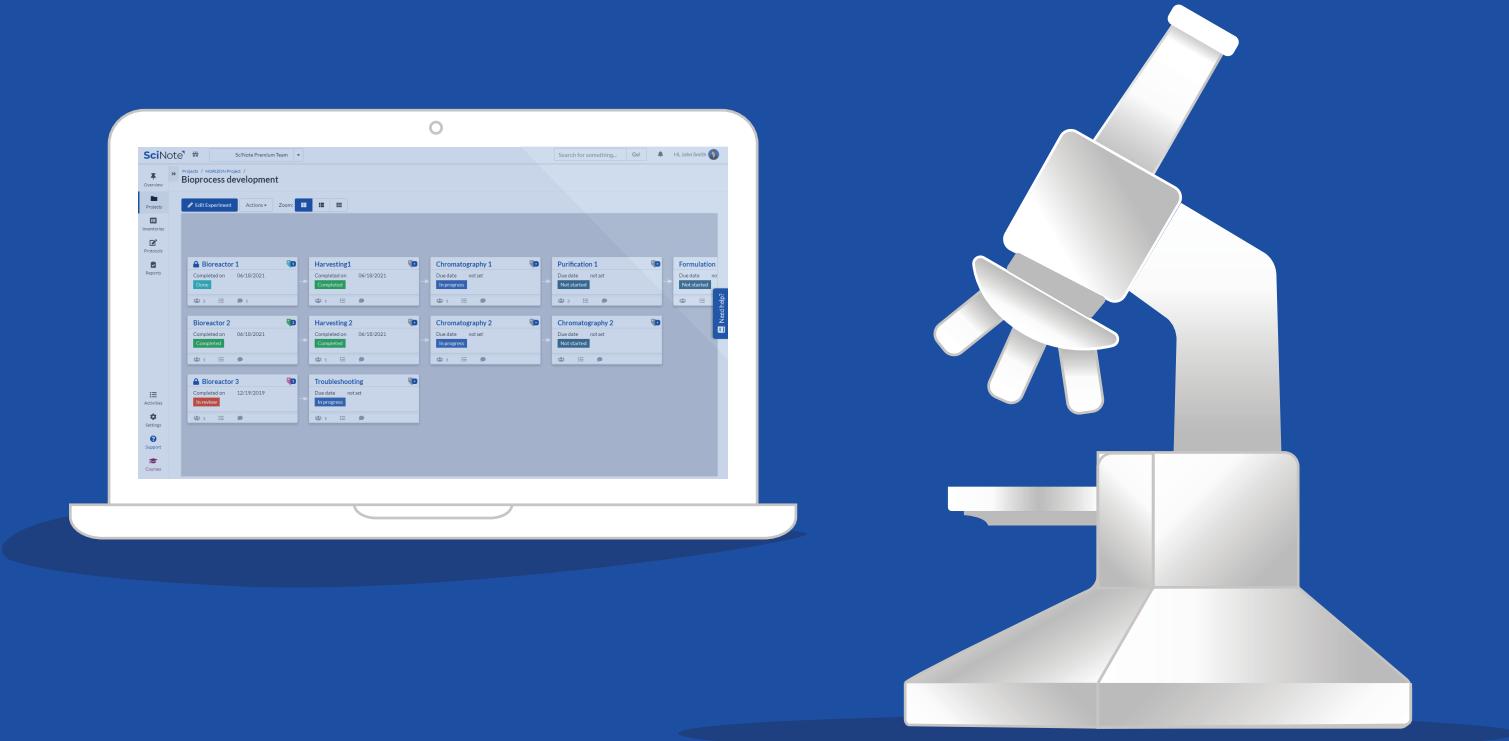


FDA 21 CFR Part 11 Compliance

SciNote is proud to be chosen as the solution used at the FDA, one of the leading United States federal executive departments.

Researchers at the FDA are at the forefront of today's scientific progress, responsible for protecting and promoting public health. We are honored to support their work.



Introduction

SciNote Premium plans include a **21 CFR Part 11 add-on** that provides a toolset for compliance with the 21 CFR Part 11 regulations, while still keeping SciNote flexible and easy to use.

The 21 CFR Part 11 add-on includes the following features: electronic signatures, electronic witnessing, audit trails and system log records. According to the FDA guidelines, electronic signatures are considered to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures.

This document provides a short overview of SciNote's 21 CFR Part 11 add-on features and their use.

21 CFR Part 11 permissions

21 CFR Part 11 permissions are accredited to the users with the following Project roles: Owner, User and Technician. This means they have a full authority of signing specific tasks that were completed within projects.

