

R&D 프로젝트 품질 관리를 위한 전자연구노트 모델 개발

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ELN Model Development for R&D Project Quality Management

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요 약 연구개발정보를 체계적으로 기록하고 관리하는 것이 연구개발 품질을 확보하기 위한 기본적인 방법이며 더 나아가 프로젝트를 성공적으로 수행하기 위한 밑거름이 된다. 특히, IT 기술의 발달로 인해 연구실 환경이 디지털화 됨에 따라 대부분의 연구개발정보가 전자문서로 기록되고 있다. 본 연구에서는 연구개발정보를 체계적으로 기록하고 관리하기 위해 도구로 사용되는 전자연구노트에 대해 살펴보고 연구환경에 맞는 모델을 제시하고자 한다.

주제어 : 연구 기록, 연구노트, 전자연구노트, 연구개발 품질, 시점인증

Abstract Laboratory Research Notebook is the recorded data of the process and the result of research and also the most basic data. To record and manage R&D information systematically is a very basic method to secure R&D quality and becomes a foundation of performing a project successfully. Especially, as the laboratory environment is getting digitalized due to development of IT technology, most R&D information is recorded as electronic documents. Therefore, Laboratory Research Notebook is used to effectively manage R&D information recorded as electronic documents. This study would like to look at Laboratory Research Notebook which is used to manage R&D information systematically and then present a model which suits research environment.

Key Words : Research Recording, Laboratory Research Notebook, Electronic Laboratory Notebook, R&D Quality, Time-stamp

1. Introduction

“Laboratory Research Notebook” is the recorded data of the result and the process of research from the beginning of the research till report/announcement of

the output of the research or the securement of intellectual property rights[1]. Korea test-operated the Laboratory Research Notebook policy referring to foreign cases since the manipulating paper related to stem cell in 2005, since then it was institutionalized an

Received 28 November 2014, Revised 31 December 2014
Accepted 20 January 2015
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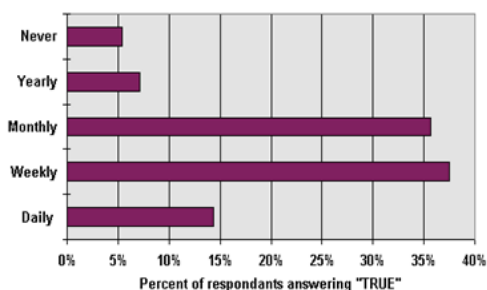
ISSN: 1738-1916

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‘instruction’ not a ‘regulation’ in 2007[2]. In 2010, 「Regulation on national R&C project management, etc. (executive order)」 made Laboratory Research Notebook become compulsory for research institutes which take part in national R&D projects[3].

Laboratory Research Notebook is not only a simple report of gained information from the research process, but also an important record which can be used as the result of research, technology protection, an ownership decision on invention, and a proof for the time of technology transfer or business. Most researchers recognize the importance of research recording like these and record Laboratory Research Notebook[4,5].

Recently the research environment has been computerized due to development of IT technology and most laboratories experiment using electronic equipment such as computers. However, it is not possible to write experimental result or data gained from the electronic equipment down fully onto Laboratory Research notebook in paper. According to Collaborative Electronic Notebook Systems Association(CENSA), more than 35% of researchers look for previous research recordings every week and almost 15% of researchers look for previous research recordings everyday[6].



[Fig. 1] Ratio to look up the record of a previous study

Like this, researchers consider R&D information important and look for methods to record, manage, and use more systematically. As a solution for this, Electronic Laboratory Notebook was about to be

developed[7]. In 1990's, the research on Electronic Laboratory Notebook was already started and the commercial softwares were developed in abroad[7]. However, a lot of researchers raise concerns over objectivity and security of Electronic Laboratory Notebook.

Therefore, this study would like to propose a Electronic Laboratory Notebook model suitable for Korean research environment. It helps record and manage R&D information effectively and systematically and secure the quality of the record and furthermore enhance the quality of the research result.

