



藥品儲存之品質風險概況

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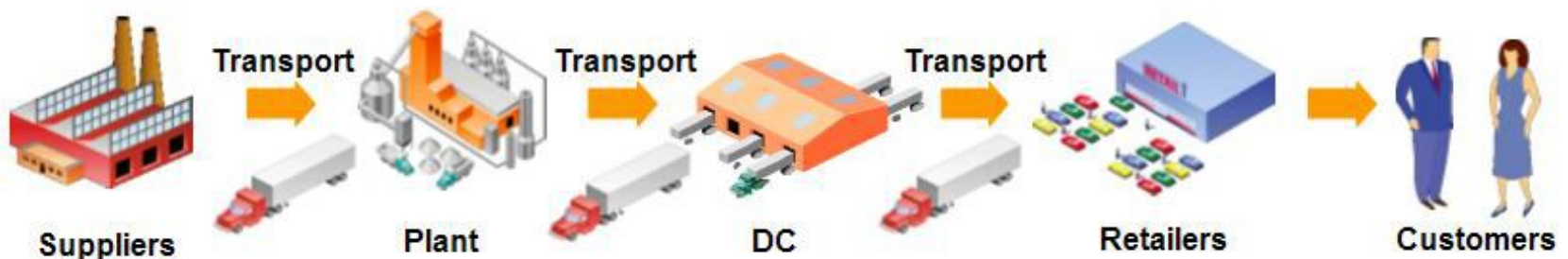
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4. Risk Assessment in GDP 優良運銷規範的風險評估

- Risk to assess, control, and review
 - What are the risk sources?

Preface

It is of key importance that medicinal products are not only made to a high quality in accordance with Good Manufacturing Practice, but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where Good Distribution Practice (GDP) comes into play.



4. Risk Assessment in GDP

- Risk Sources – Equipment 設備



1. Product packaging



2. Storage



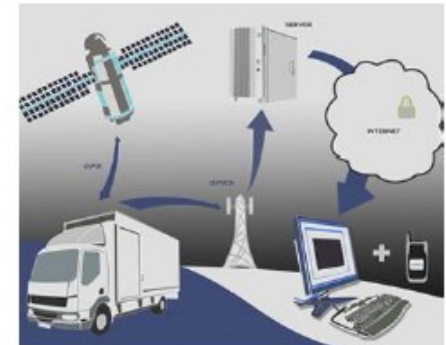
3. Shipping container



4. Transport vehicle



5. Monitoring system



6. Data- and communication system

Equipment and its components must be qualified/validated to eliminate and to reduce the risk of failures.

4. Risk Assessment in GDP

• Risk Sources – Processes 流程

1. Pre-shipment

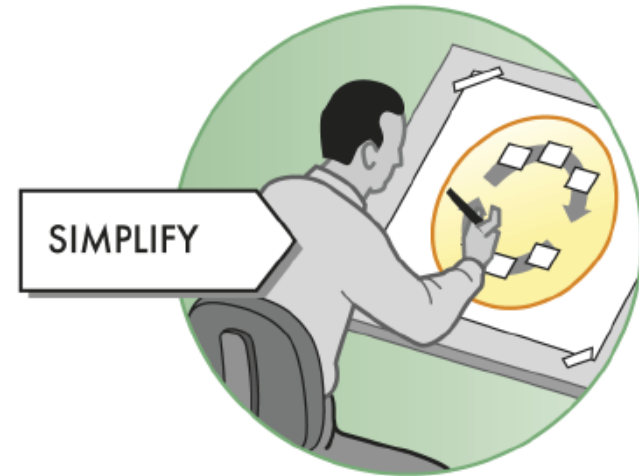
- Planning
- Procedures / SOPs / Process flows
- Risk assessments
- Contingency plans
- Equipment qualification/validation
- Packout assembly
- Export documentation

2. In-transit

- Loading/unloading transport vehicle
- Transit nodes
- Cargo handling processes
- Communication processes
- Custom inspection/clearance

3. Post-shipment

- Roles and responsibilities towards temperature excursions
- Storage of the goods
- Inventory management



Application of Lean Six Sigma drives continuous improvement of processes and reduces failures

4. Risk Assessment in GDP

- Risk Sources – People 人員

1. Skilled people

- Knowledge, experience and understanding of equipment, processes and external factors.

2. Unskilled people

- No or limited knowledge, experience and/or understanding of equipment, processes and/or external factors.

3. Bad actors

- Skilled or unskilled people who on purpose mislead others and/or mistreat products including theft, counterfeiting and exposure to extreme temperatures.



