N° Poster ??

IMPLEMENTATION OF CHANGE CONTROL IN HOSPITAL PHARMACY

Marie-Line Mottier[1], Farshid Sadeghipour [1,2]
[1]Pharmacy Service; [2]Section of pharmaceutical Sciences, University of Geneva, University of Lausanne; Switzerland

Background

Change controls are part of Good Manufacturing Practice (GMP) requirements in industry. The new version of management standard ISO 9001: 2015 also introduces this concept in the organization aspects; nevertheless, its implementation could be critical in the complex and changing environment of a hospital pharmacy.

Purpose

The aims of this work is to design a methodology to implement change controls within our organization

Material and methods

Basis

- Define what a change is
- Set up a group of key resource persons
- Rank each change and its management.

Definition of the ranking

It was rated with a score based on 2 criteria :

- Impact level for the organization (max score: 12)
- Potential risk caused by the change (max score: 64).

Definition of level follow up for each change

= combination of these scores

Management of follow up

The centralized threshold point was set as a combined score at 17/76 (22% of max. score).

- threshold was met :

  the change was integrated in a centralized monitoring matrix and tracked by the Quality officer.

- threshold not met :

  the change was considered as minor and was simply tracked internally by each pharmacy unit.

Results

In 16 processes of our organization :

- 58 different changes identified as recurrent
- 29 types of changes (50%) already addressed in our quality system

The average total score = 15 [11.25- 18.75]

- average impact score = 5.7 [4.97-6.43]
- average risk score = 9.24 [6.23-12.25].

15 (26%) exceeded the centralized follow up threshold

Conclusions

These changes monitored centrally were focused on GMP aspects and not all of them were supported by our quality system.

Thus, this work allowed us to systematize our practice and formalized it through a quantitative indicator. This typology will serve as a reference system for the different units of our hospital pharmacy helping to harmonize the process of change controls.

Impact level for the organisation

Impact level for organization (0 = no ; 1 = thinly ; 2 = important)						
Management impact : collaborators (ex : training needed, communication ?)	Material Impact : product / performance	Environmental impact : environnement / works methods	Financial impact	Collateral Impact : other area of the pharmacy	Impact on clients	level impact score

Potential risk caused by change

Risk Management of change (to 1 = minor à 4= significant)				
Occurrence rate of change	Opportunity not to detect change	Seriousness in case of failure to account for change	risk in failure to account for change	score impact + risque

Table of most important ranking changes

	Impact level for organization (0 = no ; 1 = thinly ; 2 = important)							Risk Management of change (to 1 = minor à 4= significant)				
List of potential change	Management impact : collaborators (ex : training needed, communication ?)	Material Impact : product / performance	Environmental impact : environnement / works methods	Financial impact	Collateral Impact : other area of the pharmacy	Impact on clients	level impact score	Occurrence rate of change	Opportunity not to detect change	Seriousness in case of failure to account for change	risk in failure to account for change	score impact + risque
New clinical study	2	0	2	2	2	0	8	4	4	4	64	72
Change in methods or sampling plans	2	1	1	0	1	0	5	1	3	4	12	17
New product manufactured by batch (included clinical trial)	1	2	2	1	1	1	8	3	2	3	18	26
New scientific article or data modified stability	1	1	0	0	0	0	2	2	4	3	24	26
Reject of a batch	2	1	1	2	2	2	10	2	2	4	16	26
Change in specification of a product	0	2	0	0	1	1	4	2	4	3	24	28
New product packaging or new raw material or change of provider	2	2	1	1	1	1	8	3	3	3	27	35
New quality document or modification in the quality document	2	1	1	0	0	0	4	2	4	2	16	20
Changing employee, product or cleaning procedure of cleaning room or waste mangement	1	1	2	0	0	1	5	2	3	3	18	23
Significant deviation about equipment involved in aseptic process (shutting down alarm of ventilation, pressure, temperature in cleaning room)	1	2	2	1	1	1	8	2	4	3	24	32
New software or change version of GDP/GMP aspect with new features	2	1	2	1	0	0	6	1	4	4	16	22
Occurrence of major non compliance needing a change	1	2	1	0	1	1	6	2	2	4	16	22
Major change in labeling product	1	2	0	0	2	2	7	2	4	4	32	39
Major change in protocol : new used product, new or changing provider / removal	2	2	2	1	0	1	8	3	4	4	48	56

Contact : marie-line.mottier@chuv.ch