ISSN 2228-9860 eISSN 1906-9642 CODEN: ITJEA8

International Transaction Journal of Engineering, Management, & Applied Sciences & Technologies

http://TuEngr.com

Development of an Automated Module for Preventive Measures and Internal Audits in Pharmaceutical Organizations

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Paper ID: 13A8B

Volume 13 Issue 8

Received 25 November 2021
Received in revised form 29 March 2022
Accepted 5 April 2022
Available online 25 April 2022

Keywords:
Audit procedures; Automation; Quality management; Electronic checklist.

Abstract

The article discusses the practical aspects of using a set of programs and databases for computers (cloud service of electronic checklists), called the "Service Inspector" platform (or other analogues of platforms) for preventive measures, self-monitoring and internal audits in the quality system of pharmaceutical organizations and medical organizations. The rationale for choosing the "Service Inspector" platform (cloud service of electronic checklists) for the transition to automation of preventive measures and internal audits processes is presented, and the advantages and disadvantages of the chosen platform are described. The study highlights some problems in the implementation of preventive measures and internal audits in the quality system of pharmaceutical organizations. The disadvantages that arise when working with paper checklists are described, and ways to solve them by switching to electronic checklists. A sociological study of the practice of fulfilling mandatory requirements for internal audits in pharmaceutical organizations was conducted. The proposed software module for automating the processes of preventive measures and internal audits in pharmaceutical organizations will help minimize risks within pharmaceutical organizations, eliminate and prevent inconsistencies identified during the internal audit and prevent possible errors in the future. The control tool described in the article will increase the efficiency of the quality system of pharmaceutical organizations.

Disciplinary: Pharmacy Management.

Cite This Article:

Bidarova, F.N., Remizov, O.V., Tsakhilova, E.N., Tsiklauri V.G., Karaeva, M.S., Kataev, D.O. (2022). Development of an Automated Module for Preventive Measures and Internal Audits in Pharmaceutical Organizations. *International Transaction Journal of Engineering, Management, & Applied Sciences & Technologies, 13*(8), 13A8B, 1-13. http://TUENGR.COM/V13/13A8B.pdf DOI: 10.14456/ITJEMAST.2022.149

1 Introduction

According to the annual final boards of the Federal Service for Surveillance of Healthcare in Russia by 2020, the number of pharmaceutical organizations (PO) and medical organizations (MO) that violate current legislation in the field of circulation of medicines and the provision of pharmaceutical and medical services has increased significantly (84%). In 2016, this index was 63% [1]. The current situation dictates the need to find ways to modernize the tools for optimizing the quality system of medical products and services of pharmaceutical organizations [2,3].

2 Literature Review

Currently, the Government of the Russian Federation has developed a "Road Map" [4], which provides for the rejection of the practice of maximum penalties in favor of preventive measures aimed at preventing and preventing violations by controlled entities. However, pharmaceutical organizations do not know how to practically implement the above mechanisms, and therefore do not have time to fully engage in the modernization processes.

On the other hand, an obligatory stage in the quality management system of pharmaceutical organizations [5-8] is the implementation of preventive measures and periodic internal audits, the analysis of the results (protocols) of internal audits by the head of the PO, bringing the results to all employees of the PO. Internal audits and audits are conducted in order to identify deficiencies and inconsistencies in compliance with the requirements of the legislation of the Russian Federation with subsequent corrective and preventive measures. Documenting all procedures is important in this process.

Conducting internal control procedures is currently quite a difficult task for the PO since the staff lacks the necessary knowledge and experience, there is no unified approach to self-control procedures and registration of results, which determines the relevance of the research topic [9-12].

The established rules of good pharmacy practice and good practice of storage and transportation of medicines also do not contain a full-fledged explanatory base for carrying out preventive measures and internal inspections/audits in the PO [13].

That is why it seems relevant to automate the processes of internal audits/audits in the internal quality control system of the PO. This will allow the PO to conduct internal checks/audits with high speed and accuracy, with the ability to track inconsistencies, analyze various dynamics, create analytical and operational reports, and store and accumulate them in cloud media.

3 Method

Among the many web platforms for quality control of various organizations hosted on the Internet, a ready-made specially developed web platform "Service Inspector" was selected - a cloud service of electronic checklists. This platform is used to create automation of internal control processes of any organizations [14-16].