4. Risk Assessment in GDP

- Risk Sources – People

Types of Human Error

1. Misunderstanding – Teach your written policies and procedures repetitively
2. Forgetfulness – Create a checklist or a Poka Yoke
3. Wrong identification – Mark, label, color, etc., for easy recognition
4. Lack of experience/skill – Improve your hiring or training systems
5. Willful ignoring of rules or procedures – Hold people accountable
6. Slowness – Remove bottlenecks; create standards of performance; measure results
7. Inadvertent or sloppiness – Apply an improvement methodology
8. Lack of standardization – Reduce and simplify; create procedures, templates, etc.
9. Intentional/sabotage/not caring – Warn or terminate the person immediately
10. Surprise – Unexpected, infrequent and random causes are more difficult to eliminate

4. Risk Assessment in GDP

- Risk Sources – External factors 外在環境因素

1. Environmental factors

- Natural disasters
 - Storms
 - Flooding
 - Bush fire
 - Earthquake
 - Volcanic eruption
- Extreme cold / hot weather
- Diseases / pandemic

2. Geopolitical factors

3. Economic factors

4. Technological factors

- Power supply
 - Power failure
 - Power surges (temporary increase in voltage in power lines)
 - Brownouts (power falls below the given amount from the utility)
 - Load shedding (rotating the availability of electricity between all customers)

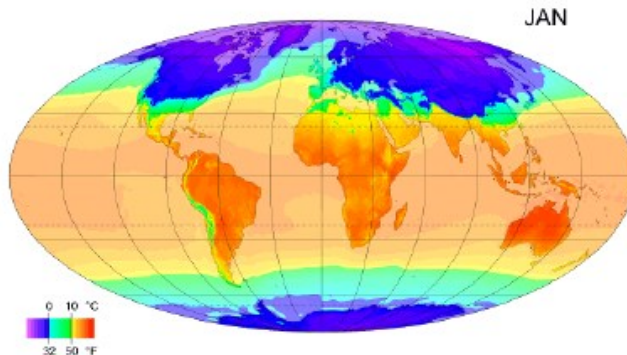


Contingency plans are critical to handle external risk factors.

4. Risk Assessment in GDP

- Risk Sources – External factors

Seasonal variation



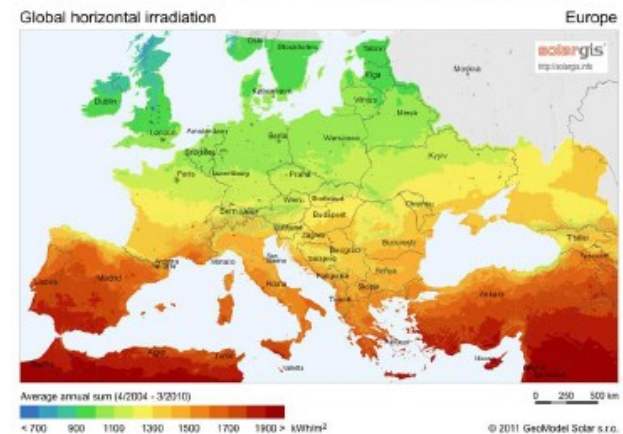
Altitude (-6.5 °C per 1000 m)



