

CUSTOMER STORY**Medical industry**

How does Sleepinnov Technology ensure its compliance to ISO 13485 and IEC 62304 standards for medical device software with Tuleap?

**2x****BETTER QUALITY OF DELIVERABLES**

Thanks to the standardization of continuous integration processes and a Quality Management System

100%**TRACEABILITY AND STANDARDS COMPLIANCE**

Traceability at all stages of development, with a cross-reference system

4x**MORE EFFICIENCY IN PROJECT MANAGEMENT**

Flexibility and improvement of daily development practices thanks to Tuleap Agile tools

Summary

ORGANIZATION

SleepInnov Technology is a high-tech company that develops medical devices for the diagnosis and monitoring of patients with respiratory complications (sleep apnea, obstructive pulmonary disease, etc.). Their products are intended for healthcare professionals, commercialized in France and internationally.

NICOLAS GAIFFE



Nicolas GAIFFE, Software Development Manager, is responsible for Sleepinnov Technology's software development. In this testimony, he explains why and how Sleepinnov uses Tuleap.

INDUSTRY CHALLENGE

Medical devices design, construction, sales and maintenance, are highly regulated which implies to respect and implement numerous standards. Amongst them, these two down below drive the daily work of developers:

- The **ISO 13485** standard which specifies the requirements for the establishment of Quality Management Systems (QMS) in the medical device industry.
- The **IEC 62304** standard which defines the requirements for the medical device software development cycle.

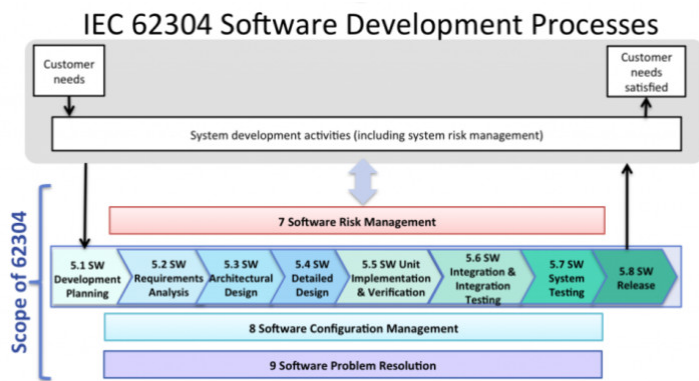
FIRST MEETING BETWEEN SLEEPINNOV AND TULEAP

It was during a demonstration at an Agile conference that SleepInnov discovered Tuleap and wanted to test it. Nicolas Gaiffe started by installing it on a virtual machine and, after a few configurations, he saw that it perfectly matched the needs of SleepInnov Technology.

According to him, the first introduction to the team generated an **encouraging enthusiasm that has not faded since then.**

“ Since using Tuleap, all our teams gained efficiency, security and improved confidence. We regularly get very positive feedback from external auditors! It is an excellent, valuable tool, all the more within such a standardized industry. ”

MEETING MEDICAL DEVICES STANDARDS



In order to meet these demanding international standards, SleepInnov Technology has set up specific processes, which are, as required by the regulations, audited once a year by independent notified instances. The IEC 62304 standard essentially defines the applicable requirements for each step of the medical software development cycle. The standard recommends in particular the use of a V-model development process. V-model various phases can be

represented by the figure above.

In addition to the sequence of steps (from left to right, following the «V»), essential links exist between steps at the same horizontal level from a normative point of view, this development cycle implies 2 essential criterias:

- Complete recording of the each step of the work in documents (or any other tools),
- Full traceability of these elements of proof and their interdependences, for each products and their own releases.

THE GROWING NEED FOR AN ADAPTED TOOL

At SleepInnov Technology, finding the right tool was quite a long journey: they got to test many tools and methods, went through deep retrospectives, frustrations and sometimes even had to backtrack. At first, it all started with onyl one source code manager, and soon a wiki was added. All project information were stored in Words and/or Excel files. This quickly represented a large number of files, tedious to maintain. Traceability was guaranteed but at the price of many clicks and documents. Because of this complexity, the system wasn't used to its full extent. Another downside of this system was security. The accidental modification or deletion of a Word document can happen to anyone and is not always detectable. In addition, only the most recent version of the file is accessible.

