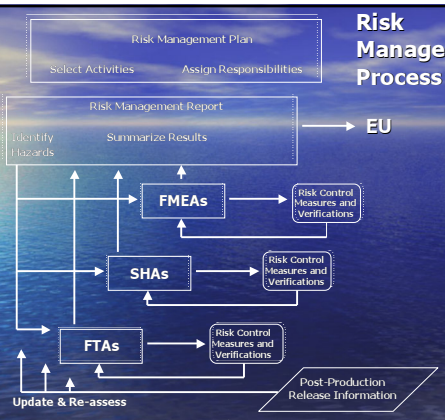
Seven Contents of HACCP

1. Conduct hazard analysis and identify preventive measures.
2. Identify critical control points.
3. Establish critical limits.
4. Monitor each critical control point.
5. Establish corrective action to be taken when deviation occurs.
6. Establish verification procedures.
7. Establish record-keeping system

Update Risk Management File with Operating and Field Experience - For product



Risk Management Process



Healthcare Process Flow

Patient Intake	Assessment	Diagnosis	Process of Care	Evaluating Care	Discharge and Billing
Functions: 1. Marketing 2. Facility 3. Registration 4. Admitting 5. Records		1. Diagnostic – Observation & Questioning 2. Diagnostic – Testing 3. Information service 4. Clinical Pathway Practice 5. Records 6. Treatment / Pharmacy Services 7. Facility / Housekeeping 8. Material Service – Supply & Waste 9. Care & Monitoring on Recovery 10. Manpower Assignment 11. Community responsibilities & governmental codes 12. Morality			Functions: 1. Records 2. Housekeeping 3. Finance 4. Sensitive Issues & Personalization 5. Followups

- Looking for the Bottleneck → Most likely errors start here
- Looking for the Queuing, Pending, Batching, Bunching, Hanging → Second most likely errors start here

Examples of Errors

Patient Intake	Assessment	Diagnosis	Process of Care	Evaluating Care	Discharge and Billing
1. Targeting on wrong customers 2. Wrong marketing strategies 3. Not enough parking spaces 4. Patients park on MD's space 5. Wrong records 6. Incompleted records 7. Administrative error in admission 8. Hospital bed availability 9. Waiting time 10. Housekeeping 11. Security 12. General feeling		1. Incorrect, or untimely diagnosis 2. Error in medication 3. Error in therapy, or other treatment 4. Untimely treatment 5. Administrative error in patient record 6. Departure from nursing standard 7. Departure from any other professional standard 8. Facilty outage or malfunction 9. Equipment outage, shortage or malfunction 10. Medical professionals fatigues 11. Food service 12. Communication among medcare provider, patient, family, and & underwriters			1. Administrative error in discharge 2. Error in pre-release patient indoctrination 3. Administrative error 4. Delayed discharge 5. Error in take-home instructions or medication 6. Error in any finance statement

Analysis on Medication Errors – Causes & Effects

Root Causes	Responsible Parties	Effects
1. Diagnosis	* MD, & Medical Technicians	
2. Diagnosis related administrative cause	* MD, RN, & LPN	
3. Distribution		
a. Pick / placement	* Pharmaceutist, manufacturer & recording clerk	
b. Re-packaging	* Pharmacist	
c. Labeling	* Pharmacist, & recording clerk	
d. Transportation	* RN, LPN, & Assistant	
4. Drug Delivery		
a. Inside facility	* MD, RN, RPN, & Patient	
b. Outside Facility	* Patient, Family, & Concerned parties	

What's next?

The 6 Sigma Program!

How to do it?

Risk Management

Questions and Answers

You can always contact the follows:

中華六標準差應用協會
Tel: 04-2298-0925 E-mail: sixsigma@pie.com.tw

Or

西緹埃（CTI）國際管理科技公司
Tel: 04-2291-0706 E-mail: cti@pie.com.tw