

Висновки. Процес управління протоколами у СУЯ фармацевтичного дистриб'ютора, відіграє важливу роль для доказу досягнутих результатів інших процесів СУЯ. Відповідно до вимог GDP, дистриб'ютори повинні зберігати протоколи не менше п'яти років, а якщо висуваються додаткові вимоги, то такий термін збільшується.

Для своєчасної доступності протоколів, їх швидкого пошуку, найчастіше протоколи фотокопіюють та переміщують до комп'ютеризованих систем або інші електронні сховища. Але часто спостерігається ситуація, коли відсутня точна інформація про місця архівування та назви протоколів, що може викликати плутанину у персоналу.

Тому одним із методів управління протоколами СУЯ, нами запропоновано:

- вносити в документовані процедури розділ «Документація, що стосується даної процедури» для строгої регламентації порядку роботи з протоколами;

- закодувати QR – кодом шляхи завантаження затверджених робочих форм протоколів та шляхи їх архівування у корпоративне сховище цифрової (електронної) інформації.

Вищезазначені методи зменшують ризик помилки персоналу, що працює з протоколами з подальшим фотокопіюванням та архівацією. Ці методи також можливо враховувати при проведенні валідації комп'ютеризованих систем, що приймають участь у процесі управління протоколами.

THE RESEARCH OF PSYCHOLOGICAL CLIMATE IN ORGANIZATIONS OF PHARMACEUTICAL PROFILE

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Introduction. Currently, the problem of the psychological climate in the team is very relevant in conditions of economic instability and low motivation of workers to work. Accordingly, this entails a high turnover rate, which in turn is harmful to the activities of pharmaceutical enterprises, if highly skilled workers often quit, respectively, a high turnover rate signals a threat to the stability and integrity of the organization and is associated with significant costs. Therefore, theorists, social psychologists, personnel specialists, internal communications specialists – and company leaders are increasingly thinking about how to improve the socio-psychological climate in the team. However, despite the relevance, this problem is still virtually unexplored from a modern point of view. The relationship between the effectiveness of the organization and its socio-psychological climate is the most important problem for company executives. Therefore, it is so important to know the components of the socio-psychological climate of the organization and their study. A favorable socio-psychological climate is the result of the systematic work and activities of managers, managers, psychologists and all employees of the organization.

Aim. The aim of the study is to analyze and evaluate the socio-psychological climate in the team. After the formulation of the goals and objectives of the study, it is necessary to choose the method by which data will be collected. We recommend a questionnaire survey as the most effective method of collecting data in medium and large teams, which, subject to conditions, provides a high guarantee of the sincerity of answers.

Materials and methods. Methodology for assessing the psychological atmosphere in a team (according to A. F. Fidler) is used to assess the psychological atmosphere in a team. It is based on the method of semantic differential. The technique is interesting in that it allows anonymous examination, and this increases its reliability. Each extreme value is assigned a number of points: the extreme negative – 8, the extreme positive – 1. Then all the indicators are added, and based on the value of the sum,

the atmosphere is evaluate in the team. The minimum total score is 10, which is an indicator of the positive atmosphere in the team; the maximum is 80, respectively, an indicator of the negative atmosphere. Based on all private assessments, an average value is calculate that will characterize the atmosphere in the team.

	1	2	3	4	5	6	7	8	
Friendliness									Hostility
Consent									Disagreement
Satisfaction									Dissatisfaction
Productivity									Unproductive
Heat									Cold
Cooperation									Inconsistency
Mutual support									Malevolence
Passion									Indifference
Entertaining									Boredom
Success									Failure

Results and discussion. The study of the socio-psychological situation at the enterprise includes several stages of work.

The first stage is preparatory. At this stage, the goals and objectives, volumes and terms of the study, responsible for organizing and conducting the assessment procedures, are identifies and agreed. Also at this stage, the final model for studying the socio-psychological situation at the enterprise is former and approve.

