QUALITY MANAGEMENT SYSTEM IN CYTOTOXIC DRUGS LABORATORY: MONITORING ACTIVITY AND IMPROVEMENT ACTIONS

A. Morichetta, S. Giorgetti, L. Scoccia, M.S. De Meo, C. Antolini , A. Minnucci, A. Giglioni
ASUR Marche AV3 Macerata, Hospital Pharmacy, Macerata, Italy

BACKGROUND

The Quality Management System (QMS) present in Hospital Pharmacy, certified according to UNI EN ISO 9001:2008, has been implemented in the antineoplastic drugs laboratory.
The purpose of this study is to present tools and evaluation's methods for work activity, in order to improve both quality and safety of therapies.

MATERIAL AND METHODS

Several specific performance indicators, with related reference values, were identified for critical activities. Moreover a questionnaire concerning the main aspects of our service was submitted to internal users. Non conformities were analysed and corrective/preventive actions were implemented.

RESULTS

PERFORMANCE INDICATORS

PROCESS	INDICATORS	REFERENCE VALUE	RETRIEVED VALUE
Compliance of preparations	n. of non-compliant preparations/ n. of preparations	3%	1-2%
Enviromental sterility	n.of enviromental controls with negative results/n. of enviromental controls	100%	100%
Products sterility	n. of sterility checks with negative results/n. of checks executed	100%	100%
Operator's shift	n. shift in the hood and n. shift to robot	± 10%	± 10%
Wards delivery	n. of delivered preparations/ n. of preparations made	≥ 80%	≥ 80%

The indicators were verified and they provided values consistent with the reference values.

The questionnaire confirmed the overall quality of the service. Delivery was considered not always on time, and the labels, included in photo-shielding envelopes, not readable. For these reasons the frequency of preparations' delivery was increased and priority to monotherapies and first therapies was given. An improvement of packaging guaranteed the visibility of the labels.

NON CONFORMITIES REGISTERED: AN EXAMPLE

OPERATOR CONTAMINED BY A DAMAGED BOTTLE OF ANTINEOPLASTIC DRUG DURING FREIGHT RECEPTION, SITUATION NOT CLEARLY DETECTED BY STANDARD CHECKS

CAUSES ANALYSIS:
Not clearly defined protection measures to be taken at the reception of antiblastic drugs.

CORRECTIVE ACTION:
Use specific I.P.D.(Individual Protection Devices) despite the apparent integrity of packaging.

The overall registered non-conformities were five, and led to four corrective and two preventive actions: it was decided to optimize staff training about the risk of cytotoxic drugs and the need for double controls during work in the hood was reiterated.

QUESTIONNAIRE OF SATISFACTION

QUESTIONS	ANSWERS
QUALITY OF SERVICE AND PHARMACIST AVAILABILITY	80% GOOD 20% EXCELLENT
CORRECTNESS OF PACKAGING	IN LINE WITH DATA SHEET
TIME OF DELIVERY	50% OFTEN ON TIME - 50% RARELY ON TIME
READABILITY OF LABELS AND ADMINISTRATION FORM	LABELS NOT CLEAR

CONCLUSION

QMS support has helped to create conditions for effective management of the laboratory since its activation, to provide appropriate instruments for activity evaluation and to identify critical issues that can be solved through joined and shared measures.

Contact: anna.morichetta@sanita.marche.it Hospital Pharmacy Macerata - Area Vasta n.3 Asur Marche