In the course of the research, the analysis of modern directions of improving production processes using information technology, content analysis, questionnaires among managers and pharmacists on the practice of fulfilling the requirements of good pharmacy practice on the

implementation of internal self-checks /internal audits were used, structural and functional methods of analysis were used [17, 18]. Place of research: Department of Pharmacy, North-Ossetian State Medical Academy, 2021.

4 Result and Discussion

The most important element of the good practices that have come into force is the quality system of a pharmaceutical organization. During the transition to work in these conditions, there was a need for an explanatory base for specialists, including with regard to the process of self-control or internal audits of a PO [19-21].

Conducting an internal audit of a PO can be represented by the main stages: planning and implementation of internal audit procedures, including the processes presented in Table 1.

Table 1: Stages of internal audit of a pharmaceutical organization

№	Stage 1 Internal audit planning	Stage 2 Implementation of internal audit procedures
	The order of the head on the beginning of the internal audit, the creation of audit groups, the distribution of powers	Observations, surveys, analysis, evaluation, documentation of inconsistencies and comments
	Development and approval of the program of goals, volumes, schedule of internal audits	Drawing up protocols, filling out checklists
	Creating criteria for verification checklists	Preliminary and final reports
	Appointment of responsible persons for corrective actions	Recommendations of the audit group on risk reduction
	Corrective action plan	

The second stage of the internal audit of a pharmaceutical organization provides for the independent development of the initial contents of a comprehensive internal audit checklist, therefore, the author has attempted to form an internal audit/self-control checklist of the PO.

To date, the checklists by the Federal Service for Surveillance of Healthcare in Russia are not complete, they do not include all the possible requirements for the PO and necessary for checking the internal quality system of the PO, and do not reflect all the issues regarding the processes that need to be checked during the PO preventive measures and comprehensive internal audits [22-24].

The checklist developed by the author is supplemented with sections, as well as parameters checked by other control and supervisory authorities, including the Federal Service for Surveillance of Healthcare in Russia, it expands the wording of some issues that are non-specific and non-exhaustive:

1. Requirements for the registration of information on the trading floor of the PO (consumer corner).
2. Requirements for the design of the signage.
3. Requirements for the infrastructure of the PO.
4. Organization of pharmacovigilance.
5. The section "organization of acceptance control" has been expanded.
6. The section "verification of compliance with the rules for the release of medicines" has

been expanded.

7. The section "personnel requirements" has been expanded.
8. Pricing procedure for pharmacy assortment products.
9. The procedure for providing information as pharmaceutical consulting.
10. Expanded and updated the section on compliance with sanitary requirements for premises, equipment
11. The section on compliance with sanitary requirements for premises, equipment and personnel has been expanded and updated.
12. The section of the checklist on quality assurance of medicines in the PO has been expanded (supplemented with a detailed complete list of all standard operating procedures, a list of journals that must be maintained in the PO, a complete list of administrative orders for the main activity).

Another distinctive feature of the author's checklist is that one question contains only one mandatory and specific requirement. The PO can use such a comprehensive checklist in full or broken down into separate sections, depending on the tasks of the internal audit.

This study also presents the results of a survey among managers and pharmacists on the practice of fulfilling the requirements of good pharmacy practice in the implementation of internal self-checks /internal audits in the Southern Federal District.

It was revealed that since the entry into force of the requirements of good pharmacy practice and the requirements of good practice for the storage and transportation of medicinal products in Russia in 2017, more than 80% of subjects of pharmaceutical circulation have not carried out internal audits. The same subjects did not know anything about the preventive measures being carried out. It was revealed that the managers of the PO do not bring information about the results of the internal audit and its analysis to the staff of the PO. Thus, the violation of the requirements of good practices, in terms of the creation of quality systems of the organization, has a systemic and ubiquitous nature and affects the quality, safety of the use of medicines and the quality of services provided. Of those who conducted internal audits, more than 83% of respondents explained that they spend more than eight hours conducting a non-comprehensive internal audit, without taking into account the preparation of accounting documentation in the form of an internal audit protocol. Basically, all the audits carried out were carried out according to checklists, which contained only individual sections to be checked. According to the results of the internal audit, 77% of respondents spend an average of 3 days on the preparation of the report. All respondents explained that the auditors were appointed from among the pharmacists who have the main official duty. They conducted audits and formed accounting documentation in their free time from their main duties.

4.1 Description of the Selected Platform "Service Inspector" (Cloud Service of Electronic Checklists) for the Program of Automation of Internal Audit Processes

The expediency of choosing a specialized software product for automating the internal audit of the PO is represented in the use of a finished product, and not in the development and programming of an individual one. There is currently no need to create a new, individual, software product according to its own requirements. You can choose it from the variety that is already widely used in the Internet network on the market.