The next, second stage is research, during which diagnostic measures and procedures are carrier out in a number of areas:

1. The study of the representations of employees about the state of affairs in the organization.

The result is a characteristic of employees' social perceptions about various aspects of the organization's life; determining the degree of employee awareness of the state of affairs in the organization and identifying the overall attitude (positive or negative) in relation to what is happening; a comparative analysis of employee perceptions and managers' perceptions of the state of affairs in the organization; description of available social and psychological resources and potential threats to the effective activities of employees.

2. The study of social – psychological climate in the team.

The result is the determination of the degree of favorable psychological atmosphere in the team; identification of areas of psychological tension in the team; determination of team cohesion at the value level; identification of employees' ideas about the goals of the organization and its unit; identification of personal goals of employees and their consistency with the goals of the organization (unit).

We conducted a survey of two teams of 15 people and established point values for evaluating the above parameters. The results of the questionnaire indicate the prevalence of positive traits among the teams: mutual support, friendliness, cooperation and a number of negative traits: boredom and failure. That shows a low interest in the activities of the enterprise.

3. The study of the level of satisfaction with the conditions of activity.

Study of employee motivation for activities.

The result is a study of the degree of satisfaction with working conditions; the study of employee perceptions of the motivating factors present in the organization; the study of the system of motivators in terms of their importance for effective activity; study of the orientation of group motivation.

4. The study of the role structures of the team.

Result: assessment of each employee, obtaining a concentrated and statistically significant opinion of the team about a specific person. Assessment of a group of employees as a whole.

One of the important stages of the study is the analytical stage. In its course, a generalization and analysis of the final results takes place.

The formation of conclusions and recommendations occurs in the following areas:

1. Does the organization (unit) have sufficient social and psychological resources to change and achieve its goals?
2. What are the limitations and potential for effective individual and group activities of the team as a whole?
3. What socio-psychological factors affect the increase (decrease) in personnel efficiency?
4. Under what conditions will the collective potential be realized to the maximum extent?
5. How and in what areas is it necessary to develop a system of managerial influences to optimize the activities of the enterprise (unit)?

At the final stage, they summarize the diagnosis and research.

Conclusions. A favorable socio-psychological climate is a condition for increasing labor productivity, satisfaction of workers, work and the team. Socio-psychological climate arises spontaneously. But a good climate is not a simple consequence of the proclaimed mottos and efforts of individual leaders. This is the result of systematic educational work with team members, the implementation of special events aimed at organizing relations between managers and subordinates. The formation and improvement of the socio-psychological climate is a constant practical task for managers of any rank. Creating a favorable climate is not only responsible, but also creative, requiring knowledge of its nature and means of regulation, the ability to provide a reliable situation in the team's relationship.

DEVELOPMENT OF MEASURES TO INCREASE THE COMPETENCE OF INTERNAL AUDITORS OF PHARMACEUTICAL QUALITY SYSTEMS

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Introduction. In addition to expanding product range and technical modernization, many pharmaceutical companies' management aims to improve the quality management system (QMS). One of the important processes of QMS is internal audit, the development of which is given considerable attention. Audit directly affects the quality of the implementation of all processes of the organization, as a consequence - the quality of products. The competence of the auditors depends on the value of the audit results, as well as the attitude to the quality issues by the staff. Audit confidence depends on the auditors' competence. The auditors should demonstrate:

- proper personal qualities;
- ability to apply professionally knowledge, skills and experience in conducting the audit;
- depending on the audit program, the organization must always determine the required level of competence of all internal auditors.

So, components of the auditor's competence are the professional knowledge, personal qualities required, experience and skills.

Aim: to substantiate the relevance, to analyze and to offer a rational approach to training of internal auditors of the quality management system based on a pharmaceutical company.

Research objectives:

- an overview of the ISO 9001 and 19011 standards;
- defining the necessary knowledge, skills and personal qualities that quality auditors should possess;