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# **Comparison of Various Risk Assessment Techniques**

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**Manager CMC Quality and Compliance**

**QBiotics Limited**

**July 2017**

# DISCLAIMER

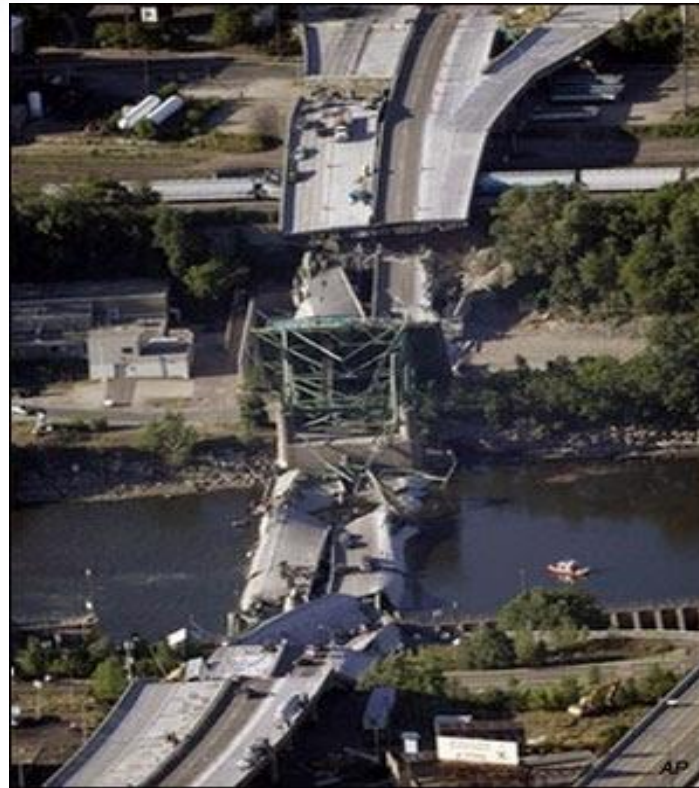
**The opinion expressed in this presentation are solely those of the presenter and not necessarily those of QBiotech Limited or PharmOut.**





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### **Mississippi**

August 1st 2007 the I-35W bridge collapsed killing 13 and injuring 145.



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**London**

June 2017, Grenfell Tower Fire killing 80+.



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**FDA Enforcement  
Statistics  
Summary Fiscal  
Year 2016**

**2847 Recall  
Events**

**8305 Products.**



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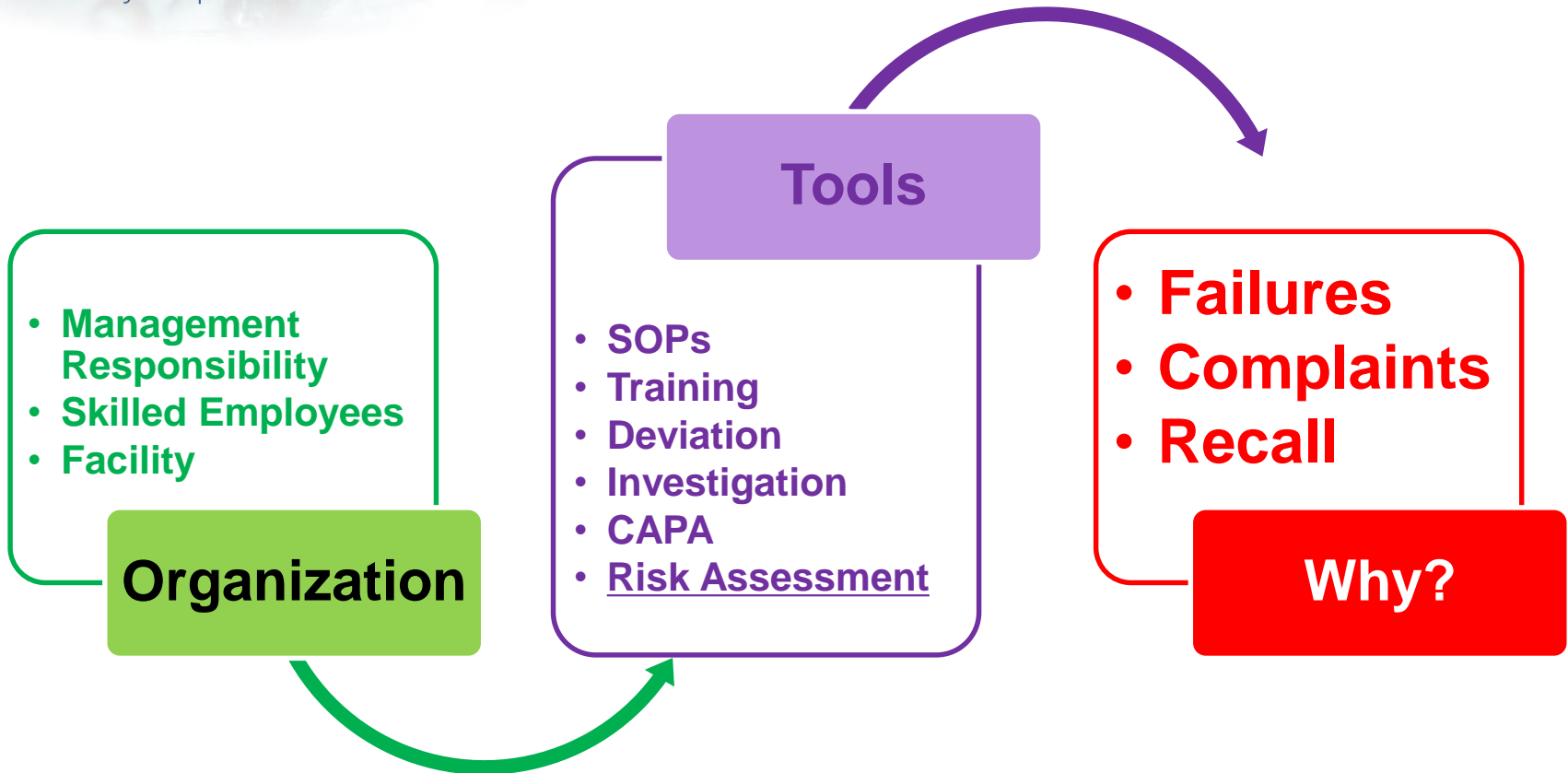
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- Design
- Material Quality
- Operations and Maintenance
- **Are we managing risks appropriately ?**