2. Advanced Research

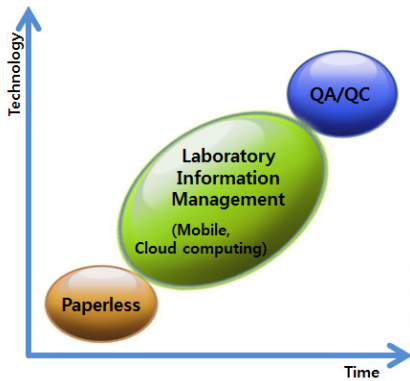
2.1 Research Quality Management

If looking at the meaning of the R&D quality, Hooker in AT&T Bell Lab. defined "R&D quality is the degree of satisfying customer's deploying expectation through products or services." The core of quality management in R&D is to manage whether the process till the result or output comes out is appropriate rather than satisfaction of the result or output of the research phase. That is, it is important for one to have researched with the exact data through the suitable methodology(procedure). There are various elements to decide R&D quality though, one of the typical elements is research recoding. Specially, the core recording is Laboratory Research Notebook among research recordings. So, to secure quality of research recording is an essential prerequisite for securement of research quality and the quality of Laboratory Research Notebook plays an important role for total research quality. Recent trend is to use Electronic Laboratory Notebook to improve research quality.

2.2 Outline of Electronic Laboratory Notebook

According to internal regulations, Electronic Laboratory Notebook is defined as "Laboratory

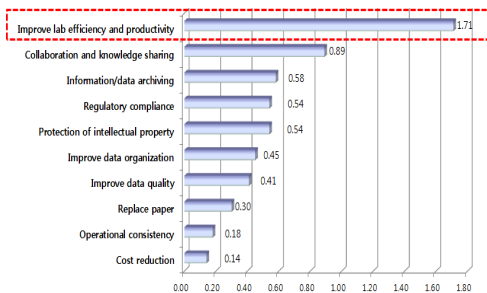
Research Notebook that records and stores contents in a form of electronic document or electronization subject document[1].” Electronic Laboratory Notebook was to be started in order to reduce the use of paper in laboratories in 1990’s. Since 2000’s it started to use IT technology to record and manage lab’s data systematically. And laboratory information management system that collects stored data in various kinds of experimental equipments and makes every researcher taking part in the project shares information was developed.



[Fig. 2] ELN Technology Trend

Source: Taewon Kyung, 2012 Research Lab. Notebook Promotion Seminar, June, 2012.

Since 2010, there are tries to use Electronic Laboratory Notebook system in order to manage quality and objectivity of laboratory data.



[Fig. 3] Why prefer ELN

Resource: Atrium Research Survey 2010

The biggest reason for researchers to prefer Electronic Laboratory Notebook is research effectiveness and productivity improvement according to ‘Atrium Research Survey 2010’[9]. Like this Electronic Laboratory Notebook is not only a simple electronization of research recording, but a tool for improving performance by QA(Quality Assurance)/QC(Quality Control) of research result[8].

2.3 Probative Requirements of Electronic Laboratory Notebook

what many researchers are worried about Electronic Laboratory Notebook is if the recording has objectivity or probative force. If Electronic Laboratory Notebook secures probative force in our country, it needs to get a inventor’s and a witness’ signature function(or electronic signature function) on electronic document and time-stamp from an authorized agency[1].

Electronic signature is digital information in a special form attached to electronic documents that tells who signed the document like signature or seal that we do on the paper documents and if the electronic document is falsified[10].

Ministry of Security and Public Administration(MOSPA) defines two kinds of electronic signature in “Article 3 (Definitions) regulations regarding the efficient operation of the administrative work” as follows.

- ① Electronic Document Signature: means drafter·reviewer·supporter·deciding officer or addresser indicates own name generated automatically in the form of electronic character on the electronic document.
- ② Electronic Image Signature: means drafter·reviewer·supporter·deciding officer or addresser indicates own name in the form of electronic image on the electronic document.

Digital Signature Act Article 2 (Definitions) of Ministry of Science, ICT and Future Planning defines

official electronic signature[10]. Official electronic signature means it has followed requisites and is based on accredited certificate.

- ① electronic signature generation information must be belong to the only member.
- ② the member must control and manage the electronic signature generation information when signing.
- ③ after electronic signature, it must be able to be verified if there is any change in the electronic signature.
- ④ after electronic signature, it must be able to be verified if there is any change in the electronic document.

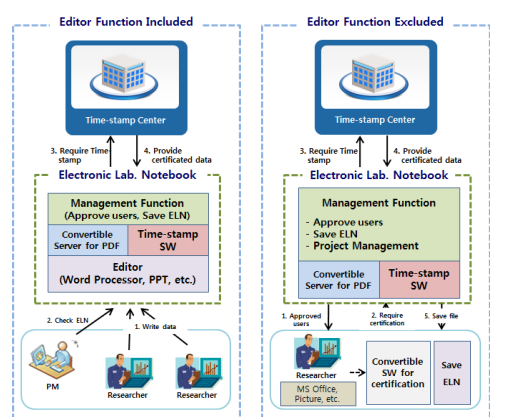
For Electronic Laboratory Notebook, recording on the time recorded is important as well as electronic signature of inventor and witness. it is because to prove the document that was recorded by the inventor at the time is mandatory requisition[1]. If one need to get reliable time-stamp, there is a way that one gets time-stamp from an authorized agency and records it on an electronic document[11,12,13].

