

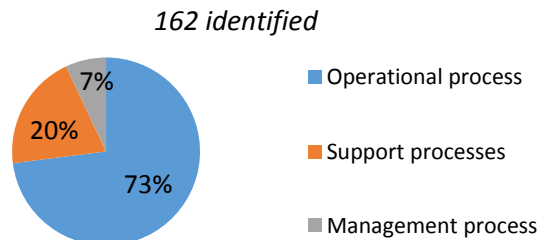
CONTEXT

Parenteral nutrition (PN) is counted as a high risk activity both through the category of patients for whom it is intended but also through its prescription, method of production and conditions of administration. As part of our ISO 9001: 2015 quality certification intent and to control the preparation process, we undertook a mapping of the risks associated with the production of adult and pediatric PN bags in the Pharmaceutical Compounding Unit.

METHODS AND RESULTS

FMECA : Failure Modes, Effects and Criticality Analysis

① Identification the potential failures



② Risk identification

By 4 people: pharmacy dispenser, resident, quality manager and pharmacist

③ Risk scoring

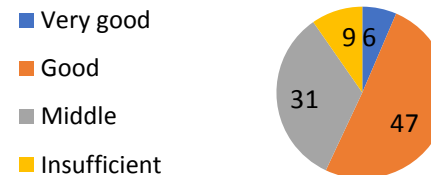
- Evaluation of gravity (G), frequency (F) and detectability (D)
- On a 4-level scale

Gross criticality = G*F*D	Number of defaults
Acceptable	39
Tolerable under control	81
Unacceptable	42

④ Attendance of a means of control ?

Yes	No
92 defaults	70 defaults

Rating according to a criticality scale :



⑤ Weighting of gross criticality = net criticality

Net criticality	Number of defaults
Acceptable	51
Tolerable under control	79
Unacceptable	32

6% decrease in unacceptable criticality

- 2 have a good means of control
- 13 have not seen their critical level decrease
- 80% of these defaults concern the operational process

DISCUSSION

Interest :

To build an inventory of the risks and existing measures to reduce them.

What about :

the achievement and effectiveness of the actuals measures

WHAT REMAINS TO BE DONE

⑥ Cause analysis 5M Method

⑦ Identification of corrective and / or preventive actions

⑧ Assignment of a level of effort

⑨ Creating an action plan

⑩ Monitoring improvement actions