Daily temperature variation

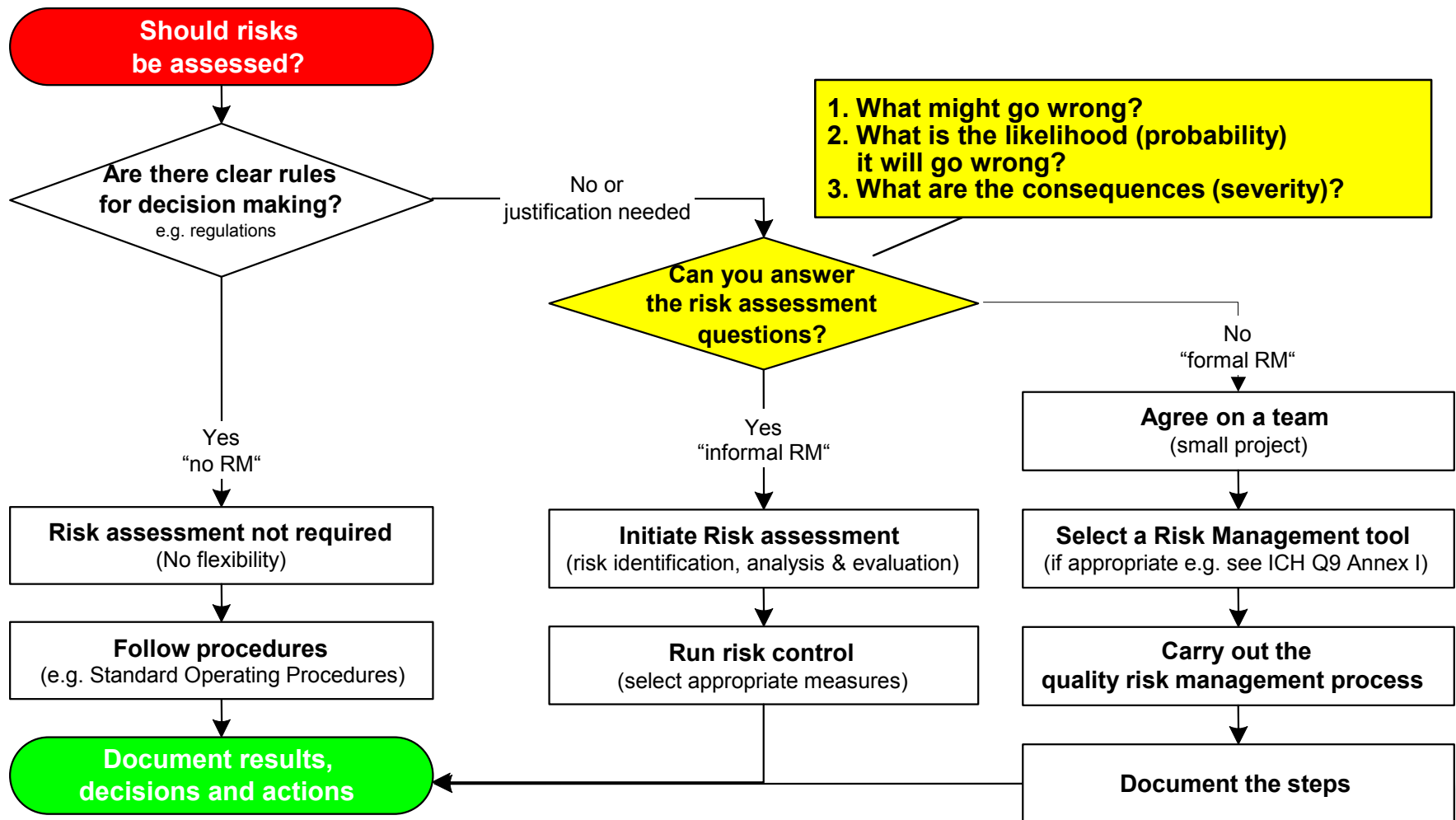


Sun insolation versus latitude



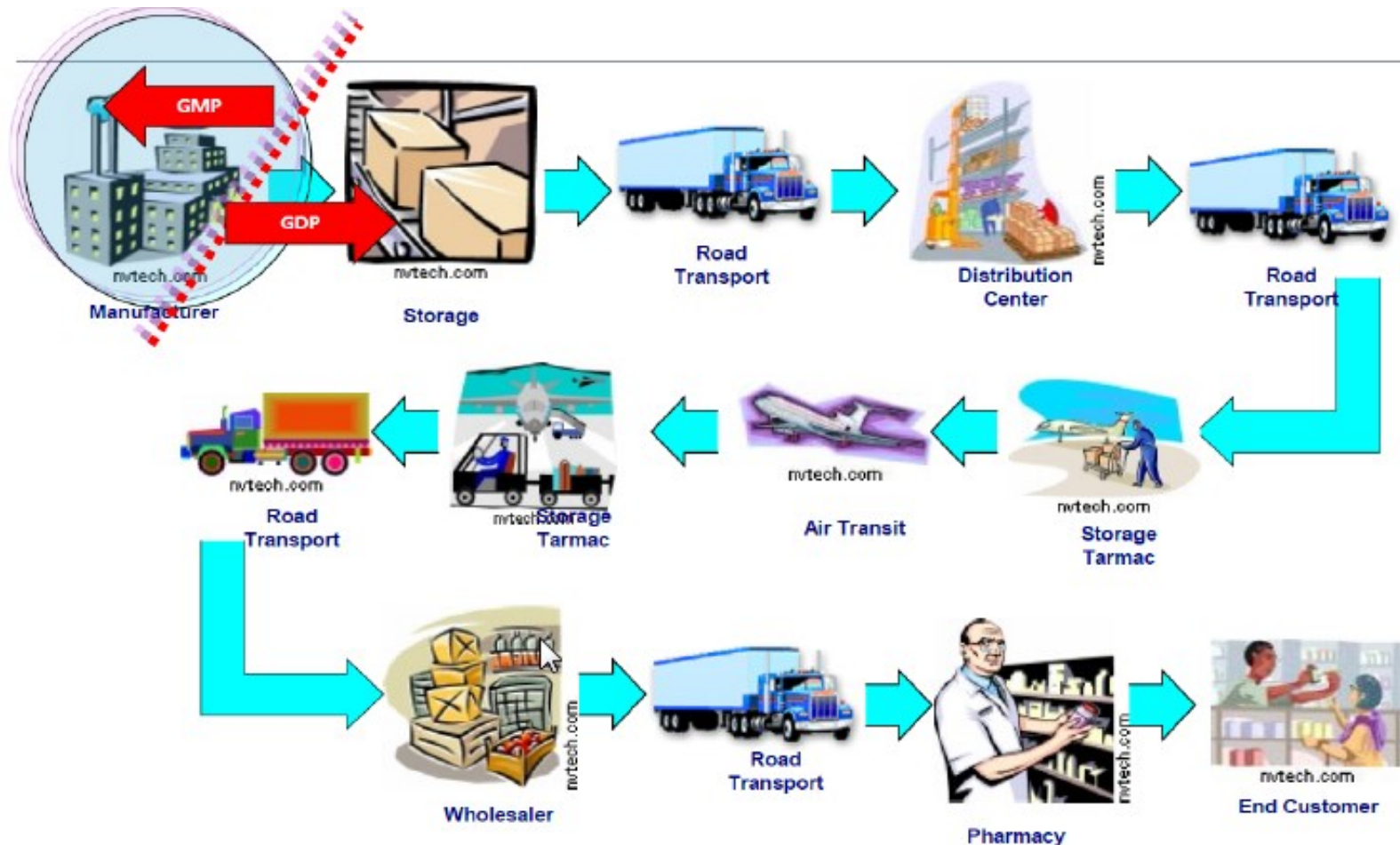
4. Risk Assessment in GDP

- When to apply Risk Assessment



Based on K. Connelly, AstraZeneca, 2005

5. Risk Assessment Tools – Process map



5. Risk Assessment Tools – FMEA 失效模式

- Identify each way the process can fail
- Identify the possible consequences of each failure mode
- Assign numerical rankings

5. Risk Assessment Tools – FMEA

- Quantitation of Risk: Severity 嚴重性

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

5. Risk Assessment Tools – FMEA

- Quantitation of Risk: Probability 發生率

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

5. Risk Assessment Tools – FMEA

- **Quantitation of Risk: Detectability** 可偵測性

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

5. Risk Assessment Tools – FMEA

Risk Evaluation Score

(Severity X Probability X Detectability = RPN)

