



EN - Ellistat Software Compliance with CFR21 Part 11

Functional needs

In order to meet the CFR21 standard, it is necessary to meet the following features:

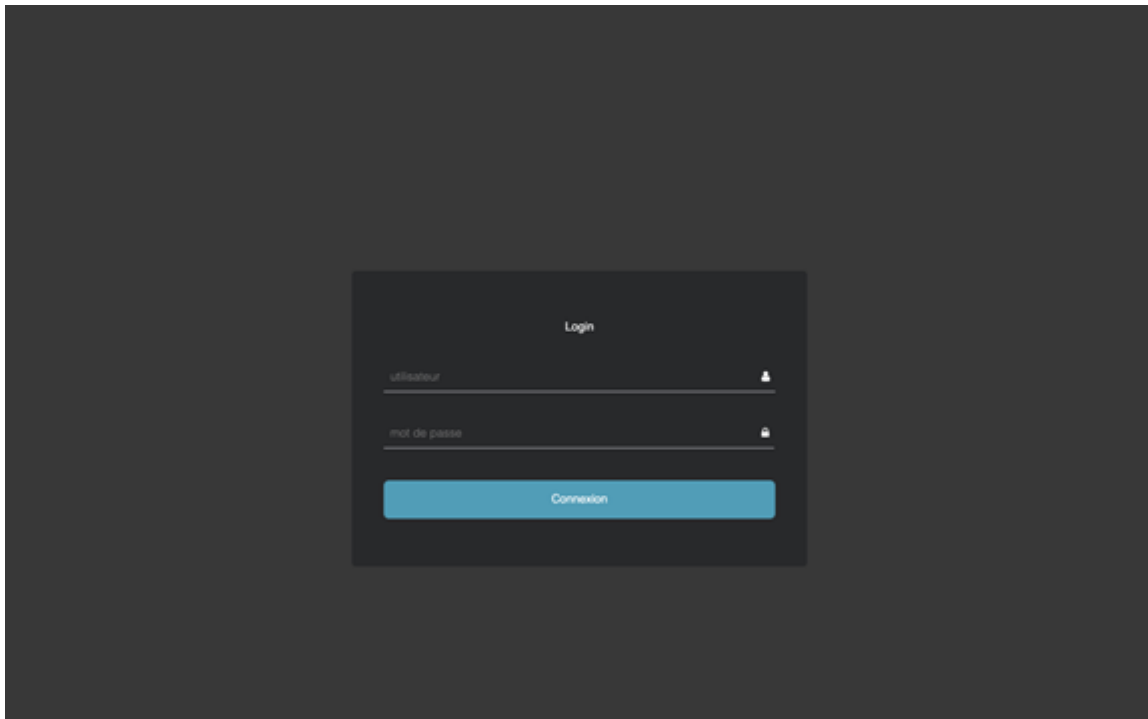
- Authentication and management of the identity of each user of the software in a reliable, secure and unique way (two users must be able to be distinguished at any time during the life cycle of the application).
- The management of the rights of the said users, different rights must be able to be applied according to the level of qualification of the user in the company.
- Management of the lifespan of a user session. It must be allowed to expire after a certain period of inactivity.
- Traceability of important actions carried out via the software by users.
- The follow-up of the measuring instruments used for each measurement
- The storage in a secure place (inaccessible to the users lambda) of the sensitive data allowing the traceability.
- The signature of the documents produced by the application, also in a process of traceability of the documents.

It should be noted that all the functionalities listed above are equally important. Indeed, if one of them were to suffer a defect, this would put the entire validity of the standard in question. For this reason, Ellistat natively supports all of these features and it is not necessary to activate any parameter to meet the requirements of the CFR21 standard.

