Original Research Article

Assessment of occupational risks in the Toxicology and Pharmacology Laboratory using the FMECA method

ABSTRACT

The Toxicology and Pharmacology Laboratory is a high-risk work environment, especially the chemical risk that appears when people are exposed to reagents and chemicals. A corrective approach is required to identify and control these risks. The aim of this study is to determine how to manage the analytical risks at LTP designated for the dosage of drugs and poisons (narcotics, pesticides, mycotoxins, etc.). For this purpose, the risk analysis applying the FMECA method, a risk management tool that aims on the one hand, to qualitatively analyze the process, to analyze the failure modes, the causes and their effects, and to on the other hand, rate the criticality defined by the parameters of frequency of occurrence, severity and detection that will allow a quantitative analysis of each of the failure modes.

Thus, the criticality calculation will help to determine the critical risks to be corrected, and to recommend corrective and preventive actions to be implemented within the service.

Introduction

The analyses performed at the Laboratory of Toxicology and Pharmacology (LTP) are subject to a potential risks from the sampling stages (pre-analytical phase) until the results are returned to the prescriber (analytical workstation phase). The risks incurred by employees can result from contact with chemicals and poisons, as well as work related accidents and/or the development of specific diseases known as: occupational diseases. The occupational risk is defined as a danger whose inherent property or capacity of an equipment, substance or working method can cause damage to the health of workers [1]. Among the risks incurred in Toxicology and Pharmacology Laboratories (LTP), we found thoseemanating from exposure to chemicals (corrosion, allergy, cancer, etc.); constitute a real problem in the professional environment [2]. Exposure of the upper and lower respiratory tract to solvents in the absence of appropriate preventive safety and control measures is likely to present the greatest occupational risk contracted at the Laboratory. Additionally, Laboratory workers are exposed to a multitude of risks related to the materials they use and the methods they apply during their work. The normal practices of the Laboratory of Toxicology and Pharmacology (LTP) do not only involve the handling of toxic substances, but also the use of chemical reagents and biological samples, as well as

laboratory animals (guinea pigs). Risk management at LTP should be seen as an area of primary interest; which focuses not only in coordinating or federating regulated health vigilance, but also in putting in place a comprehensive prevention and risk reduction policy to ensure the health safety of laboratory users [3]. As such, the risk assessment within the LTP for drugs and poisons handling makes it possible to control, as a corrective and preventive measure, the risks of non-compliance which can negatively affect the quality of chemical acts. The general objective of this work is to use in practice, the FMECA tool (Analysis of Failure Modes, their Effects and their Criticality) which would allow us, by controlling risks, to improve chemical actswithin the Laboratory and to raise awareness, directly and indirectly, of the "risk culture". Thus this work has for specific objectives to:

- **Make an inventory;**
- **Identify risks;**
- **Identify possible occupational exposures;**
- **Propose an occupational risk assessment approach for the Laboratory;**
- **Implement preventive and corrective actions;**

Risk is defined by AFNOR as an event whose occurrence is uncertain and whose occurrence is likely to affect the objectives of a project. An effect is a deviation, positive and / or negative, from an impairment [4]. It is the probability of occurrence of a defined problem, in a specific population, in a hazardous environment, during a given period. Thus, the occupational risk is defined as a danger whose property or intrinsic capacity of an equipment, a substance, a working method can cause damage to the health of workers [5]. The risks incurred in the laboratory vary according to several criteria, such as the nature of the laboratory, the techniques applied, the equipment used, and the personnel. There are 3 main types of risks in the laboratory: Chemical risks, Physical risks, andBiological risks.

Chemical risks: These are the risks associated with occupational exposure to chemical substances. The identification of the dangers induced by these substances helps to distinguish them into explosive, oxidizing, flammable, toxic, noxious, corrosive, irritant, sensitizing, carcinogenic, mutagenic, toxic for reproduction and dangerous for the environment substances [6].