However, when choosing a "batch" version, it will be necessary to go through the process of adapting this product to the specifics of a specific PO, technology, structure and the current system of control and risk management, methodology of internal audit.

The choice of a software product for automating the internal audit process in the PO was carried out based on the following tasks:

1. Reduction of time for self-control/verification/audit;
2. Coverage of an unlimited number of processes and subprocesses;
3. Reduction of processing time for totals and results;
4. The possibility of appointing responsible persons for the elimination of identified inconsistencies.
5. Remote control capability.
6. Receiving automatic reports after completing the checklist.
7. Availability of results on the website and in the mobile application.
8. The ability to conduct analytics, track dynamics and changes, find weaknesses and quickly make decisions that will improve the PO control system.

Our chosen platform (cloud service of electronic checklists) "Service Inspector" provides maximum automation of information processing at all stages of internal audits, has an easy interface, an intuitive algorithm of work that allows you to learn quickly. This platform is adapted to the accumulation of a large number of documents that require processing, analysis, systematization, storage and other operations. The platform also ensures the efficiency of all stages and provides a full cycle of the internal audit process. On the other hand, the Service Inspector platform reduces the influence of the "human" factor, the possibility of errors when processing audit protocols, and there is no need to allocate a special staff.

This digital electronic checklist platform has an administrative module and a checklist module with a set of necessary functionality presented in Table 2.

Table 2: Modules and functionality of the digital platform of electronic checklists

№	Functionality of the administrative module	Functionality of the Control Checklists module (Inspector)
	"Setup"	"Setup"
	"Creating control checklists/audits (Inspector)"	"Creating the audit itself in the application"
	"History of audits conducted"	"Conducting an audit"
	"Reporting in Inspector"	"Reports"
	Sending reports	-

The platform allows you to develop any necessary checklists, modify and supplement them, store them in cloud spaces, specify the regulatory framework in the checklist, use all possible templates or create questionnaires for your own tasks.

If necessary, this platform can be scaled not only for internal audit but also used for self-monitoring by staff and the manager as a secret buyer. These additional features are described in Table 3.

Table 3: Scaling capabilities of the "Service Inspector" platform

№	Additional features of the Service Inspector platform	Description of additional features of the Service Inspector platform
	Inspection/ Internal audit of the PO	An inspector (auditor, quality commissioner, manager, director, manager) checks the work of employees/ departments using checklists, photographing shortcomings and commenting on them in the mobile application
	Secret guest / buyer	The mystery shopper provides an independent assessment of the quality of pharmaceutical services/service. All the shortcomings are fixed with photos and comments
	Self-monitoring of staff/employees	The staff performs the work according to the points in accordance with the checklist, photographing the fact of its completion in the mobile application

The platform allows you to build a rating of employees, departments, measure key performance indicators and build a motivational program for staff.

From all the variety of automated programs, we have chosen a hybrid model of a web application for a mobile platform in combination with an independent website. This model allows you to completely abandon paper checklists. The program provides the possibility of autonomous work of auditors with the possibility of combining data into a single database.

The procedure of self-control or internal audit is recorded in the mobile application. It allows you to fix inconsistencies, take photos and videos, reflect explanations or clarifications, enter the date and time for the elimination of inconsistencies, appoint responsible persons, etc.

Following the completion of the questionnaire and the completion of fixing inconsistencies in the mobile application, the results are automatically transferred to the web platform of the site in the cloud. From the web platform the site, the results of the completed self-control or internal audit can be sent to any e-mail address to interested parties.

The cloud in this development allows you to store a certain amount of information and provides the ability to synchronize data with the application and the website.

Using the web platform, you can monitor the status of internal audit execution online.

The selected platform "Service Inspector" (cloud service of electronic checklists) has the following functions:

The function "general data entry". The section "checked objects".

The "general data entry" function is the collection and transformation in the application of data such as:

- Number of employees

- Positions
- Objects to be checked
- The contents of the checklist
- Checklist Report Editor

The function of entering the data of the checklist is the ability to create a full-fledged electronic checklist with the ability to create ordered sections in one checklist. At this stage, you can use the data of the developed author's checklist of the integrated internal audit of the PO. This function is fundamental in the development of an automated system.

The data entered into the program is securely stored in cloud storage, which is virtual memory.

