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Comparison of Various Risk Assessment Techniques

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QBiotics Limited

July 2017

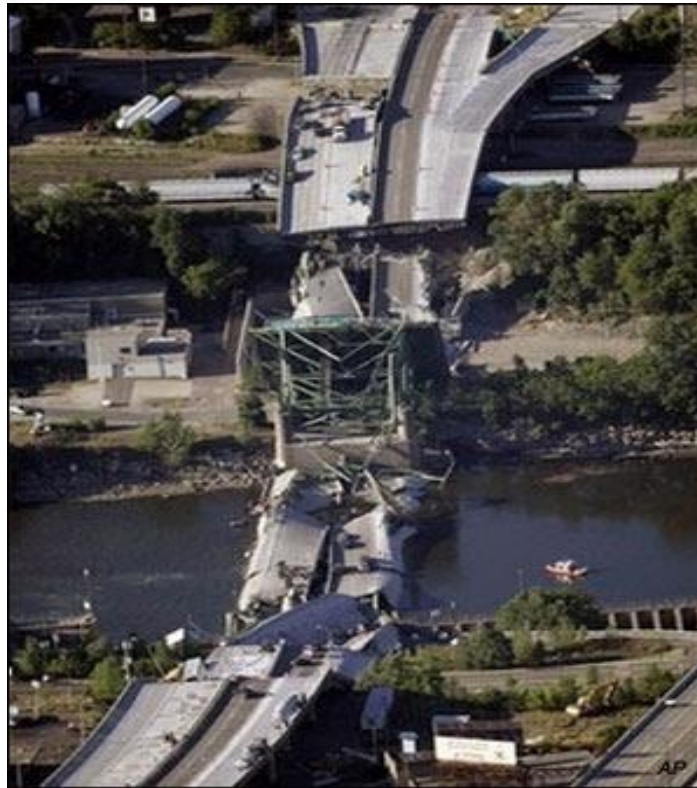
DISCLAIMER

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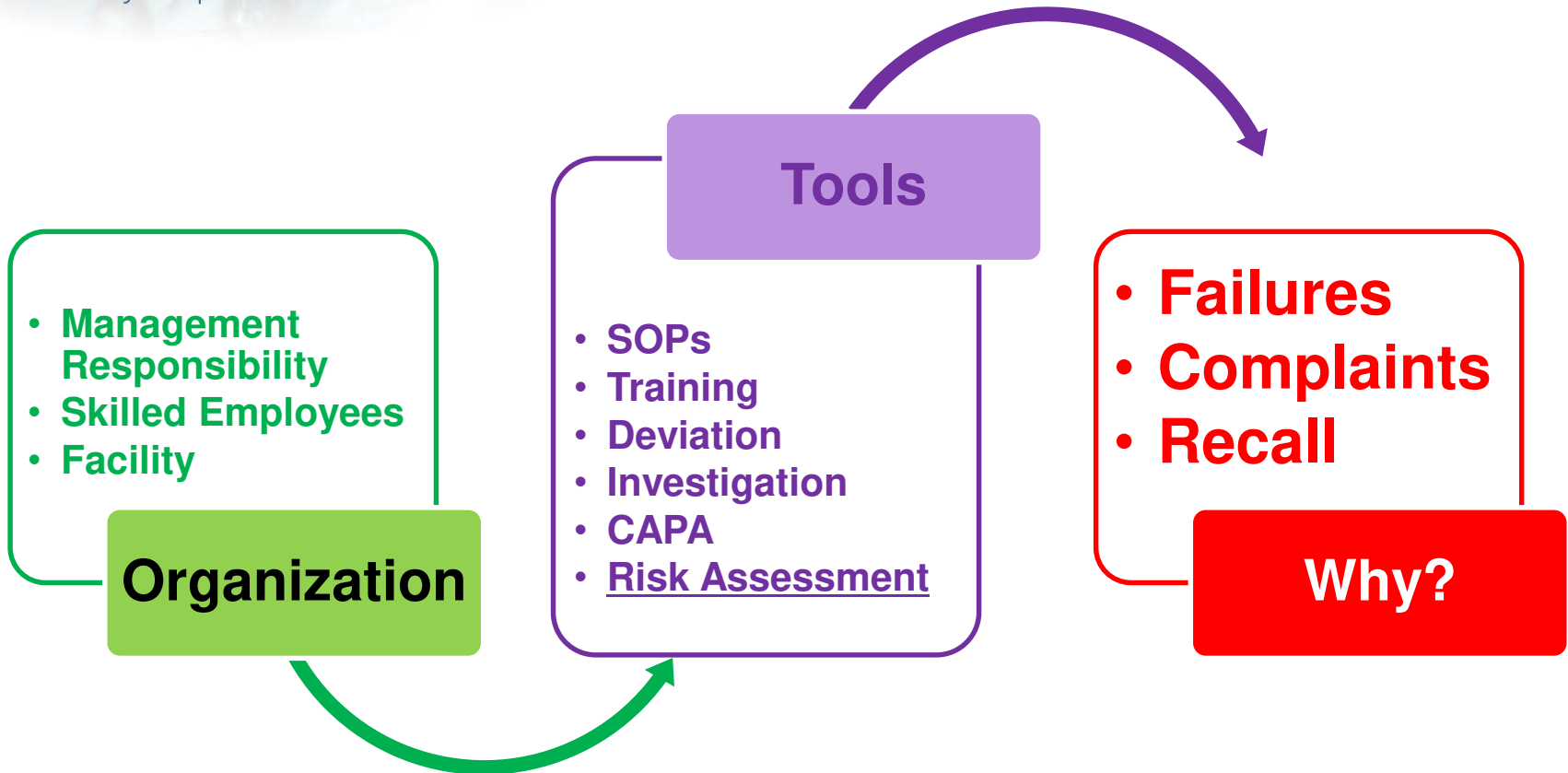
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- Design
- Material Quality
- Operations and Maintenance
- **Are we managing risks appropriately ?**