Physical risks: Physical risks are generally understood to mean those induced by occupational exposure to energy sources. These are risks linked to the working environment (thermal environment, sound environment, vibrations, and lighting) and to radiation (ionizing, ultraviolet, and infrared or electromagnetic radiation).

Biological risks: These risks are linked to the presence of pathogenic biological agents in the workplace. Pathogenic biological agents are responsible for infectious diseases in humans. They include bacteria, viruses (to which we relate prion diseases), parasites and fungi. The risk of infection

may result from occupational or accidental contact, such as; AES (HIV, HCV, HBV, etc.), germs that are transmitted by air (Coronavirus, tuberculosis), germs that are transmitted by direct contact (staphylococcus, scabies, etc.), and handling of waste [7]. We also distinguish:

- Risks for humans and the environment: All of the laboratory personnel is potentially exposed to the various risks, whether inside or outsidethe laboratory.
- Risks associated with waste on humans: The health effects vary widely, depending on the chemical wastes, the biological agents present in the samples, the conditions of exposure, and certain individual factors. There are four types of health effects that these exposures can cause: infections, allergies, toxic effects, and cancer [8].
- Risks related to waste on the environment: The elimination of waste is one of the essential stages of compliance with hygiene regulations, not only inside establishments but in general [8].

In addition to the risks to human health due to direct contact, waste from healthcare activities can have a negative impact through contamination of water sources during waste treatment, and also through air pollution due to the emission of highly toxic gases following incineration [9]. Releases to air from municipal and medical incinerators are identified as sources of dioxins and furans from the combustion of plastics, such as PVC, increasingly used in medical packaging [10]. These toxic substances also cause dangers which are persistent organic pollutants.

Failure Mode, Effects and Criticality Analysis (FMECA) is a preventive analysis method used to analyze potential problems. In the 1950s, FMECA was applied in the US aerospace and military industry. The aim was to achieve operational safety.

Between 1960 and 1970, this method was popularized in France within the automotive, nuclear and chemical industries under the French name of AMDEC. Currently, this method is still very widespread in the industry and widely introduced in quality standards (ISO 9000 standards) to facilitate the establishment of a quality management system for a structure [11]. The analysis of failure modes, their effects and their criticality, consists of a methodical analysis of a system or process and risk based on prevention. AFNOR defines FMECA as an inductive method which makes it possible to carry out a quantitative and qualitative analysis of the reliability of a system by examining the failure modes, their effects and their criticality on the operation of all process [12]. It is implemented within the laboratory for analytical processes where customer requirements are high and for which the factors of uncertainty are not fully controlled by the laboratory. The principle of this analysis is to identify all the potential causes of each failure mode and assess the criticality. This method is essentially predictive. It helps to imagine the dysfunctions that may arise. The reflection focuses on the breakdown, in a systematic way, of a system in order to: Identify the potential risks to assess their probabilities and consequences in the

prerequisites for the FMECA approach [13]. It is essential to be familiar with the system being analyzed with the corresponding environment. The methodology then breaks down into four stages

1. Constitution of a working group: The reflection is based on collegial work. The creation of a multidisciplinary and involved group is necessary, the experience of each participant making it possible to reduce the subjectivities specific to each. The purpose of the project must be clearly explained and the planning of meetings must allow its outcome.

2. Assessment of potential failure modes: The assessment of potential failure modes is based on the response to 4 questions summarized in Table 1.

Table 1: The four basic questions of FMECA. According to Landy G (14).

Potentiel failure mode	**Possible effect**	**Possible causes**	**Monitoring plan**
What could go wrong?	What could be the effects?	What could be the causes?	How to see this?

The logical continuation of this reflection is as follows: One (of) cause (s) induce failure modes responsible for effect (s), (Causes→ Failure mode → Effects).

• **A "potential failure mode"** is the basic research of FMECA. The underlying question is "What could go wrong?". It is about comprehensively identifying "potential problems" - that is, how a function cannot continue to perform well. This initial question must be carefully analyzed and considered. Exhaustive questioning helps anticipate problems that could make the initial process more difficult, harm the end customer or have unexpected economic consequences.