Another important section is adding testable objects. With the help of this program, you can select the necessary checklist, and select the employee responsible for the audit, after which it is necessary to create a database or register of the audited units, facilities and/or branches.

A database of the objects to be checked is created in the "management" section on the administrative panel of the program.

When adding the database of "checked objects", it becomes possible to quickly search for objects at the beginning of the audit by entering any combination of letters from the name of the object, even if it is the address of the object.

Upon completion of entering the primary necessary data and selecting an automated checklist, you can audit the selected organization

4.2 Presentation of the practical functionality of the program

Working with an automated checklist is based on the system of choosing the answer "yes or "no". If the question is irrelevant and/or inapplicable, you can skip it. An example is shown in Figure 1.

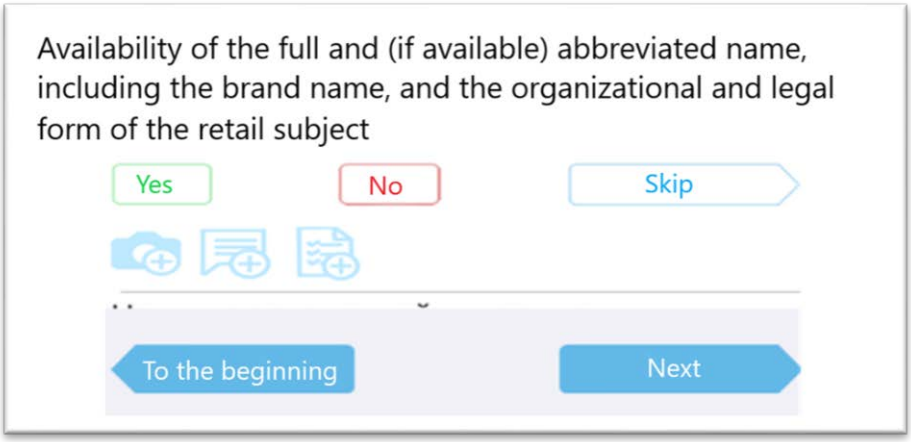

Figure 1: Structure of responses

It is possible to return to the previous point for self-control. At the end of the audit, the application requires confirmation of the action, where you can return to the checklist, correct the error, and conduct self-control again before completing the audit (Figure 2).

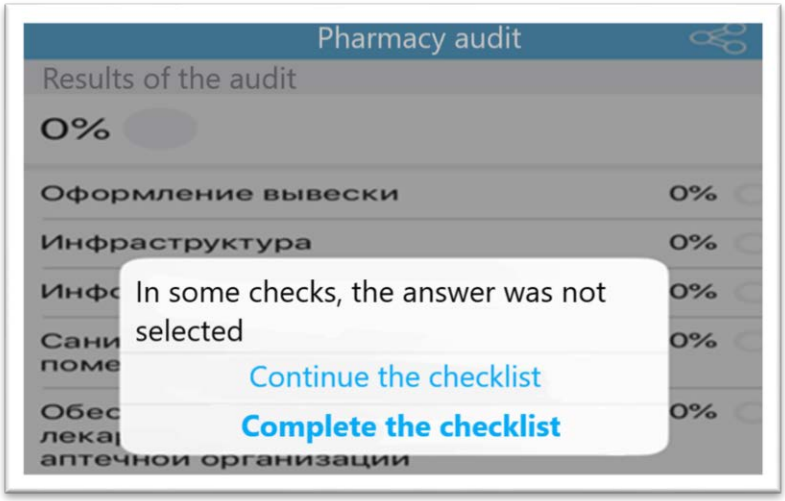

Figure 2: Confirmation of the end of the audit

The "reports and inconsistencies" function

After the audit is completed, the program will offer you to familiarize yourself with the report beforehand and, as an option, send it to the desired e-mail address of interested parties (Figure 3).