On the other hand, Tuleap gathers all information but allows **to trace file accesses, to keep a history of all its transient states** as changes occur, and **to define different access rights for each user**.

All employees can have access to general information, still, certain information can remain accessible only to some users, depending on their project and profile. It guarantees confidentiality and considerably limits manipulation errors, which is vital in a regulated environment: traceability must not only be ensured for on-going projects but also preserved intact over time.

How Tuleap helped SleepInnov achieve ISO 13485 and IEC 62304 compliance?

COLLABORATIVE WORK ENVIRONMENTS

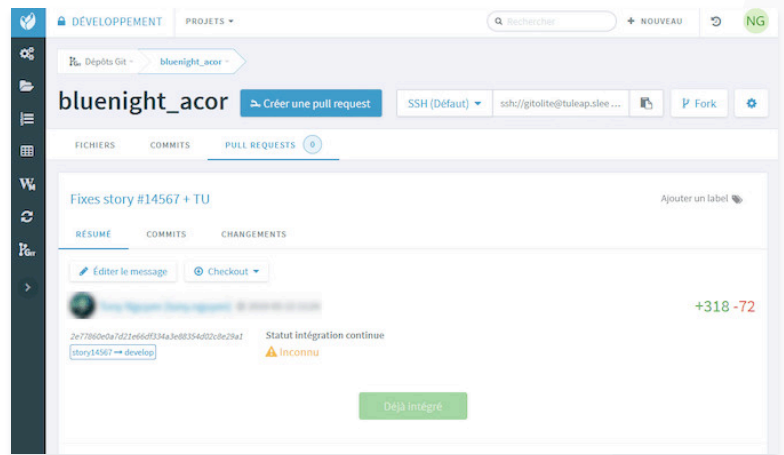
« Tuleap has a large pannel of tools covering the whole software development lifecycle. There is no need to buy any other softwares, sometimes expensive. »

« The tools are entirely configurable: we were able to adapt them very quickly to meet the needs of each team. »

After tested out many tools, SleepInnov finally settled for the best they could find and chose **to rely on Tuleap to manage these projects management processes and ensure optimal follow-up of all phases of their developments**. Once installed, this is how their Tuleap platform was configured:

The screenshot displays the Tuleap platform configuration interface. It features two main sections: 'Analyse' and 'Action corrective'. The 'Analyse' section includes two text input fields, 'Impact' and 'Cause', each with a 'Format' dropdown menu set to 'Text'. The 'Action corrective' section includes a radio button group for 'Une action corrective a-t-elle été ouverte ?' with options 'A définir' (selected), 'Oui (référence requise)', and 'Non (justifiez)'. It also includes a 'Référence de l'action ou justification' text input field with a 'Format' dropdown menu set to 'Text'.

- Each product has its own dedicated project (BlueNight Screener, BlueNight Trainer, Agil-IT, Spiri...). Regarding the development of the activity, one project by software thematic with several Git repositories.



Tuleap Git interface: definition of Pull Request for the associated User Story

- Several trackers per project.** Some are identical, while others are specific to each project, with different fields depending on the field of application.
- Customized search forms and dedicated fields** have also been added and sorted in order to fit with the terminology of their **Quality Management System** (QMS) and to reinforce the traceability of every activity.
- Their source code is hosted and accessible directly on Tuleap, initially via Subversion, and more recently with Tuleap Git Enterprise™.
- Each project also contains a **wiki** (Mediawiki), a **document manager**, and a deliverable manager for commercial versions.
- Code review** via Tuleap Pull Request and Git as well as the **continuous integration** with the Tuleap Jenkins connector™ are systematically applied to any type of projects (even including internal POC or small R&D projects).

GOING AGILE FOR MEDICAL PROJECTS MANAGEMENT

Tuleap has definitely improved SleepInnov Technology's daily routines of development and quality, allowing them to increase the number of software engineering tools, step by step.