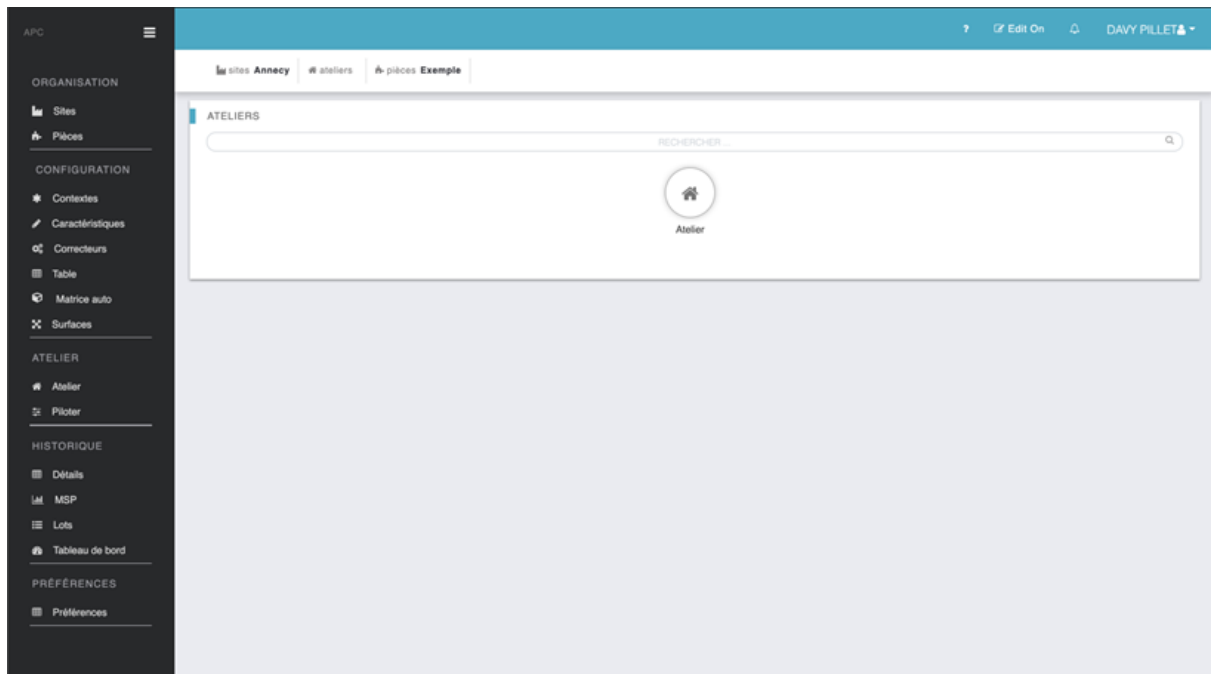
1. Authentication and identity management for each user

Authentication and identity management of each user of the software in a reliable, secure and unique manner (two users must be distinguishable at any time in the application's life cycle).

To ensure that each user is authenticated, Ellistat uses a login system. In order to use Ellistat services, it is necessary to log in to the application via a login page:



Once connected, it is possible to know at any time which user is connected to the system, the name of the connected user being displayed at the top right of the screen. In the following example, the user connected is *Davy Pillet* :



For optimal security, passwords are encrypted in the database so that no one can decipher the users' passwords even if they have access to the database.

2. Lifetime of a user session

The management of the lifetime of a user session. The session must be allowed to expire after a certain period of inactivity.

The user can log out of the application at any time, using the logout button. In any case, if the user does not perform any action during 2 hours (Duration modifiable in the preferences), he is automatically disconnected.



3. Rights management

The management of the rights of these users, different rights must be able to be applied according to the level of qualification of the user in the company.

Each user has a level of rights depending on his profile type.

	NOM	EMAILS	ROLES	GRUPE	
<input checked="" type="checkbox"/>	e		Admin		▼ + 🗑️
<input checked="" type="checkbox"/>	e1		KeyUser	Groupe #1 ×	▼ + 🗑️
<input checked="" type="checkbox"/>	e2		User	Groupe #1 ×	▼ + 🗑️
<input checked="" type="checkbox"/>	Davy Pillet		Admin		▼ + 🗑️

There are 3 levels of rights:

- **Admin**: This level has all the rights (Creation/Modification/Deletion of a user, Modification of preferences, Creation/Modification/Deletion of a range, Addition of measures)
- **KeyUser** : This level has all the rights to create and modify a range (Create/Modify/Delete a range, Add measures)
- **User** : This level has only the rights to add measures

In addition, each user has a group that allows all the users in this group to have access to

- The sites visible by the users of this group
- The workshops visible to the users of this group
- The tabs available in the main menu of the users of this group

GESTION DES GROUPES		
NOM	SITES	ATELIER
Workers	Annecy	a
Groupe #149	Annecy Bologna New site Grenoble	a b Plant 1 Workshop Atelier 1