Decrease Detectability



Increase Severity & Probability

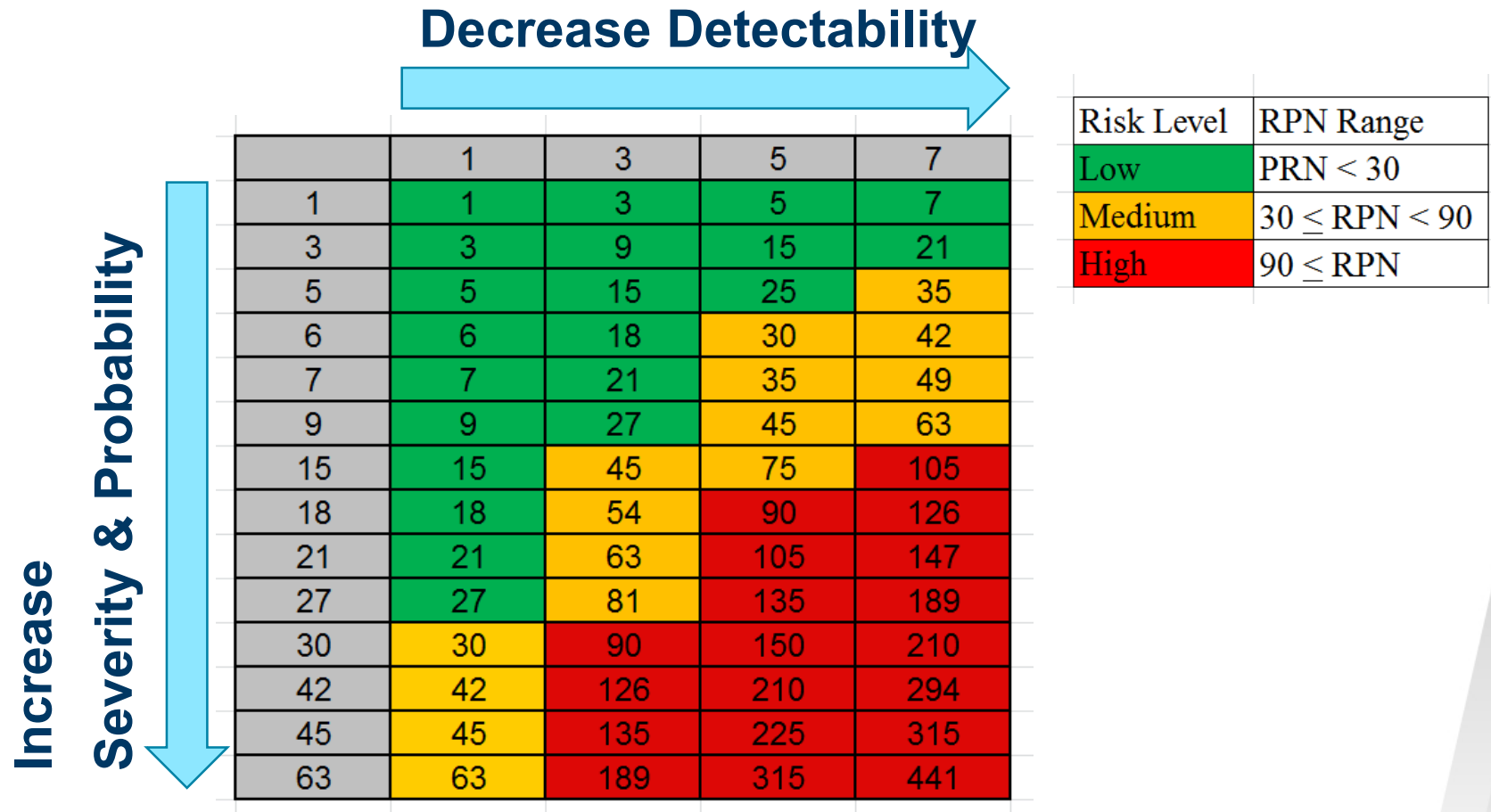


	1	3	5	7
1	1	3	5	7
3	3	9	15	21
5	5	15	25	35
6	6	18	30	42
7	7	21	35	49
9	9	27	45	63
15	15	45	75	105
18	18	54	90	126
21	21	63	105	147
27	27	81	135	189
30	30	90	150	210
42	42	126	210	294
45	45	135	225	315
63	63	189	315	441

Risk Level	RPN Range
Low	RPN < 30
Medium	30 ≤ RPN < 90
High	90 ≤ RPN

5. Risk Assessment Tools – FMEA

Risk Evaluation – Risk Acceptance?



5. Risk Assessment Tools – FMEA

How to design a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (<u>S x P x D = RPN</u>)

→ Risk sources (phenomena and root cause)

Based on the historical data (e.g. deviations), interview, experience, and etc.

5. Risk Assessment Tools – FMEA

How to create a FMEA table

Q13													
	Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting W/	Detectability	RP	Remediation action	RNP After Remediation
1	Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
2	Temperature	Temperature variation leads to product exposure under unacceptable condition	Environmental effect (day and night switch)	Impurity, AS	3	Warehouse HVAC control system	1	Temperature monitored by RMS	automatic	1	3	Not required	N/A
3	Temperature	High excursion during Summer	Seasonal environmental effect	Impurity, AS	3	Warehouse HVAC control system	1	Temperature monitored by RMS	automatic	1	3	Not required	N/A
4	Temperature	Low excursion during winter	Seasonal environmental effect	Impurity, AS	1	Warehouse HVAC control system	1	Temperature monitored by RMS	automatic	1	1	Not required	N/A
5	Vibration	Drum breakage during packaging	Dropping or bumping of the drum	Appearance	1	Drums are wrapped by wrapping plastic	1	1. Checked by packing personnel at MFG site 2. Checked by QA at packaging site	Manual	3	3	Not required	N/A
6	Vibration	Bulk product breakage	Dropping or bumping of the drum	Appearance	1	Bubble wrap application in the inner drum	1	1. Monitored by packing operator at packaging site 2. Packaging site QA sampling	Manual	3	3	Not required	N/A
7	Humidity	High excursion	Environmental effect (sunny and raining day)	Impurity, AS	3	1. Warehouse HVAC control system 2. Product is double-bagged 3. Desiccant application	1	Humidity monitored by RMS	automatic	1	3	Not required	N/A
8	Humidity	Low excursion	Environmental effect (sunny and raining day)	Impurity, AS	3	1. Warehouse HVAC control system 2. Product is double-bagged	1	Humidity monitored by RMS	automatic	1	3	Not required	N/A
9	Process	Drum or lid cracking	Improper packaging (piling) of the drums leads to drum or lid cracking	Appearance	1	SON for equipment safety operation process	3	1. Checked by packing personnel at warehouse 2. Checked by QA at packaging site	Manual	3	9	Not required	N/A

Temperature

Vibration

Humidity

Process

5. Risk Assessment Tools – FMEA

How to create a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (<u>S x P x D = RPN</u>)

Evaluation standard for **Severity**

5. Risk Assessment Tools – FMEA

Example 1, Drum appearance: Severity = 1

Example 2, API Degradation: Severity = 3

Example 3, Low toxic impurity: Severity = 6

Example 4, High toxic impurity: Severity = 9

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

5. Risk Assessment Tools – FMEA

How to create a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> ($S \times P \times D = RPN$)

Evaluation standard for Probability

5. Risk Assessment Tools – FMEA

Example 1, Temp controlled: Probability = 1

Example 2, Softbox during Spring: Probability = 3

Example 3, Softbox during Summer : Probability = 5

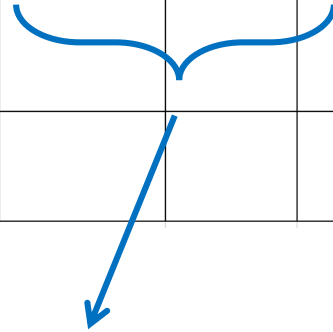
Example 4, N/A during Summer: Probability = 7

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

5. Risk Assessment Tools – FMEA

How to create a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (<u>S x P x D = RPN</u>)