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Are we managing risks appropriately ?

Technique

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

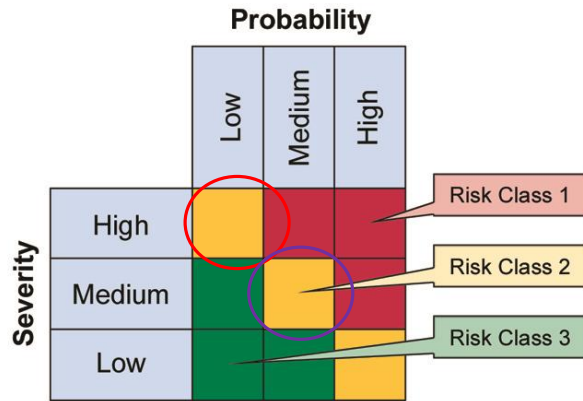


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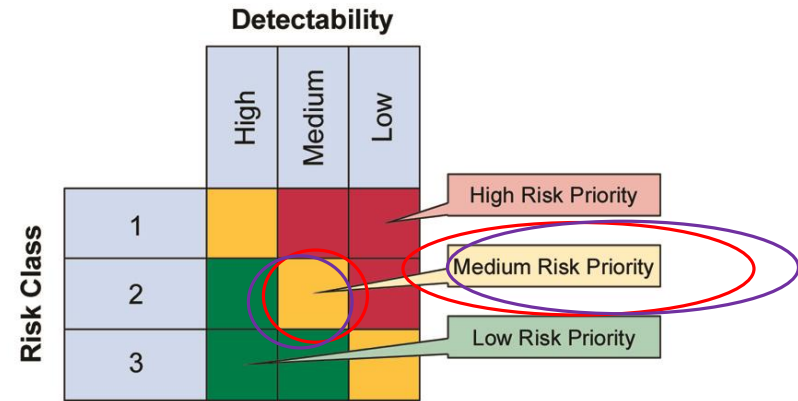
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RISK ASSESSMENT TECHNIQUE