It is possible to co-sign a task or reject a signature, if there are two levels of supervision within an organization. Once signed, the task cannot be co-signed by the same user. Every signee can also revoke his/her own signature and only the Organization administrator has the permission to revoke other peoples' signatures, if necessary.

Electronic signatures and witnessing

You are able to sign tasks in SciNote. Tasks are parts of the experiments you are working on, and you can change a status of the task according to the progress of your work.

Once you've completed the task you can move it to the *In review* state for review and approval. In the *In review* status the task gets locked for editing and it requires at least one signature, before it can be moved to the final *Done* state. The *Sign task* button appears below the task status and is visible to users with the permission to sign the task.

Details 

Start date: + Add starting date

Due date: Completed on 11/16/2020 07:48

Assigned users: Tags: Wet lab Results for patent Pathogenic virus

Notes

PCR is a method where an enzyme (thermostable DNA polymerase, originally isolated in 1960s from bacterium *Thermus aquaticus*, growing in hot lakes of Yellowstone park, USA) amplifies a short specific part of the template DNA (amplicon) in cycles. In every cycle the number of short specific sections of DNA is doubled, leading to an exponential amplification of targets. More on how conventional PCR works can be found [here](#).

Status  The task is locked

In review

 Sign task

Each electronic signature is unique to one individual person. It is based on a combination of the individual's e-mail and password, and cannot be reused or reassigned to anyone else. Electronic signature record provides the date and time when the signature was executed.

Sign task

To sign the task you need to enter your email and password.

Enter your email

Enter your password

Comment (optional)

Enter your comment

If there are two or more levels of supervision within an organization, additional signature(s) can be requested from specific people or user groups.

Signatures

Sign this task or request other people to sign it.

John Smith  as Project members   Request signature 

Invite people to sign this task

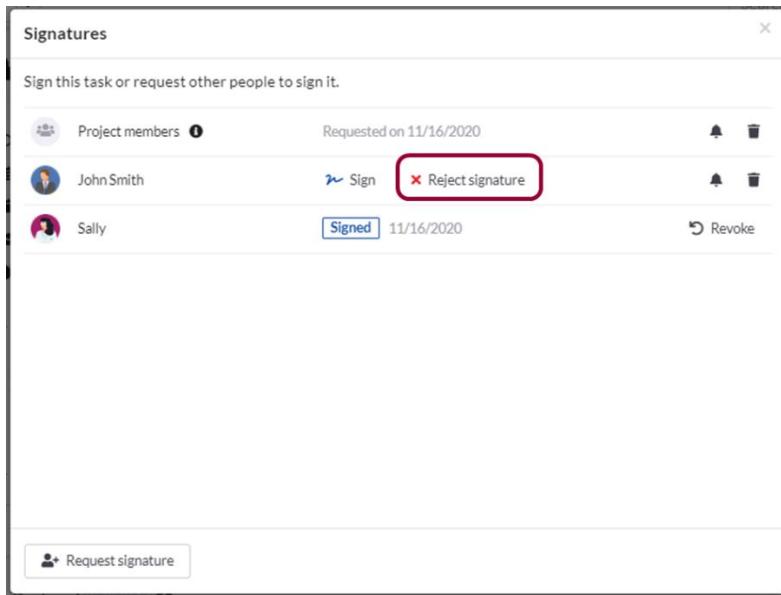
If you want to invite somebody to sign this task, you can request their signature below.



 Request signature 

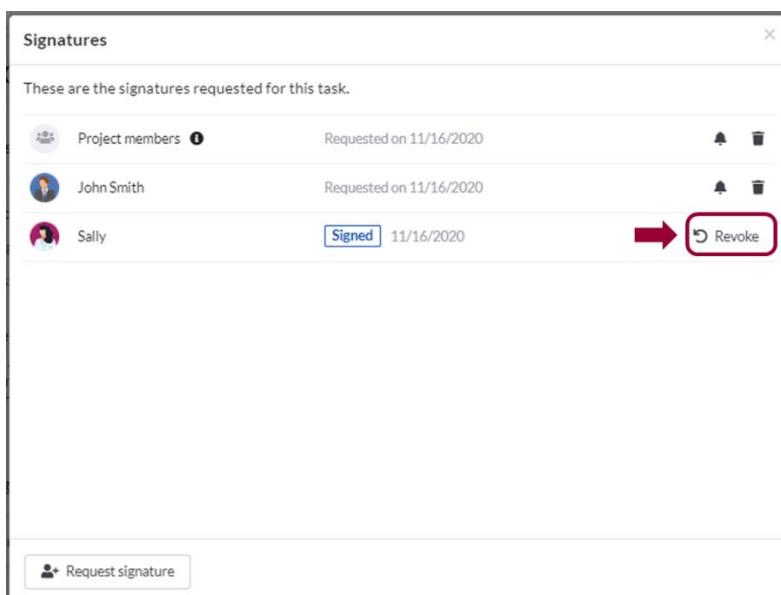
When the signature request is added, the reviewer gets the notification of the request on the dashboard and the option to sign the task.