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# Are we managing risks appropriately ?

## Technique

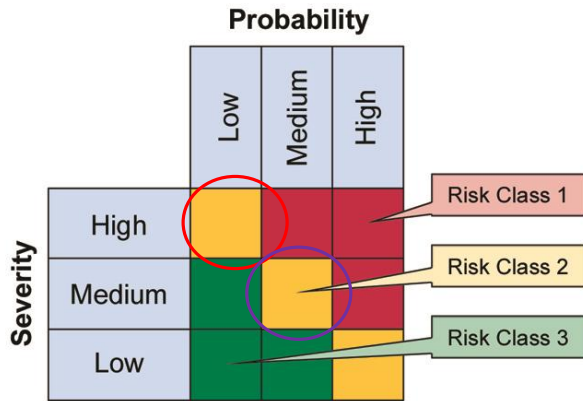
- **Selection of risk assessment tool**
- **Meaningful policy**
- **Fit for the purpose**



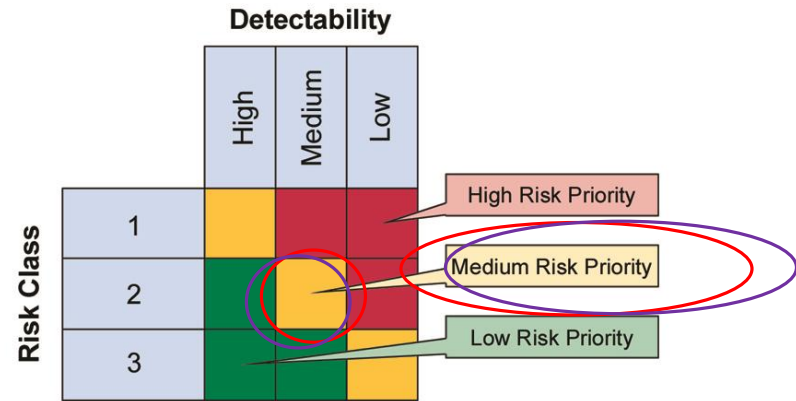
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# RISK ASSESSMENT TECHNIQUE Low Medium High Vs RPN



**Severity** = Impact on Patient Safety, Product Quality, and Data Integrity (or other harm)  
**Probability** = Likelihood of the fault occurring  
**Risk Class** = Severity × Probability



**Detectability** = Likelihood that the fault will be noted before harm occurs  
**Risk Priority** = Risk Class × Detectability

Source: Figure M3.5, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

**Red**

Severity = High  
 Probability = Low  
 Risk Class = 2  
 Detectability = Medium  
 = **Medium Risk Priority**

**Purple**

Severity = Medium  
 Probability = Medium  
 Risk Class = 2  
 Detectability = Medium  
 = **Medium Risk Priority**