• "Possible causes"help to identify the anomalies leading to the system failure. Several causes can be responsible for a failure mode and the same cause can intervene in different failure modes.

• **The "possible effects"** are the consequences of the problem and its realization. They can be immediate or delayed, direct or indirect and themselves lead to a new failure mode.

• **The monitoring plan** is an important point of FMECA since it allows to high light the means of detection of failure modes, to judge the relevance of the proposed actions and their effectiveness.

It is therefore in the interest of FMECA to identify and implement: "Emergency measures" to reduce the severity of the effects "Preventive measures" to limit the occurrence and frequency of problems. For this, actions can be;

Corrective: short actions to restart quickly following the occurrence of a risk at the present moment Preventive: actions planned before the dysfunction occurs improvement: actions modifying totally or partially a step in order to make the problem disappear.

3. Failure assessment and criticality calculation

Although FMECA advocates completeness, the purpose of this method is to determine priorities in the actions to be implemented. This point is based on the calculation of a criticality also called IPR (Index of Risk Priority - or RPN: Risk Priority Number) [15]. Each failure mode is quantified using three items: - The severity of its effect (s) - The occurrence / frequency of its cause (s) - Detectability in relation to current or planned action plans The quantification is based on the calculation of the following product, (Gravity X FrequencyXDetestability = Criticality).

The rating scale to be applied to each of these items is not imposed by FMECA.The FMECA working group must make its own ratings according to its process and concerns.As the "0" rating does not exist (zero risk does not exist), the scale is generally chosen between 1 and 10. The rating for each failure mode must be assigned independently of each other and in a consistent manner. The FMECA practical guide provides a summary table to be completed which includes the methodology associated with the quantification of potential problems (Table 2).

Table 2: Summary of the FMECA approach (Landy G) [16]

Potential failure	**Potential effects**	**Severity**	**Possible causes**	**Ocurrence**	**Monitoring plan**	**détection**	**IPR**
What could go wrong?	What could be the effects?	What is the relative severity of the effects ?	What could be the causes?	What is the relative probability of occurrence?	How do I see this?	What is the relative effectiveness of the controls ?	What is the priority of the points listed ?

4. Prioritization of potential failure modes: The IPR makes it possible to prioritize activities in terms of criticality. In itself, the value of the IPR is not important. It is the difference with the other scores (for example between 20 and 200) which makes it possible to identify the most critical failure modes and to determine what must be mastered as a priority. To identify them more precisely later, it is also possible to look more precisely at the rating of each item (severity, frequency, detectability). - advantages and disadvantages of FMECA

a- The advantages of the methods proposed by the FMECA guide are: The search for customer satisfaction corresponding to good handling of the request [17-18]:

- A regular review of FMEA in the Deming wheel contributes to the dynamism of the method (obtaining results then determining objectives to be achieved).
- It is a tool for improving communication: FMECA is the result of group work with the most varied participants, who discuss their practices and use their common sense in the same logic.

- The goal is to improve the stability of the process, product, highlighting the weaknesses of the process, its most critical points, makes it possible to better understand it, improve its control and make it less dangerous.
- The approach reduces costs: within a structure, you have to know where the flaws are and where to allocate resources to reduce the risks for preventive purposes.
- In this way, it is also possible to reduce the cost of curative actions.
- FMECA also allows for optimization of controls since it is illusory to be able to monitor everything.
- Knowledge of the entire process facilitates the elimination of the causes of failure through the implementation of the action plan and preventive actions.
- Finally, a final advantage is the transition from an oral culture to a written culture allowing the implementation of its quality management systemincluding useful documents.

b- The difficulties of the FMECA method are presented as being:

- The importance of knowing your process, product which is the object of the process.
- This is at the start of a tedious, time-consuming and human-resource-consuming method, but the purpose of which is to save time afterwards.
- The approach has a cost and the means of continuous improvement that also result from it.