The latest additions to SleepInnov have been the implementation of the Tuleap Agile Dashboard, particularly the Scrum Workspace.

« This is an another interesting aspect with this platform. Tuleap enables to advance at your own particular speed. For example, you can start with a simple code version manager and a tracker, and then later adding document management tools, planning tools, etc... »

« This allowed us to have a more structured work planning while guaranteeing a better fit with a small business environment. We are starting being agile while still being compliant. »

This guarantees confidentiality and considerably limits big manipulation errors. This is vital in a regulated environment: traceability must not only be ensured for on-going projects but also preserved intact over time.

Description

Objectifs

Suite à la suggestion #14566 :
Implémenter ce nouveau champ dans la configuration.

Notes d'implémentation :

- L'interface `UserSettings` dispose désormais d'une propriété booléenne nommée : `ShowCommunicationLoss` (autre formulation possible, à débattre)

Critères d'acceptation *

- La version du fichier de configuration n'évolue pas (reste en version 5)
- Son format est désormais comme suit (ajout de la balise `"show_communication_loss"`, avec valeur `"true"` ou `"false"`) :

```
<?xml version="1.0" encoding="utf-8" ?>
<config version="5">
  <auto_delete_exams>false</auto_delete_exams>
  <auto_database_backup>true</auto_database_backup>
  <date_format>yyyy/MM/dd</date_format>
  <paths>
    <database>C:\ProgramData\SleepInnov Technology\BlueNight Accor+</database>
    <patients>C:\Users\JohnDoe\Documents\Yes_patients</patients>
  </paths>
  <show_communication_loss>true</show_communication_loss>
</config>
```

- L'affichage des interruptions de communication est désactivé par défaut.
- Le paramètre est éditable depuis l'PHM (Pop-in "configuration de l'application")

Précisions

Aucun(e)

Fichier(s) joint(s)

Aucun(e)

Références

Liens

Liens entre artefacts

Aucun(e)

Afficher les artefacts qui référencent cet artefact

Références

Liste des objets référencant cet objet. Voir les objets référencés par cet objet

Commit Git

git #blueight_accor5411bdc31976bdc0295586776750edda21605 j, git #blueight_accor2e77960b0a7d21e66d334a3e88354602db29a1 j

Artifact Tracker v5

release_plan #4046 j

Git Pull Request

pullrequest #299 j

Détails de l'enregistrement

ID	#14567	Rang dans le Dashboard Agile	3815
Créé le	06/05/2019 17:41	Dernière modification le	27/07/2021 16:31
Créé par	Nicolas Gaffie (nicolas.gaffie)	Dernière modification par	Nicolas Gaffie (nicolas.gaffie)

QMS: Details of a User Story resulting from a suggestion

Artefacts associated with the same story

CONTINUOUS INTEGRATION TO AUTOMATE TESTS

A recent progress on the usage of Tuleap at SleepInnov is the implementation of integration with Jenkins.

What's the goal? To set up and automate a continuous integration system.