Evaluation standard for **Detectability**

5. Risk Assessment Tools – FMEA

Example 1, Temp logger: Detectability = 1

Example 2, QA and Operator checking: Detectability = 3

Example 3, Operator checking: Detectability = 5

Example 4, N/A: Detectability = 7

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

5. Risk Assessment Tools – FMEA

How to create a FMEA table

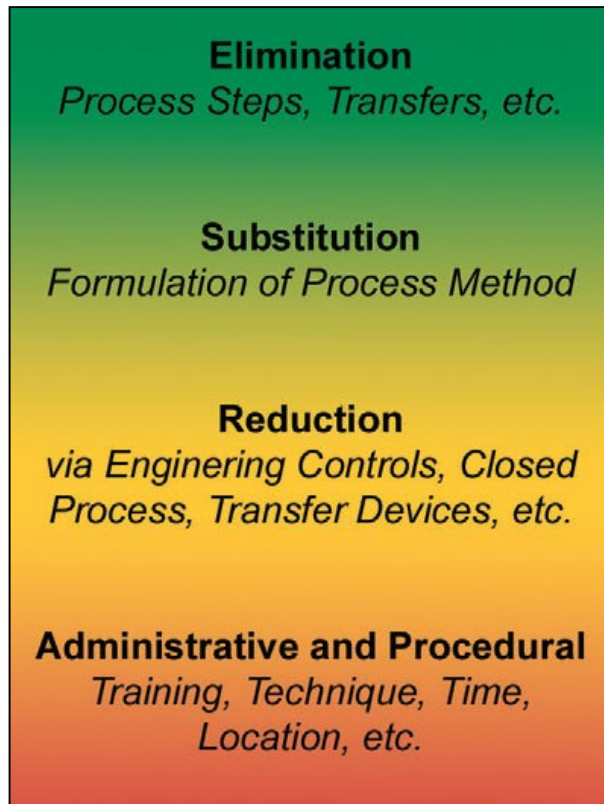
<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (<u>S x P x D = RPN</u>)



Risk Control: implement control actions to **reduce risk** (**Risk Reduction**)

5. Risk Assessment Tools – FMEA

How to create a FMEA table



Do not ship via this route

Change to a better packaging material

Request VUN in the airport

Revise SOP for personnel training

5. Risk Assessment Tools – FMEA

How to create a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> ($S \times P \times D = RPN$)

	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 Control: reduce risk level to **acceptable** level (**Risk acceptance**)

6. Case Study I – Warehouse Temperature

Create a FMEA table

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Temp.	Temperature variation leads to product exposure under unacceptable conditions	Environmental effect (day and night switch)	Impurity, AS									

6. Case Study I – Warehouse Temperature

Create a FMEA table

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Temp.	Temperature variation leads to product exposure under unacceptable conditions	Environmental effect (day and night switch)	Impurity, AS	6								
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											

6. Case Study I – Warehouse Temperature

Create a FMEA table

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Temp.	Temperature variation leads to product exposure under unacceptable conditions	Environment-al effect (day and night switch)	Impurity, AS	6	Warehouse HVAC control system	1						
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											

6. Case Study I – Warehouse Temperature

Create a FMEA table

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Temp.	Temperature variation leads to product exposure under unacceptable conditions	Environmental effect (day and night switch)	Impurity, AS	6	Warehouse HVAC control system	1	Temperature monitored by RMS	Automatic	1			
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											

6. Case Study I – Warehouse Temperature

Create a FMEA table

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Temp.	Temperature variation leads to product exposure under unacceptable conditions	Environmental effect (day and night switch)	Impurity, AS	6	Warehouse HVAC control system	1	Temperature monitored by RMS	Automatic	1	6	Not required	N/A

Risk Evaluation Score:

Severity X Probability X Detectability = RPN

$$6 \times 1 \times 1 = 6$$

Risk Level	RPN Range
Low	PRN < 30
Medium	30 ≤ RPN < 90
High	90 ≤ RPN

6. Case Study II – Warehouse Humidity

<u>Category</u>	<u>Failure mode</u>	<u>Potential Cause</u>	<u>Potential Effect(s) of Failure</u>	<u>Severity</u>	<u>Current Control</u>	<u>Probability</u>	<u>Detection Strategy</u>	<u>Detecting Way</u>	<u>Detectability</u>	<u>RPN</u>	<u>Remediation action</u>	<u>RNP After Remediation</u> (S x P x D = RPN)
<u>Impax TW Warehouse</u> Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												

6. Case Study II – Warehouse Humidity

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Humidity	High excursion	Environmental effect (sunny and raining day)	Impurity, AS		N/A		Humidity monitored by RMS	automatic		42		

Risk Level	RPN Range
Low	PRN < 30
Medium	30 ≤ RPN < 90
High	90 ≤ RPN

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

6. Case Study III – Warehouse Vibration

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Vibration	Bulk product breakage	Dropping or bumping of the drum	Appearance	1	Bubble wrap application in the inner drum	1	1. Monitored by packaing operator at packaging site 2. Packaging site QA sampling	Manual	3	3	<u>Not required</u>	<u>N/A</u>