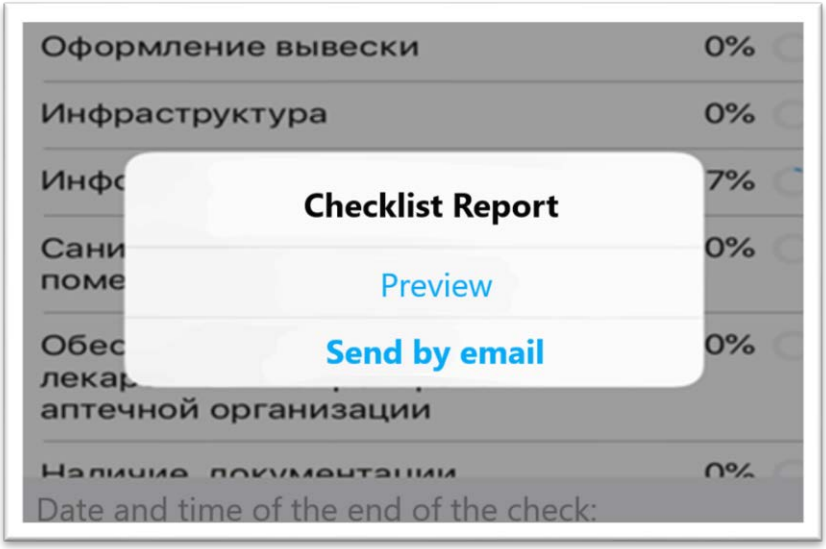

Figure 3: Report on completed internal audit

According to the completed internal audit, this program outputs only non-conforming verification parameters to the report, therefore the reporting form does not contain all the checked items on the checklist. This version of the audit report will further help to carry out competently corrective and preventive measures for identified inconsistencies.

The report displays:

1. Contact information of the inspection organization.
2. Contact information of the object being checked.
3. Name of the auditor.
4. Date of the audit.

5. Audit start time/audit completion time.

6. Inconsistencies identified during the internal audit.

7. The percentage of completion of the checklist.

8. Both PDF and Excel uploads are available for reports.

It is also possible to add a field for the auditor's signature, as well as a field for the seal of the organization that conducted the internal audit.

The function "forming comments and/or notes".

This function allows you to form explanations for the detected comments and/or inconsistencies for their specification in the form of an evidentiary and/or review base. In addition to the ability to enter a note, you can record and photograph the discrepancy in real-time (Figure 4). You can also attach a photo report/comment after the audit.

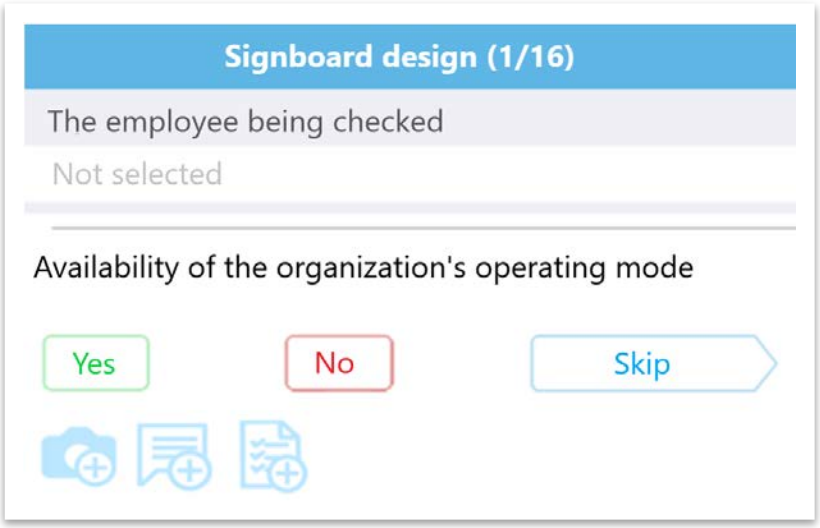

Figure 4: Panel for adding notes, photos, and comments to the discrepancy

This program has developed the ability to create a comment/note indicating the timing of the correction of nonconformity and the person responsible for the implementation of corrective measures.

The application also notifies about the ending period of correction of a violation. This function will allow you to eliminate the identified inconsistencies in a timely manner by setting a limited deadline for completing the task.

The task setting function allows you to control the processes of corrective actions (Figure 5).

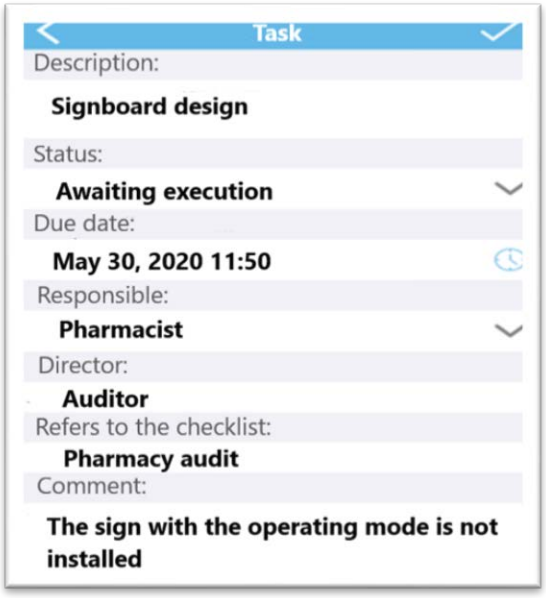

Figure 5: Formation of the task of correcting the discrepancy, commenting, and entering deadlines for the elimination of the identified violation.