3. ELN Model Design

3.1 ELN System

Electronic Laboratory Notebook system is composed of mainly document edition function, management function, time-stamp function, and a variety of added functions. However, the system may not include document input function according to the character of research institute.

[Fig. 4] above shows the concept drawing of Electronic Laboratory Notebook system; editor function included(4-a) and editor function excluded(4-b).



(a) Editor Function Included (b) Editor Function Excluded
[Fig. 4] ELN System Concept

3.2 Time-stamp Function

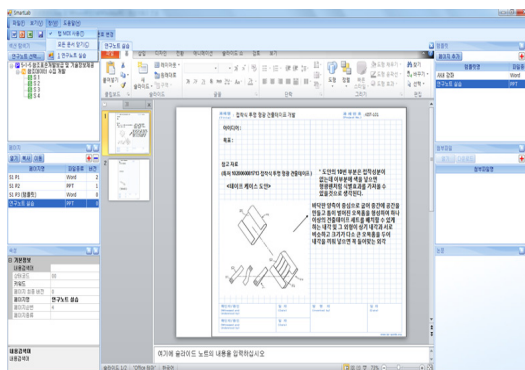
Time-stamp is the time displayed on a location to prove that data existed at the time and it has not been changed since then. it is a time displacement parameter that displays the time epoch referred commonly[14].

When a researcher generates electronic document that R&D information was recorded, he/she extracts its own hash-value from the electronic document, combines it with time-stamp from certificate authority, and inserts it back into the electronic document. The document that time-stamp is inserted into gets the mark of “The Original.” If the content of document has been changed, it gets “Falsification.” That is how one can check whether it is original or falsified.

4. Introduction Cases of Electronic Laboratory Notebook

By the end of 2012, there are 9 establishments that built Electronic Laboratory Notebook system in accordance with Electronic Laboratory Notebook requisition of ‘Laboratory Research Notebook Guide’. Five of 9 establishments included editor function, but 4 of them did not include editor function.

4.1 Editor Function Included



(a)

4.2 Editor Function Excluded



(a)



(b)

[Fig. 5] K University's ELN



(b)

[Fig. 6] P Institute's ELN

In the case of K University, there are researchers working in a various fields because it is a school. Hence most researchers use MS-office which they are used to as editor function. Researchers record R&D information with MS-Word, PowerPoint, Excel, etc. that they prefer. After an witness confirms it, they get time-stamp on electronic document and store it in the Electronic Laboratory Notebook system. Even though it has a limitation to express chemical constitutions or mathematics mainly used in the field of chemistry or bio, it has secured versatility because a lot of researchers got used to those editor functions.

P institute does not have Electronic Laboratory Notebook system include separate editor function. Researchers record R&D information by using preferable SW and upload it to Electronic Laboratory Notebook system. If there is a witness, they get confirmation from him/her and store it into Electronic Laboratory Notebook database. This system help researches record R&D information in various forms of special SW, Word processor, image files, and so on.

5. Conclusion

The size of R&D projects is getting bigger and more complex and the importance of gained information from the process is high as well as the importance of R&D result. Like this, the degree of R&D should be

systematically recorded, managed, and used in terms of intellectual property. However, most institutes and researchers simply use paper Laboratory Research Notebook and it does not show high rates that it is recorded and managed accordance with requisitions.

One of the methods that perform R&D projects successfully is research recording. To record and manage R&D information systematically gained during R&D project process is an essential requisition and quality of Laboratory Research Notebook plays an important role for the quality and success of entire research. Electronic Laboratory Notebook can be used as a useful tool to record and manage R&D information systematically.

This study suggested the reason why R&D information should be recorded and managed systematically in terms of intellectual properties and proposed a Electronic Laboratory Notebook model as a method to improve R&D quality in terms of project management. It described concepts of two models that are applied to according to the environment of research establishments. And it also suggested the necessity of time-stamp and importance to secure objectivity and reliability of R&D information. By this study, one can see how important that R&D information should be recorded, managed, and used systematically and I expect that it will be a chance to heighten the value of R&D result.

Further, there should be a study on systems that Electronic Laboratory Notebook spreads not only universities and public research institutes but private enterprises and how to support the systems.

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