Risk Level	RPN Range
Low	PRN < 30
Medium	30 ≤ RPN < 90
High	90 ≤ RPN

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

6. Case Study IV – Warehouse Process

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
Impax TW Warehouse Control Spec.: Temperature: 20-25 °C, Relative humidity: 65%												
Process	Drum or lid cracking	Improper packaging (piling) of the drums leads to drum or lid cracking	Appearance	1	SOP for equipment safety operation process	3	1. Checked by packing personnel at warehouse personnel 2. Checked by QA at packaging site	Manual	3	9	Not required	N/A

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

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

6. Case Study V – Apron Temperature

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)
ULD Area Apron in TPE Airport												
Temperature	High excursion during Summer	Seasonal environmental effect	Impurity, AS	3	1. Night freight during the period of Apr to Oct 2. VUN requested. The time at the apron is controlled in 1-3 hours 3. Insulated packaging to control temperature variation	5	TT4 monitoring	Automatic	1	15	Not required	N/A

Risk Level	RPN Range	Score	Risk Severity
Low	RPN < 30	1	No or negligible harm/ quality alert
Medium	30 ≤ RPN < 90	3	Loss of product activity/ drug appearance or package damage
High	90 ≤ RPN	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

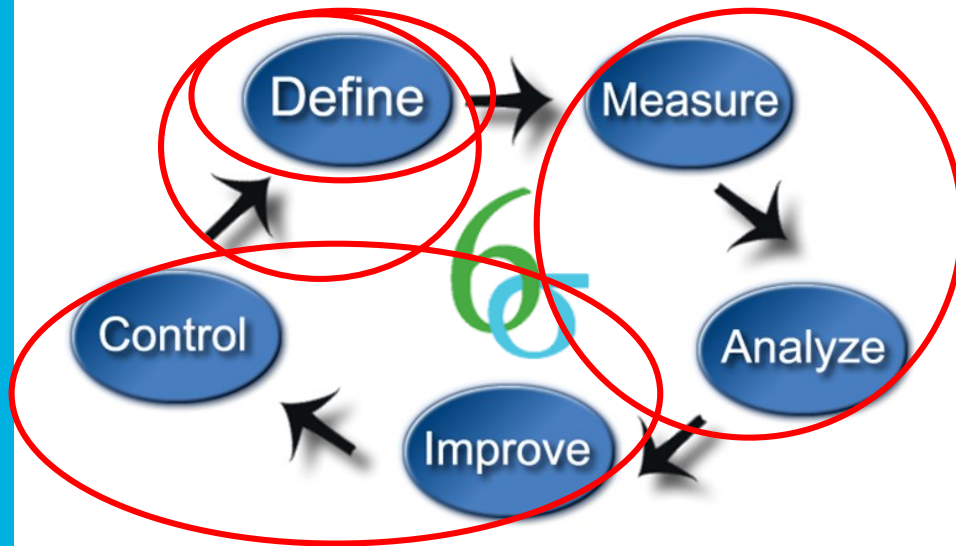
6. Case Study VI – Your term

Category	Failure mode	Potential Cause	Potential Effect(s) of Failure	Severity	Current Control	Probability	Detection Strategy	Detecting Way	Detectability	RPN	Remediation action	RNP After Remediation (S x P x D = RPN)

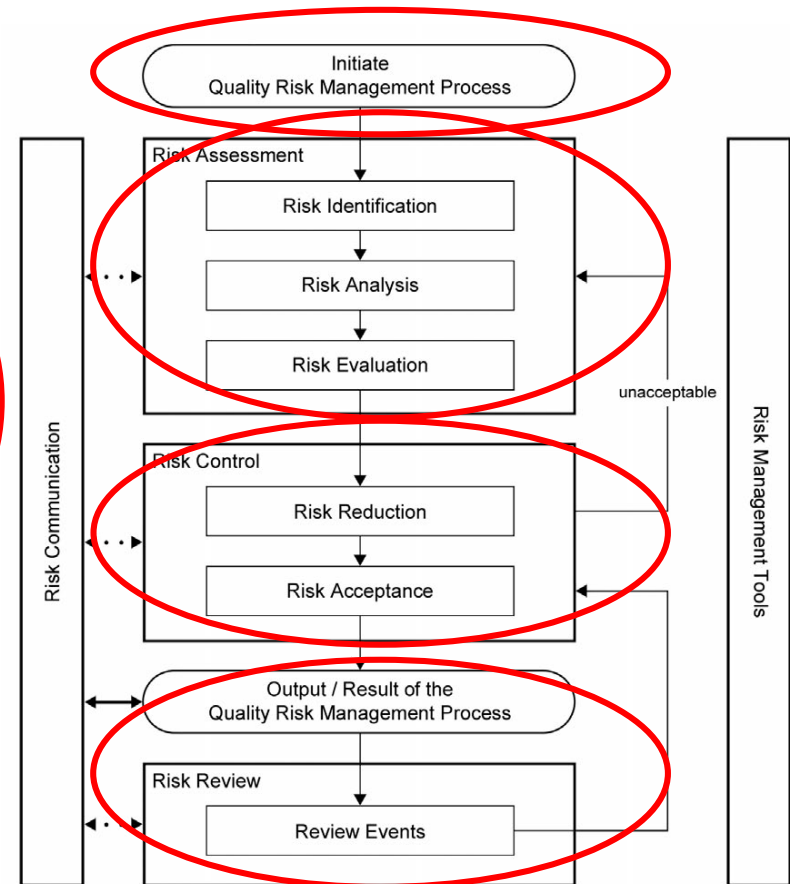
Risk Level	RPN Range
Low	$RPN < 30$
Medium	$30 \leq RPN < 90$
High	$90 \leq RPN$