Tuleap-Jenkins integration: view of an automatic Jenkins job

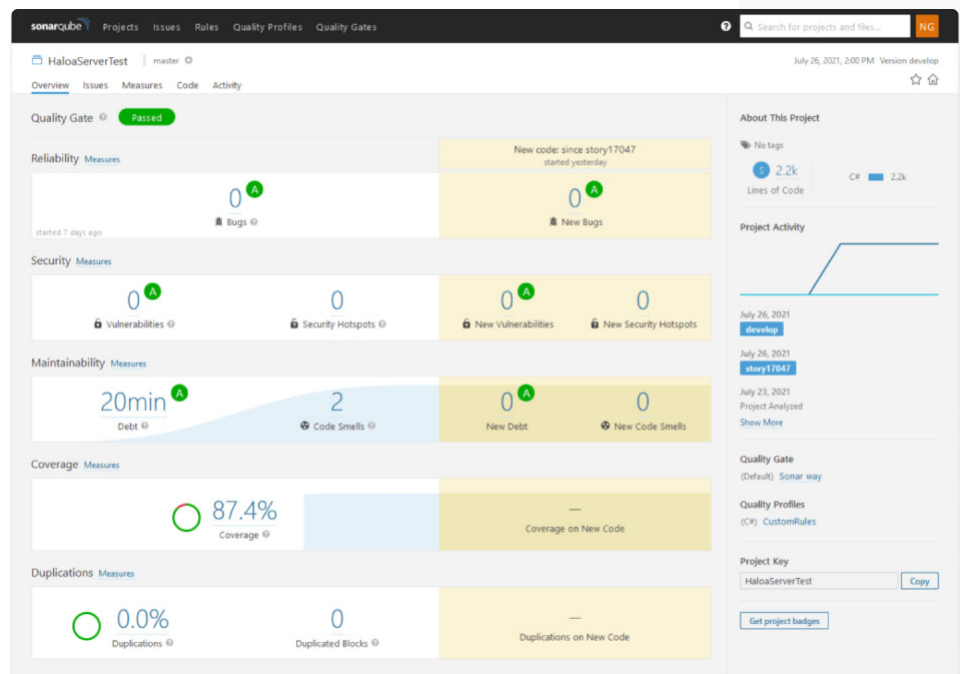
Each time a developer pushes a new change in a project, continuous integration is triggered and the corresponding information is automatically transmitted on the discussion channel used internally (in this case, Slack) so that all team members remain informed of every updates.

“ Continuous integration has become a well established internal process. It is now essential for the efficiency and productivity of the development team. ”

| Nicolas GAIFFE, Software Development Manager, Sleepinnov Technology

INTEGRATION WITH SONARQUBE

At the same time, in addition to Jenkins, SleepInnov Technology has integrated a new tool in its continuous integrated process: Sonarqube, another open source software that measures source code quality.



Sonarqube interface: automatic code analysis tool, updated with each Jenkins Build.

How works the integration between Tuleap and Sonarqube?

When a Git is launched in Tuleap, the continuous integration is automatically triggered in Jenkins. Among the tasks to be completed, a static code analysis is systematically performed: **an important element for the quality assurance of delivered products.**

Finally, this is a further evidence of Tuleap flexibility and adaptability, even to a very specific technical environment. The platform will not fail to help you achieve your goals, especially in terms of performance, software quality assurance and standards compliance.

Results: easier and more efficient compliance audits

“ Since using Tuleap, all our teams gained in efficiency, security and improved confidence. We regularly get very positive feedback from external auditors! It is an excellent, valuable tool, all the more within such a standardized industry. ”

| Nicolas GAIFFE, Software Development Manager, Sleepinnov Technology

For Nicolas, Software Manager, **the cross-reference system that Tuleap offers is likely one of the best examples of what this tool can bring: complete traceability at every development step.** This is an even more important aspect to meet the essential requirements of the European directives to be applied in terms of compliance, security and quality management. According to the current standards framework for both the manufacturers and suppliers of medical devices software, SleepInnov Technology's software quality system must undergo several regular audits including:

- **CE Marking audits:** when launching a new product, the manufacturing company must have a CE mark: it is a necessary condition to sell medical devices within the European Union. In order to obtain this conformity marking, SleepInnov, like other medical companies, has to provide the Notified Body that has been designated to carry out the audit with a comprehensive technical file.

“ As for software development traceability, I believe there is nothing more we could do. With Tuleap, we achieve very detailed levels. ”

| Nicolas GAIFFE, Software Development Manager, Sleepinnov Technology

With Tuleap, SleepInnov Technology **set a unique and secure repository that centralizes all elements related to these software projects.** Teams can now track, store and link under one roof all files and activities that are related to the **development and maintenance of their software devices.** This way, they can easily show the implemented quality system and track all changes.

Next step : code review

SleepInnov is planning the implementation of a dedicated code review tool, Gerrit, which also benefits from an integration in Tuleap. This last step in the structuring of the development cycle is not a priority at the moment, as the code review natively integrated in Tuleap via Git and Pull Request sufficiently meet the needs of the teams. However, this feature will be the subject of a further optimization of process efficiency for the benefit of customers.



www.tuleap.org