

# QUALITY RISK MANAGEMENT FOR PREPARED STERILE PRODUCTS IN HOSPITAL PHARMACY

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## OBJECTIVES

To **DESCRIBE AND TO ASSESS THE QUALITY RISK** of different prepared sterile products (PSPs) in the hospital pharmacy departments and **PRIORITIZE THE PREVENTATIVE MEASURES IMPLEMENTATION**.

## STUDY DESIGN



- ↪ The **FAILURE MODE AND EFFECTS ANALYSIS (FMEA)**: a procedure to identify and reduce/prevent failures in processes and products.
- ↪ Three FAILURE MODES (FM) were considered: **COMPOUNDING (C)**, **PACKAGING (P)** and **STERILITY (S)**.
- ↪ Every FM was evaluated for **OCURRENCE (O)**, **SEVERITY (S)** and **DETECTION (D)**, which value guidelines are shown below:

	VALUE GUIDELINES		
	OCURRENCE (O)	SEVERITY (G)	DETECTION (D)
9 or 10	Very likely to occur	The effect on the scope renders end item unusable.	There is no detection method (DM) available or known that will provide an alert with enough time to plan for a contingency.
7 or 8	Will probably occur	The effect on the scope changes the output of the project and it may not be usable to client.	DM is unproven or unreliable; or effectiveness of detection method is unknown to detect in time.
5 or 6	Equal chance of occurring or not	The effect on the scope changes the output of the project and it will require client approval.	DM has medium effectiveness
3 or 4	Probably will not occur	The effect on the scope is minor but requires an approved scope change internally and maybe with the client.	DM has moderately high effectiveness.
1 or 2	Very unlikely	Changes are not noticeable.	DM is highly effective and it is almost certain that the risk will be detected with adequate time.

↪ **RISK PRIORITY NUMBER (RPN) = O x G x D.**

↪ The **TOTAL SCORE** for each PSP is the sum of the RPN of each FM.

## RESULTS

TOTAL SCORE	Risk assessment
≤ 100	Low risk preparation
>100	High risk preparation

All prepared sterile products studied except antibiotics have total score values above 100, therefore they are considered as high risk preparations.

The cytostatics compounding has the highest NPR value, ie, entails the highest quality risk for patients.

PSP	FM	G	O	D	RPN
ANALGESIA-ANESTHESIA	C	8	3	1	24
	P	10	3	1	30
	S	8	1	9	72
				<b>TOTAL</b>	<b>126</b>
CYTOSTATICS	C	10	3	8	240
	P	5	3	4	60
	S	7	1	9	63
				<b>TOTAL</b>	<b>363</b>
PARENTERAL NUTRITION	C	8	2	7	112
	P	8	1	1	8
	S	8	1	7	56
				<b>TOTAL</b>	<b>176</b>
ANTIBIOTICS	C	2	2	4	16
	P	4	2	5	40
	S	2	1	9	18
				<b>TOTAL</b>	<b>74</b>

## CONCLUSIONS

1. The cytostatics compounding entails the highest quality risk for patients, therefore our efforts will be focused primarily on these products.
2. After the study, we possess reference values for quality risk comparisons in different situations and circumstances within the same process.
3. We are able to evaluate the effect of preventative measures.