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

7. Summary

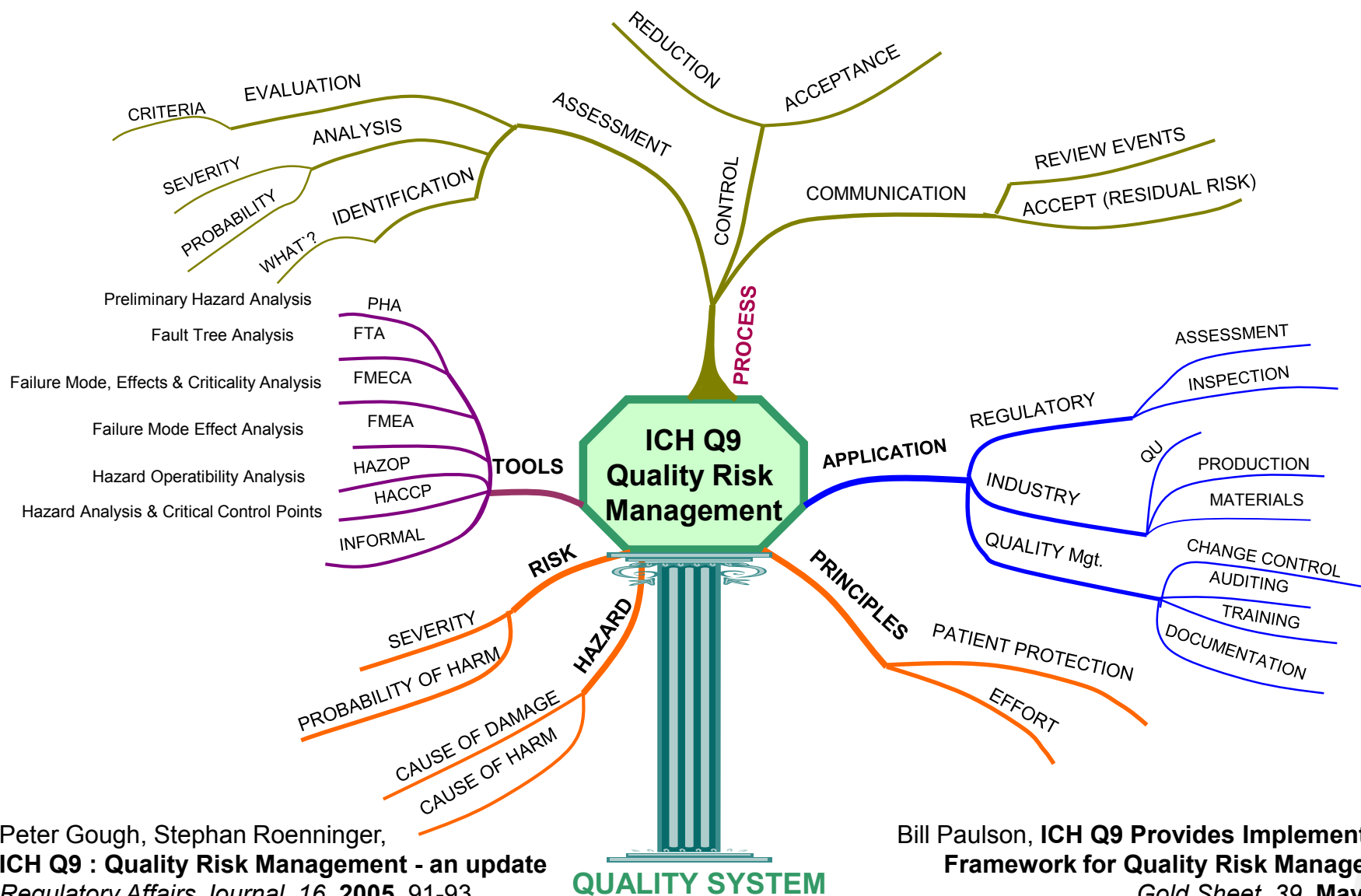


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ICH Q9

7. Summary



Peter Gough, Stephan Roenninger,
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Regulatory Affairs Journal, 16, 2005, 91-93

Bill Paulson, **ICH Q9 Provides Implementation Framework for Quality Risk Management**
Gold Sheet, 39, May 2005

Thank you for your attention

Questions?