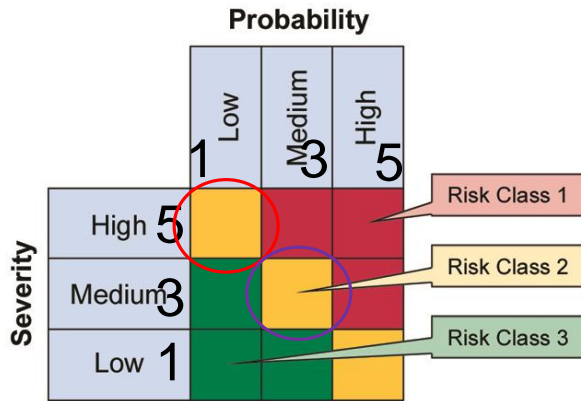


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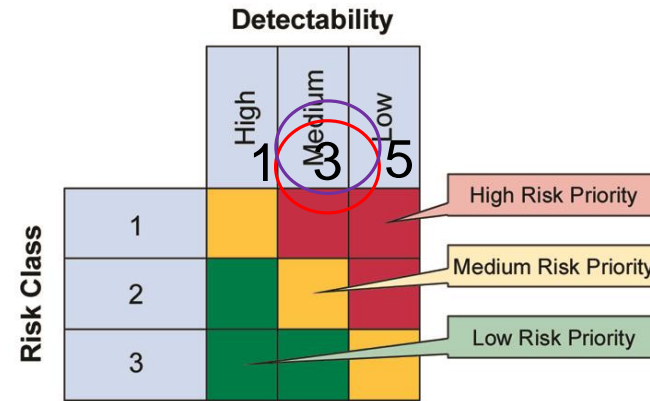
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# RISK ASSESSMENT TECHNIQUE

## Low Medium High Vs RPN



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Red

Severity = High = 5

Probability = Low = 1

5X1= 5

Detectability = Medium = 3

= **Medium Risk Priority = 15**

Purple

Severity = Medium = 3

Probability = Medium = 3

3X3=9

Detectability = Medium = 3

= **Medium Risk Priority = 27**



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# RISK ASSESSMENT TECHNIQUE

## 10 Layers, 5 layers, or 3 layers

### 10 Layer Severity

#### Patient Safety impact

- 1 = Low
- 2 = Negligible
- 3 = Marginal
- 4 = Moderate
- 5 = Marginally Critical
- 6 = Critical
- 7 = Very critical
- 8 = Catastrophic
- 9 = Dangerously catastrophic
- 10 = Disastrous

### 5 Layer Severity

#### Patient Safety Impact

- 1 = Negligible
- 2 = Marginal
- 3 = Moderate
- 4 = Critical
- 5 = Catastrophic

### 3 Layer Severity

#### Patient Safety Impact

- 1 = Low
- 2 = Medium
- 3 = High



# TECHNIQUE

## “Low Severity”

### What exactly it means

Low  
Severity

Minor impact  
on patient  
safety or  
product quality

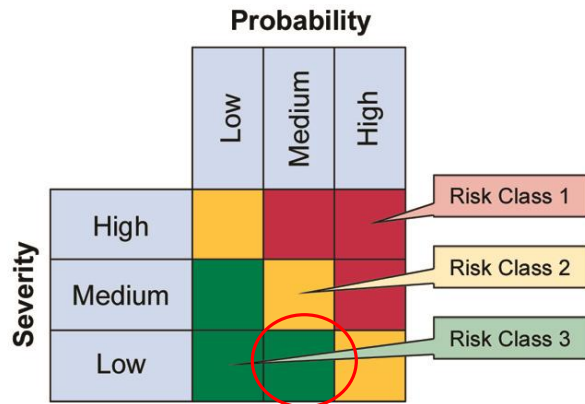
Low  
Severity

No impact on  
patient safety or  
product quality

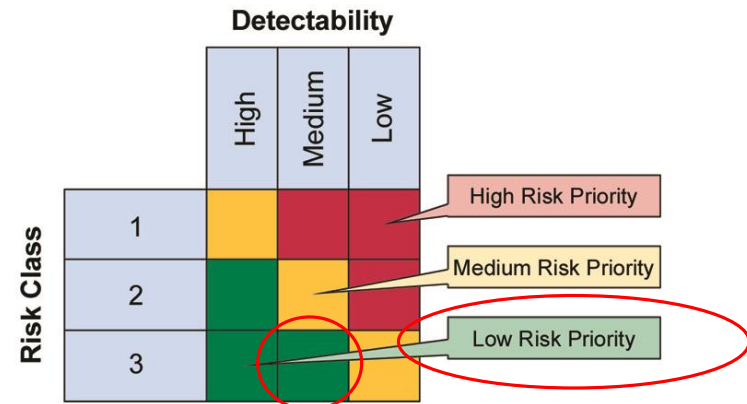
# TECHNIQUE

## “Low Severity”

### What exactly it means



**Severity** = Impact on Patient Safety, Product Quality, and Data Integrity (or other harm)  
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Severity = Low  
 Probability = Medium  
 Risk Class = 3  
 Detectability = Medium  
 = **Low Risk Priority** **No action**