At TLP, the FMECA method aims to reduce the criticality of activities related to analyzes. This involves evaluating the potential failure modes impacting the quality of examination results and, consequently, the care of patients and staff. The SH GTA 04 guide of April 4, 2015 highlights the FMECA method for risk control. It defines potential risks as those which can provide results that are erroneous, too late, and inaccurate or accompanied by an inappropriate interpretation that may have an impact on the results. The identification of risks, their estimation according to FMECA ratings (severity, frequency, delectability) and their prioritization is requested in the method validation files. The aim is to control risks by putting in place appropriate actions [19].

Material and methods

1. Place and period of the study: Our study spanned over a period of 6 months, from June 2020 to December 2020 in the LTP.

2. Type of study: It was based, as expected, on observation of staff activity, observation of service structures, and analysis of working conditions.

3. Laboratory structure: The laboratory is an analytical chemistry unit whose mission is to carry out toxicology and pharmacology analysisfrom sampling until the transmission of results to applicants. 4.

4. Study population

The study involved all laboratory staff, for a total of 13 people, which included: biologists, laboratory assistants, service agents, and thecleaning and collection personnel.

5. Data collection: This method is based on observation; it is considered a stage of reflection based on the observation of laboratory staff during the performance of their activities, each according to their profile as well as the locations and equipment.

6. Determination of the causes and modes of failure: To highlight the causes and modes of failure we used: The FMEA method which generates and classifies ideas or hypotheses concerning possible causes of problems within a process. This analysis tool sums up a large amount of information by showing the links between events and their actual or possible causes.

7. Classification of the categories of causes: The causes will be classified according to whether they are: Educational, Professional, Organizational.

8. Determination of the Criticality Index: After determining the rating indices for the various scales, the criticality is calculated according to the following formula:

$$C = F \times D \times G$$

A decision matrix was developed by the working group for the definition of the risk levels according to the criticality class. In our study, the criticality will be denoted Ci, that is to say the criticality index with i which corresponds to the number assigned to a failure mode which will be seen more explicitly in the rest of the work.

8. Proposal of a risk control plan and reassessment of the level of criticality after corrective action:

The corrective action proposals took place in two stages: A first step where all the improvement actions have been formulated without holding back or taking the context into account. Then these various improvement actions were studied by the person in charge and the quality manager in order to put them in line with the real context of the Laboratory of Toxicology and Pharmacology.

After evaluation of the criticality levels, all the steps that will be in criticality class 3 will require immediate corrective action which will be presented in the rest of the work.

Results

We identified 39 risks over an observation and analytical follow-up period of 6 months in the Toxicology and Pharmacology Laboratory. As part of the analysis of failure modes, their effects and their criticality (FMECA), a number of 11 risks were identified in the pre-analytical phase during the sampling stage, labeling and the conditions oftransport, and will be treated while respecting the plan adapted for this method.

Risk identification and analysis			**Risk assessment**				**Risk actions**	
Phase	**Process**	**Risk**	**O**	**G**	**D**	**C**	**Actions to be implemented**	**Causes**
The pre-analytical phase	Identification	Absence of the request	**2**	**2**	**1**	**4**	Request for additional information from the sampler	Lack of staff attention / Administrative problem (secretariat)
		Invisibility of the date and time of the sample	**2**	**1**	**1**	**2**	Request for confirmation and additional information from the sampler	Lack of staff attention
		Absence of the stamp	**1**	**1**	**1**	**1**	Request for confirmation and additional information from the sampler	Administrative problem
	Sampling	Sampling Identity mismatch between the sample and the prescription sheet	**3**	**3**	**2**	**18**	Sample refusal	Default related to the prescriber
		Insufficient quantity of the sample	**1**	**3**	**3**	**9**	Request for a new sample / Information from the sampler	Poor training of the sampler
		Opened or damaged vial	**2**	**4**	**2**	**16**	Request for a new sample	Failure to close the bottle after sample deposit
		Inappropriate sampling method	**3**	**3**	**3**	**27**	Refusal of the sample / Information of the collector	Poor training of the collector
	Labeling	Labeling Date and time of samples not provided	**1**	**2**	**1**	**2**	Information request to the sampler	Sampler error
		Two requests simultaneous with the same identity	**1**	**3**	**1**	**3**	Request for confirmation and supplement information to the sampler	Error related to the sampler
	Conditions of transport	Delayed direct debit transmission	**2**	**2**	**1**	**4**	Request a new sample and make a complaint	Vehicle problem /Traffic jams
		Temperature not respected	**2**	**4**	**2**	**16**	Request a new sample and make a complaint	Problem with the cooler

