Risk analysis of non-sterile preparation activity and impact of computerization on the preparation circuit

Azam Camille, Jurado Camille, Ramjaun Zoubeir
Préparatoire, Pôle Pharmacie, CHU de Toulouse, FRANCE

COM24-57812

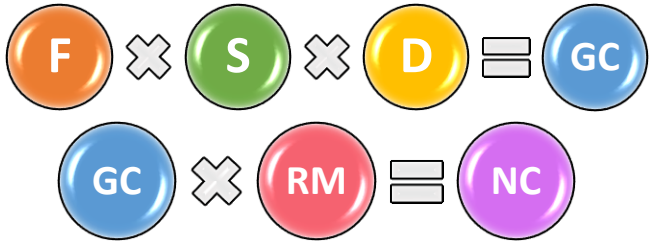
Context

The non-sterile compounding cycle relies on several tools: faxes, emails, prescription software, Excel® and Word® files. This insecure system is a source of error in the production of pharmaceutical preparations. **The aim is to carry out a risk analysis of the circuit and to assess the contribution of a software package to the management of non-sterile preparations.**

Materials and methods

What type of analysis? FMEA: Failure Mode, Effect and Criticality Analysis
What scope? All processes involved in the supply chain: demand analysis, inventory management, preparation, dispensing, control and support processes (management, HR, hygiene, safety and equipment).
What steps are involved?

1) **Risk identification:** Non-conformity queries, observations, bibliography, previous risk analyses, etc.
2) **Risk assessment:** Gross Criticality (GC) and Net Criticality (NC) via an in-service survey.



Criteria	Quotation
Frequency	Exceptional (1) to Very Frequent (8)
Severity	Minor (1) à Critical (6)
Detectability	Always (1) to Impossible (6)
Risk management	Insufficient (1) to very good control (0,25)

3) Comparison to a criticality scale

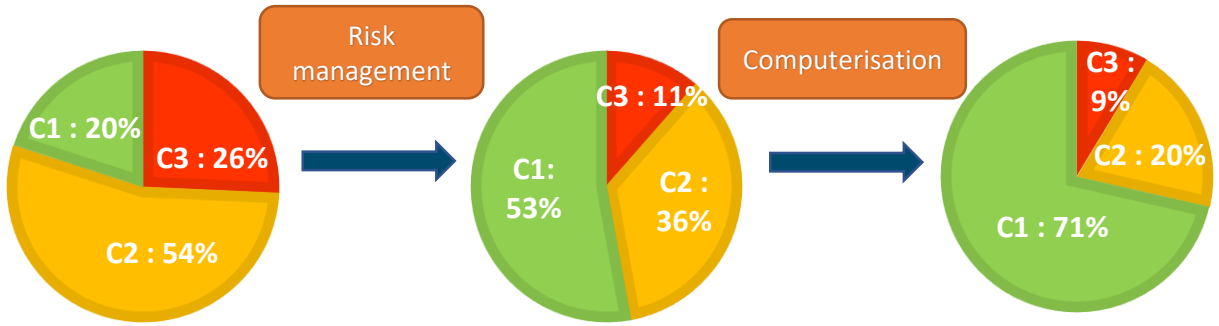
Score	Criticality	Risk
1 to 4	C1	Acceptable as is
6 to 16	C2	To be monitored
24 to 288	C3	Priority treatment

An example to make things clearer?

Risk identified: Forgetting to add a raw material to a preparation
GC = 1 (F=exceptional) x 6 (S=critical) x 4 (D=difficult to detect) = **24** C3
NC = 24 (GC) x 0.5 (RM=good control) = **12** C2
With computerisation, modification of D and RM, **NC = 1.5** C1

Results

70 risks identified, of which 40% related to preparation and control processes



➡ **Significant reduction in the criticality of risks** with the control measures put in place, enhanced by the use of a single software package.
➡ **Computerisation reduces the criticality of half of the risks identified.**

Discussion

Although our system uses non-specific computerised tools, it is not sufficiently secure, with re-transcription being a source of error. The use of a single software package could significantly reduce these risks **by automating processes and improving traceability**. This would also help to ensure the **safety of the medication cycle** and the dematerialisation of our tools, in line with **Good Preparation Practices**.

To discover all the results, scan here