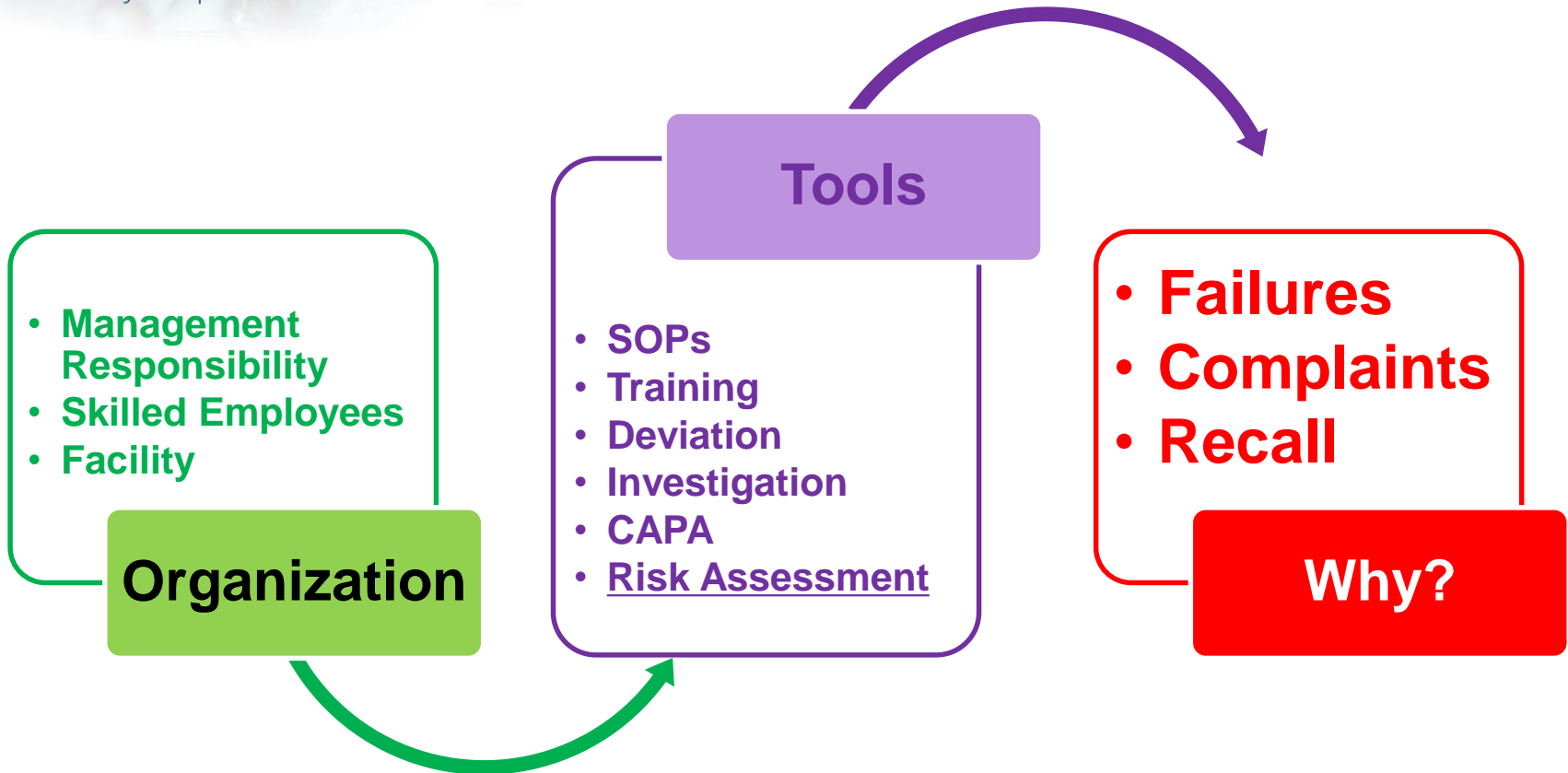
Low Severity = **Minor** impact on patient safety or product quality. **No action**

Low Severity = **No** impact on patient safety or product quality. **No action**



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Quality *may be* free.  
But it is *certainly*  
NOT a gift.





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**FMEA**

**Fishbone – FMEA**

**FTA-FMEA**

**Brainstorming-FMEA**

**HPLC vs HPLC-MS**



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**THANK  
YOU!**