4. Traceability

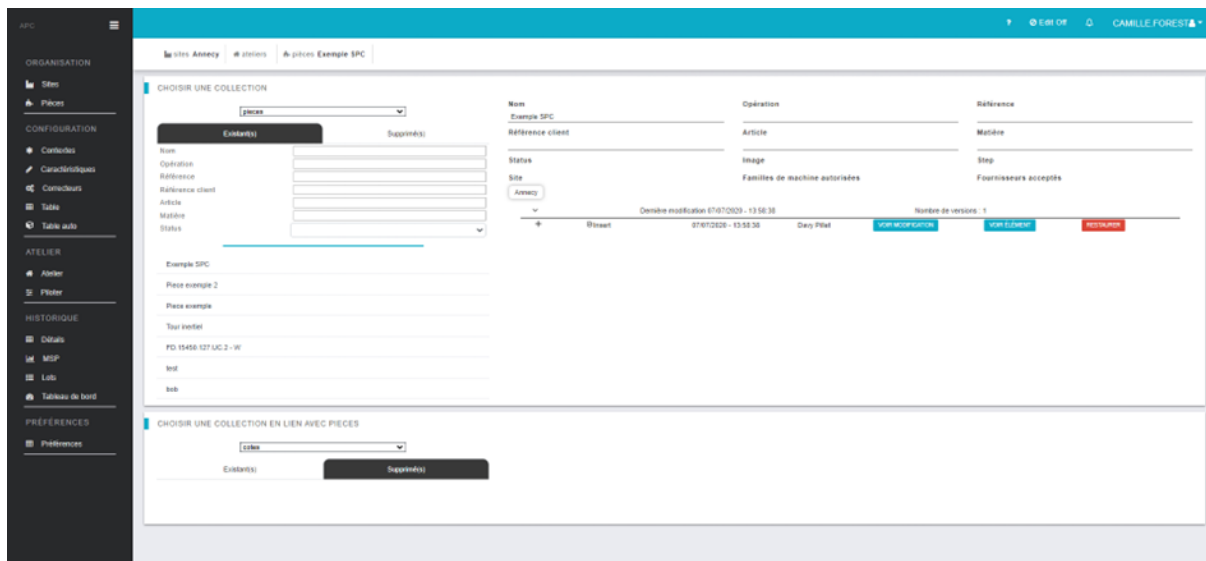
The traceability of important actions carried out via the software by the users.

To allow a simple archiving of data, it is possible to duplicate and archive documents to keep a document in its current state without it being modified by other users. To do this, simply change the status of the document to "archived".

PIÈCE		
Nom	Opération	Référence
Piece Exemple		
Référence client	Article	Matière
Status	Image	Step
archive	<input type="button" value="Choisir un fichier"/>	<input type="button" value="Choisir un fichier"/>

Because this type of archiving is manual, it does not necessarily ensure that no major changes have been made by a user inadvertently. For this reason, Ellistat automatically records all changes made to the database.

To allow complete traceability of important actions performed via the software by users, it is possible to display the history of all actions performed in the software with the user's name, the actions that were performed, the date and time. To do this, simply go to the "preferences" menu and "track changes in data".



This page allows you to follow in an intuitive way the actions and modifications that have been made on the database. To obtain a text version of all the modifications, you just have to export the "DocumentVersion" collection which will provide in JSON format, all the modifications made on the database.

5. Data storage

The storage of sensitive data in a secure location (inaccessible to ordinary users) allowing traceability.

Data storage is done in a replicated MongoDB database to ensure data redundancy.

On each Ellisseting implementation, the database is replicated on 3 different instances. Thus, only the changes made by the application are replicated and saved in the database.

These databases are secured inside a Docker container which prevents any modification by a Lambda user or by a malicious action.

6. Monitoring of measuring instruments

The follow-up of the measuring instruments used for each measurement.

To allow you to track the number of measuring instrument used during your SPC or sample control, you must activate the option "Ask for the name of the measuring instruments used". This option will allow the user to add for each characteristic the measuring instrument used.

CHOISISSEZ LES INSTRUMENTS DE MESURE UTILISÉS

VALIDER					
NOM	NOMINAL	TOLÉRANCE MIN	TOLÉRANCE MAX	INSTRUMENT TYPE	APPAREIL DE MESURE
La	31.5	-0.05	0.05	SteinWald1	▼
Lb	5	-0.05	0.05	SteinWald1	▼
Lc	16	-0.05	0.05	SteinWald1	▼
Ld	8	-0.05	0.05	SteinWald1	▼
Lint	21	-0.05	0.05	SteinWald1	▼
d1	22	-0.05	0.05	SteinWald1	▼
d2	27	-0.05	0.05	SteinWald1	▼
d3	22	-0.05	0.05	SteinWald1	▼
dint	17	-0.05	0.05	SteinWald1	▼

If it turns out that one of the instruments was not compliant, you can then search for all the batches that used this measuring device in your production history.

7. Signature of documents

Signature of documents produced by the application, again with a view to document traceability.

Ellistat can produce two types of documents:

- .pdf files, which cannot be modified by the user and can therefore be used as traceability files
- .xlsx files, which can be modified in Excel and cannot be used directly as traceability files.

8. Validation of calculations

All calculations performed in Ellistat have been validated with a reference document in order to guarantee the accuracy of the values proposed by Ellistat.

The reference documents we use to validate the calculations are :

- Introduction to statistical quality control 6th edition, Douglas C. Montgomery
- Measurement Systems Analysis, MSA 4th edition,
- International standard, ISO 2859-1, Second edition,
- ISO 3951-1:2013



The comparison of the results is available in the Excel document: "Validation of Ellistat results.xlsx"