Thus, in the analytical phase a number of 18 risks were identified during the following stages:

- Reception;
- Sorting;
- Extraction;
- Preparation of extracts for analysis;
- Analysis.

Risk identification and analysis			Risk assessment				Risk actions	
Phase	**Process**	**Risk**	**O**	**G**	**D**	**C**	**Actions to be implemented**	**Causes**
The analytical phase	**Reception**	High sample reception room temperature	**2**	**3**	**2**	**12**	Checking and repairing the air conditioner / Temperature recording installation	Lack of maintenance of air conditioners
		Lack of information on the sample	**2**	**3**	**1**	**6**	Reinforcement and traceability of communication	Communication problem
	Sorting	Code mismatch between the bottle and the prescription sheet	**2**	**3**	**2**	**12**	Checking the codes by another technician	Lack of attention from the staff
		Malfunction of the high	**1**	**4**	**1**	**4**	A regular review of the High Maintenance	Cut electricity
		Contamination by standards during handling	**2**	**4**	**2**	**16**	Separation between standards and samples	Awareness and training of personnel BPL
		Power cut Poorly done extraction	**1**	**3**	**4**	**12**	Checking the condition reagents before use Inappropriate storage of reagents	Conservation inappropriée des réactifs
		Emulsion of the extraction phases	**1**	**3**	**3**	**9**	Composition of a new mixture of extraction solvents	Incompatibility of extraction solvents
		Insufficient extract for analysis	**3**	**2**	**2**	**12**	Adapt and properly unblock the extraction cartridges before use	Lack of special attention during extraction
		Loss of organic phase during centrifugation	**2**	**3**	**1**	**6**	Repeat the extraction, close the tube well before centrifugation	Evaporation of the extraction solvent during centrifugation
		Contamination of the reagent preparation room	**1**	**3**	**3**	**9**	Avoid handling with equipment from other rooms	Materials unsuitable for the extraction room

		Incomplete separation of the organic phase and the aqueous phase	**1**	**2**	**2**	**4**	Check the rotation speed of the centrifuge and redo the extraction	Fault in maintenance of the centrifuge
		Leakage of hydrogen in the laboratory	**1**	**4**	**3**	**12**	Checking the hydrogen circuit Installation of a hydrogen level detector in the laboratory	Lack of permanent monitoring of hydrogen in the laboratory
The analytical phase	**Analysis by automata**	Insufficient volume injected into HPLC	**2**	**2**	**2**	**6**	Cleaning the syringe And reinjection of extracts	Failure to clean the injection syringe
		Changing peak retention times	**2**	**3**	**1**	**6**	Mobile phase change	Old mobile phase / Lack attention from staff
		Unstable baseline	**2**	**2**	**1**	**4**	Detector lamp change and baseline start	Defective detector lamp / Preventive maintenance fault
		High background noise	**1**	**2**	**2**	**4**	Changing the filters of the mobile phase	Impregnated with the mobile phases / forgetting to clean the filters
		Significant variation in peak air in the chromatogram	**1**	**2**	**2**	**4**	Cleaning the source at the detector	Delay in preventive cleaning of the source by the after-sales service/ Maintenance failure

For the post-analytical phase, a number of 10 risks have been identified during the following stages:

- Validation of results;
- Interpretation of the results;
- Recording of results;
- Preservation of samples;
- Waste Management.