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

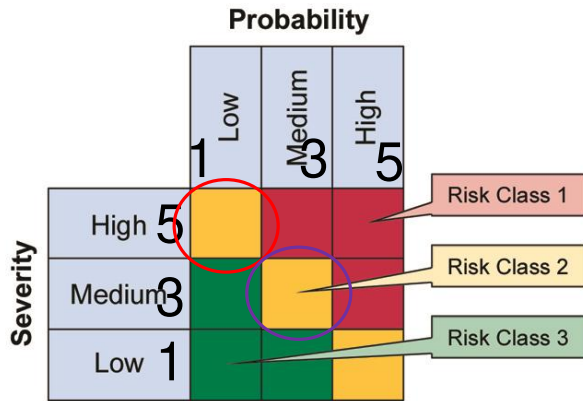
Severity = Medium
 Probability = Medium
 Risk Class = 2
 Detectability = Medium
 = **Medium Risk Priority**



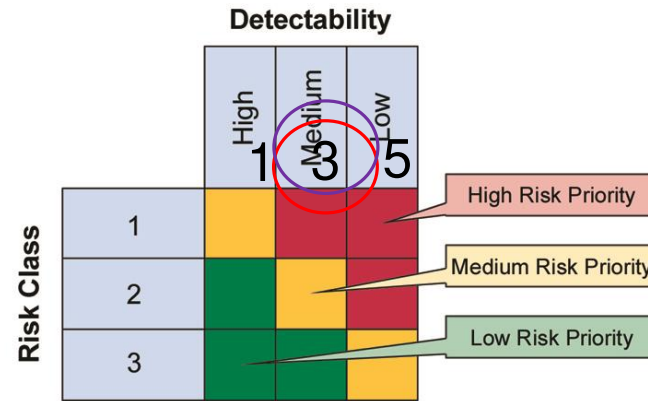
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RISK ASSESSMENT TECHNIQUE Low Medium High Vs RPN



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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

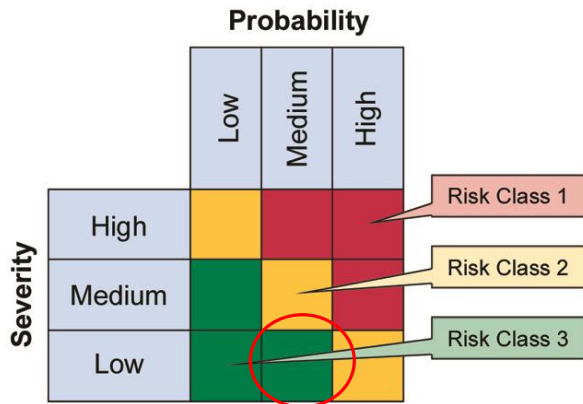
Low
Severity

No impact on
patient safety or
product quality

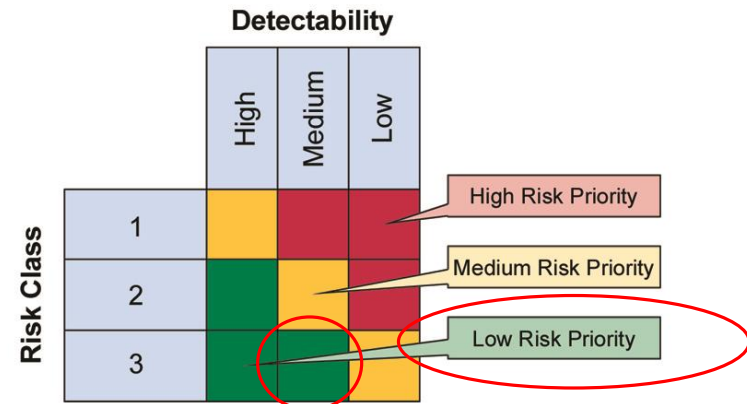
TECHNIQUE

“Low Severity”

What exactly it means



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Severity = Low
 Probability = Medium
 Risk Class = **3**
 Detectability = Medium
 = **Low Risk Priority** **No action**