Comments/notes and photos are also displayed in the report. In the electronic version of the report, it is possible to enlarge or open the attached photo report.

The "archival documentation on completed audits" function of the platform allows you to analyze the audits conducted, search for them by a specific, specified period, as well as manage archival documents of completed audits of certain periods (Figure 6).

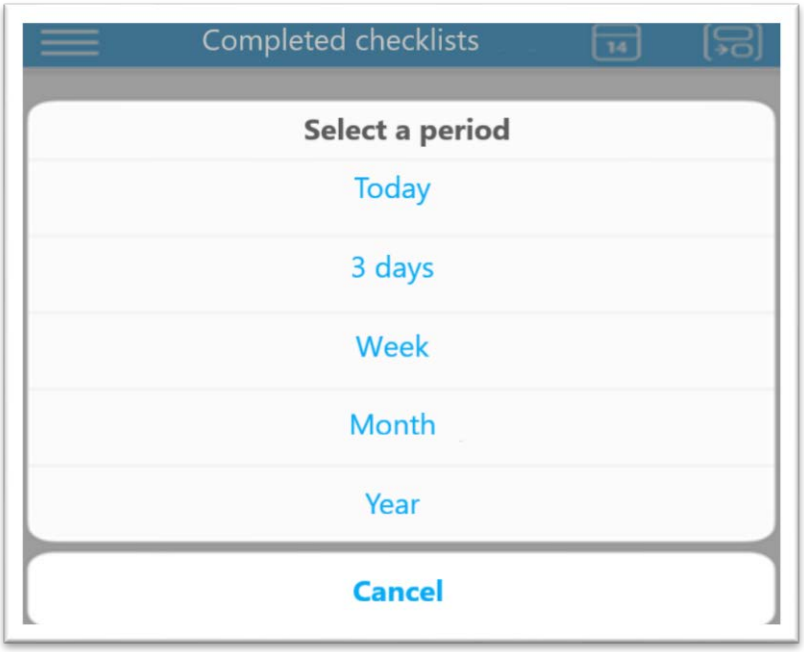

Figure 6: The "archival documentation on completed audits" function

In the computer version (administration), it is possible to search for reports on a specific date. You can also hide audits from the general list.

The program has cloud storage that is synchronized with the web panel so that the platform can store all the completed audits. With the help of the synchronization function of completed

audits and the administrative panel system, it is possible to monitor the implementation of corrective measures in real-time. This function is available after synchronization on the website of the personal computer and through the application on the mobile device.

The selected software of the "Service Inspector" platform (cloud service of electronic checklists) is supported on two phone platforms – IOS and Android. Currently, it is also optimized for tablet devices of the same platforms.

5 Conclusion

The checklist developed by the author for conducting a comprehensive internal audit of the PO has been transformed into the software of the Service Inspector platform on a cloud web platform in the form of an automated checklist.

The internal audit automation module, through the use of the ready-made "Service Inspector" platform (cloud service of electronic checklists), will improve the efficiency of internal audits in the quality system of the PO. This solution does not require specialized personnel capable of operating the software product, does not require specialized work methods, and is not expensive.

Thus, the internal audit automation module proposed by the author, through the use of the ready-made "Service Inspector" platform (cloud service of electronic checklists), will improve the efficiency and quality of the internal audit of the PO, significantly saving time on its implementation, instantly generate reports on the results of the audit (self-control), with the possibility of their prompt distribution to interested parties. This option of automating the internal audit process will also help automate risk management processes. The "Service Inspector" platform used by us (cloud service of electronic checklists) can be configured and detailed for specific tasks of the organization in order to obtain a complete and high-quality result of self-control and allows to reduce the human factor, labor costs during the audit procedures of the PO.

6 Availability of Data And Material

Data can be made available by contacting the corresponding author.

7 Acknowledgement

The work was carried out with the help of the Center for Collective Use of the North Caucasus Federal University.

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