Risk identification and analysis			Risk assessment				Risk actions	
Phase	**Process**	**Risk**	**O**	**G**	**D**	**C**	**Actions to be implemented**	**Causes**
The post-analyticalphase	**Validation of the results**	Absence of the peak of the internal standard in the chromatogram	**1**	**3**	**1**	**3**	Redo the extraction and the injection	Forgets to add the internal standard / Lack attention from staff
		Appearance of a peak during the negative control	**1**	**3**	**1**	**3**	The control must be done under a high with the GLP compliance	Contaminatio n during handling Interpretation of the results
	Interpretation of results	Non-significant result	**4**	**4**	**1**	**16**	Redo the sample / redo the extraction	Problem in handling or sampling
		Poor interpretation of results	**1**	**3**	**3**	**9**	Redo the interpretation	Poor staff training / discrepancy between genes
	Recording	The record Data loss	**1**	**4**	**1**	**4**	Call in a computer technician / save a paper version	System failure computer science
		Discrepancy between files	**1**	**4**	**2**	**8**	Files must be encrypted The conservation of samples	Files not identified
	Sample storage	Damaged sample	**1**	**3**	**4**	**12**	Samples should be stored at -20 ° C	Failure to respect the cold cycle
		Contamination of other products	**1**	**3**	**3**	**9**	Samples should be stored in isolated places at -20 ° C	Storage Samples with reagents Waste
	Waste management	Management Contamination of hygiene personnel	**2**	**4**	**4**	**32**	Hygiene personnel must be dressed in accordance with the BPH	Non-compliance of BPH
		Accumulation of waste	**1**	**2**	**1**	**2**	Establish a regular program for waste collection	Irregular management of waste

It is noted that the analytical phase has a remarkable criticality compared to the other phases, it being taken into account that the risks identified in this phase represent an unacceptable level (figure).

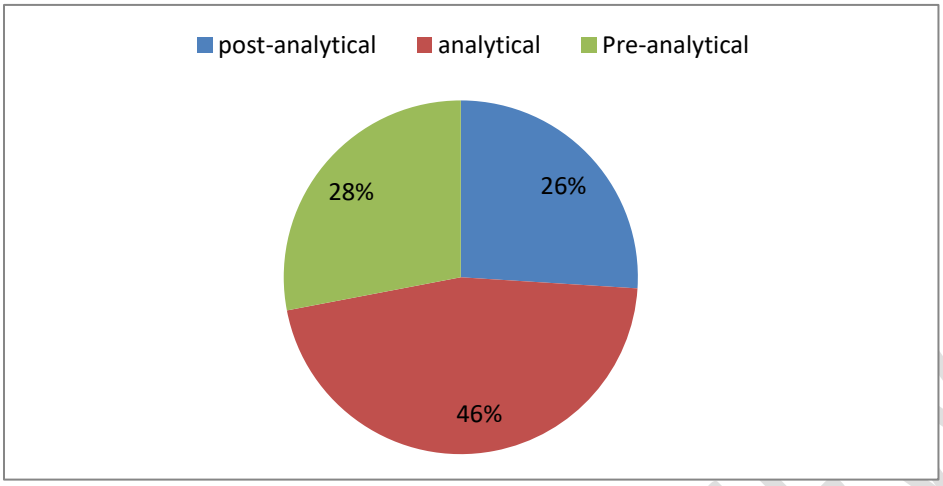

Figure: The criticality of each phase

Discussion

Our study describes the comprehensive and collegial risk analysis carried out on the pre-analytical, analytical and post-analytical processes within the Laboratory of Toxicology and Pharmacology. After determining the criticality of each hazard, it was possible to target the critical points (CCP) in order to control them. These CCPs are present in different phases:

1. **The pre-analytical phase**

During this phase we were able to distinguish 4 stages: prescription, sampling, labeling and transport conditions. When prescribing, which is an act performed by staff authorized to prescribe, it must contain with precision and legibility all the acts for which the prescriber expects results to support his diagnosis. The main risks identified in the prescribing process are the absence of the request, the absence of the patient's name and / or first name, and the absence of the stamp. These represent an acceptable level of risk with CCP respectively of 2, 2 and 1. Unlike other studies such as that of Oudghiri MI, which revealed that the risks associated with the prescription phase can be a major source of error [18-20]. The risks related to the sample are greater than those related to the prescription. The most identified risks concerning the direct debit are:

- Inappropriate sampling method with a CCP of 27;
- Patient identity mismatch between the vial and the prescription sheet with a CCP of 18;
- Open or broken tube with a CCP of 16;
- Insufficient quantity of the sample with a CCP of 12.

