Risk assessment of pharmaceutical preparations control process by FMECA methodology

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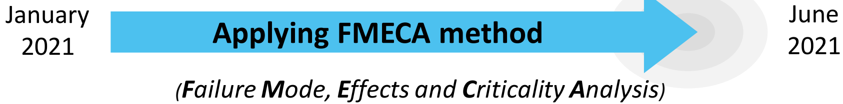
Context and Objectives

The main activity of the control laboratory affiliated to our university hospital is to transmit information to its customers regarding compliance with the specifications of a batch of pharmaceutical preparation.

Objectives :

- to identify failure modes
- to assess their potential impact on the process
- to take appropriate corrective actions

Material and Method



(Failure Mode, Effects and Criticality Analysis)

- Multidisciplinary team
- For each identified failure mode, assessment of the impact on : the information/preparations/the laboratory/the customers
- Severity was rated on a scale constructed by the team (example of the laboratory below)

Severity	Impact on the laboratory
1	No impact
2	Image (loss of business, discredit, opportunity...)
3	Production (loss of time, disorganization, equipment issues...)
4	Safety, security, environment

Sum of the relative severities of the different impacts = **Total severity**

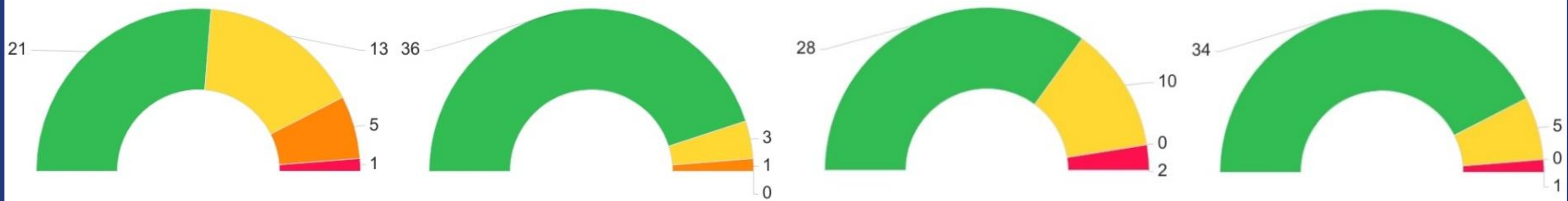
Critical Number (CN) = Occurrence x Total Severity

Risk Priority Number (RPN) = CN x Detection

Results

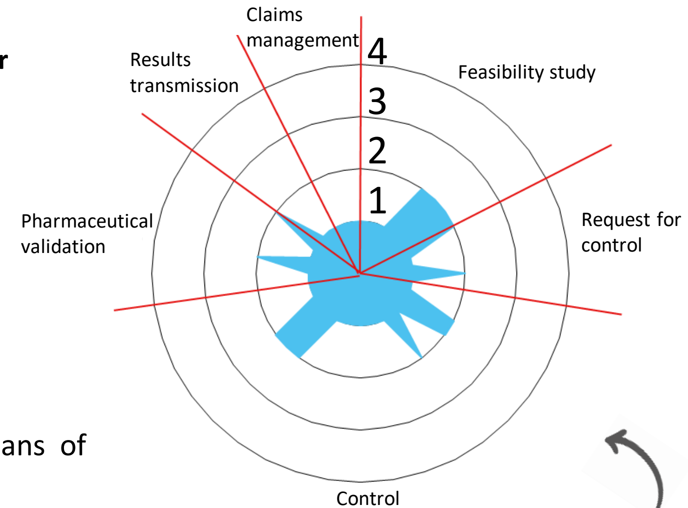
→ **40 failure modes identified** : mainly concerned control (42.5%), feasibility study (20%) and pharmaceutical validation (12.5%) steps

Risks distribution according to their CN, depending on their impact on :



Risks distribution according to their CN

Risks distribution according to their RPN



→ 1 **critical** risk, 1 **major**, 7 *(5)** **moderate** and 31 *(33)** **low**

** after taking detection into account*

→ Control request step appears to be the most at risk

→ Small difference between CN and RPN, explained by weak means of control, leaving a large field for improvement

Means of control evaluation, according to realisation reliability, supervision, formalisation and relevance of the existing means of control

Conclusion

Further development of **quality culture** − Highlight of the elements most affected by the failure through the **separation of impacts into 4 categories** and subjectivity limitation − **Weakness of the means of control** identification − **Priorities for action** and targeted corrective actions definition