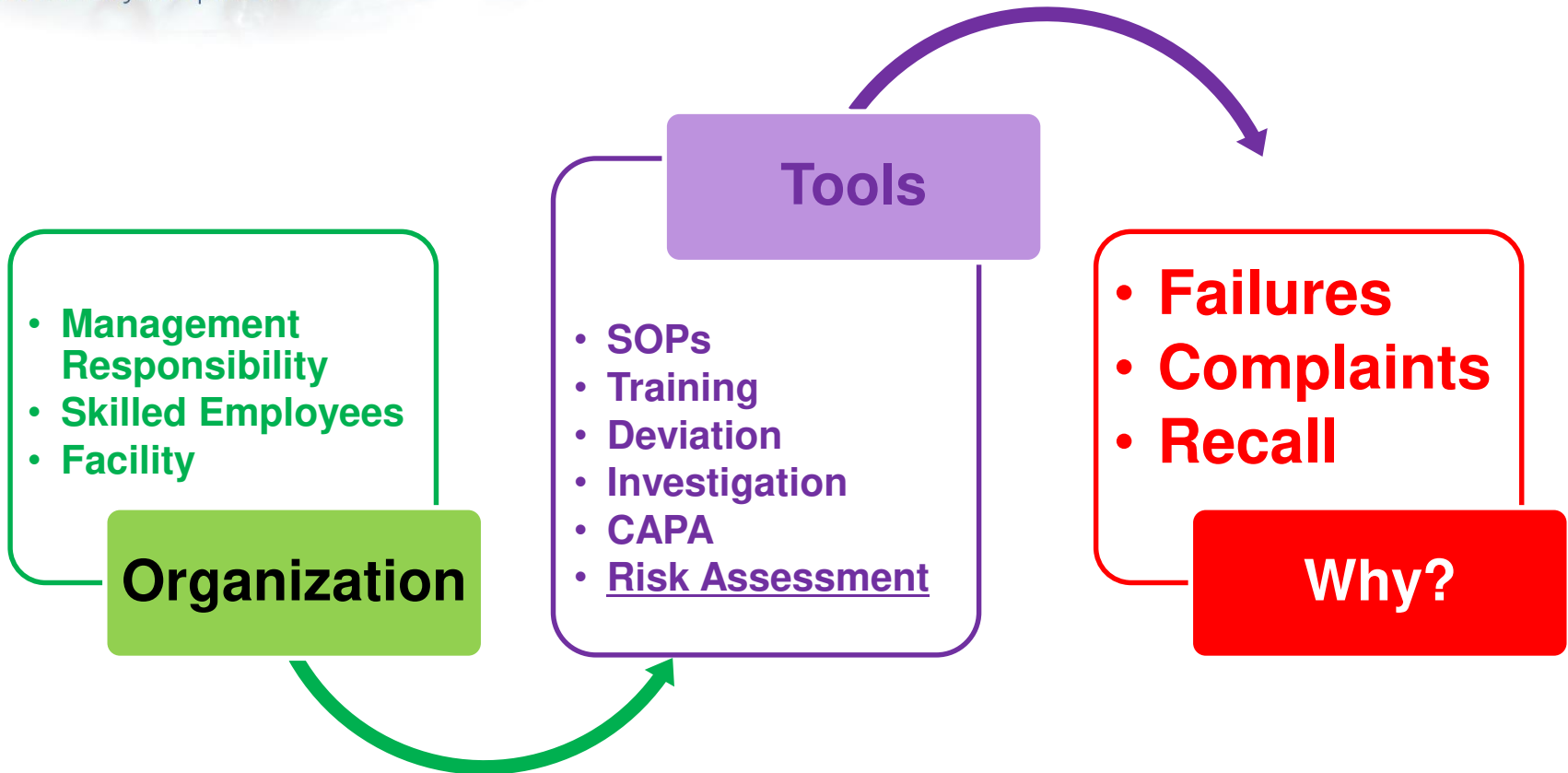
Low Severity = **Minor** impact on patient safety or product quality. **No action**

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!**