The sampling volume of the sample taken is supposed to be sufficient to ensure a better performance of the requested examination, thus to allow the biologist to make a possible confirmation in case of 'error or doubt. From these results, it can be seen that the first two risks

represent an unacceptable level of risk which requires risk reduction measures to be put in place immediately while the other two represent a tolerable level of risk under control and only requires organization of residual risk management monitoring.

2. The analytical phase

During the analytical phase, which includes all the events that may occur during the analysis, 4 stages could be distinguished:

- Reception;
- Sorting;
- Extraction;
- Analysis.

From the results obtained it can be seen that in the instrumental analysis stage, the risk of discrepancy during the deposition of the extraction products on the cartridge occupies the most critical risk in the analytical phase with a CCP of 32, the latter is due to the poor preparation of the extraction cartridge and / or the lack of attention of the personnel, thus it represents an unacceptable level of risk which requires risk reduction measures to be put in place immediately such as adaptation of each cartridge before use. In the same context we notice that in the extraction stage, the most critical risk is linked to the quality of the extraction cartridge and more precisely when the elution liquid floats on the cartridge because of the bad centrifugation or poor mixing, the latter represents an unacceptable level of risk (CCP = 27) which requires risk reduction measures to be put in place immediately.

3. The post analytical phase

During this phase, which concerns all the events that may occur after the analysis, we were able to distinguish 5 stages:

- Validation of results;
- Interpretation of the results;
- Recording of results;
- Preservation of samples;
- Waste Management.

According to the results obtained, it can be seen that in the waste management stage, the risk of contamination of hygiene personnel and the risk of the transmission of infectious agents in the laboratory constitute the most critical risks in the post-analytical phase, and are due respectively to non-compliance with good hygiene practices and ineffective or irregular disinfection of the work surface and / or poor training of hygiene personnel. Contamination of hygiene personnel represents a CCP of 32 with an unacceptable level of risk which requires risk reduction actions to be implemented immediately. The transmission of infectious agents in the laboratory also represents a

CCP of 32 with an unacceptable level of risk which requires risk reduction actions to be implemented immediately.

Finally we can deduce that the analytical phase is the phase which includes the greatest number of risks with a remarkable criticality compared to the other phases and this can be explained by the fact that this phase is the most important since it is in which the handling of the sample where there is the direct impact with the technicians as well as the automatic influence of the post-analytical phase. After the risk assessment, risk control strategies must then be developed. The first step is to reduce or even eliminate the risks identified, whenever possible. Residual risk prevention measures are then designed and implemented: they include organizational and technical aspects (work organization, collective and individual protective equipment, etc.), medical prevention and specific training for the personnel concerned [21].

Conclusion

The reliability of the results of Toxicology and Pharmacology analyses implies mastery of the pre-analytical phase which is the first part of the quality circle that begins with the sampling, continues with the execution of the analysis in the laboratory (analytical phase), and ends with the interpretation of the result and the transmission of the result (post-analytical). This work has highlighted, using the FMECA method, a significant number of risks in the pre-analytical, analytical and post-analytical phase; identification problems, errors related to the prescription sheet, non-compliance with transport and delivery conditions as well as the risk of contamination, etc. This has led us to set up a risk management system for the pre-analytical, analytical and post-analytical phase within the LTP, which will contribute to improving quality and safety of patients and staff which is a major concern. The risk analysis and assessment allowed us to put in place corrective and / or preventive measures based on the use of quality management tools through written control procedures corresponding to the most critical points that we were able to identify. Further steps will be taken as the adverse reaction management system is put in place.

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