Everyone who has the permission to sign the task also has an option to reject signing it, if he/she considers that the task needs to be improved.



Rejecting a signature invalidates all the existing signatures on the task. Task should then be moved back to the unlocked state to be edited. When the task is moved back to the *In review* state, the signing and reviewing process restarts from the beginning.

Every signee can also revoke his/her own signature, if he/she would like to withdraw his/her signature from the task.



All electronic signatures are automatically recorded under the *SIGNATURES* tab within a task.

The screenshot shows the SciNote interface with the following details:

- Left sidebar:** Overview, Projects, Inventories, Protocols, Experiment design.
- Top navigation:** Biochemistry Group, Search bar, Hi, John Smith.
- Task view:** [NEW] Demo project by SciNote, Polymerase chain reaction, Data analysis - ddCq, Data quality control (highlighted with a red box), Experiment design.
- Content area:** **Data quality control** (locked). PROTocols, RESULTS, ACTIVITY, SIGNATURES (highlighted with a red box), ARCHIVED RESULTS.
- Table:** Signature, Email, Role, Timestamp, Event, Status, Comment.

Signature	Email	Role	Timestamp	Event	Status	Comment
Billie Rubin	billie@scinote.net	User	09/25/2020 07:23	Co-sign	Valid	I approve.
Polly Ester	polly@scinote.net	Owner	09/25/2020 07:22	Sign	Valid	Reviewed and approved.

Audit trail

SciNote also maintains an audit trail i.e. a recorded history of all changes made in the system.

You can find the Audit trail for each individual team, by selecting *Teams* in the Settings and choosing the team of interest.

The screenshot shows the SciNote interface with the following details:

- Left sidebar:** Overview, Projects, Inventories, Protocols, Reports, Activities, Settings, Support, Academy.
- Top navigation:** Antibody production, Search bar, Hi, Polly Ester.
- Team view:** Account, Teams (highlighted with a red box), Members, Organization.
- Content area:** Antibody production, Created on: 25-Feb-2020, Created by: Polly Ester (polly@scinote.net), Space usage: 76.1 MB.
- Section:** Audit trail (highlighted with a red box).
- Table:** + Add team members, Name, Email, Role, Joined on, Status, Actions.

Name	Email	Role	Joined on	Status	Actions
Al Bumin	al@scinote.net	Normal user	17-Apr-2020	active	
Billie Rubin	billie@scinote.net	Normal user	17-Apr-2020	active	
Petri Dish	petri@scinote.net	Normal user	21-Apr-2020	active	
Polly Ester	polly@scinote.net	Administrator	25-Feb-2020	active	

In the Audit trail records you can select which record type you want to see: projects, experiments, tasks, samples, results, files, signatures, etc. and in which time period.

You will see the detailed overview of all changes made in the system: date and time, user who made a change, what was the change, etc. If you expand individual records you can also see what the values were before and after the change.

Audit trail

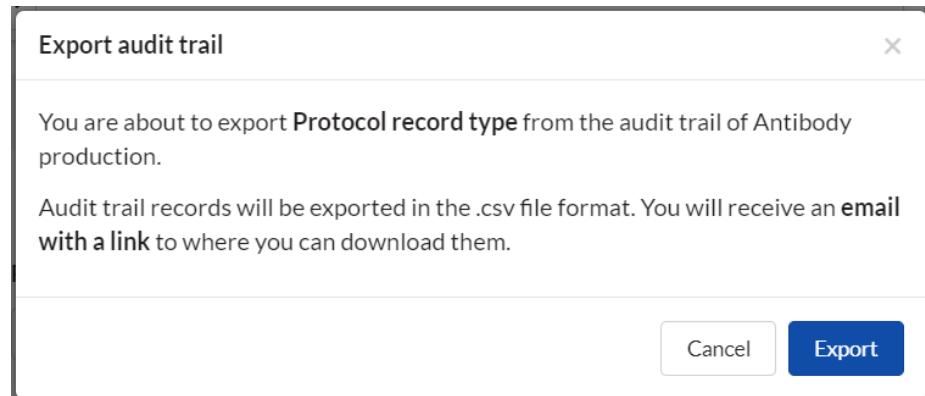
Start date
End date
Record type
 Export

From
To
Protocol
 Filter
 Clear filters

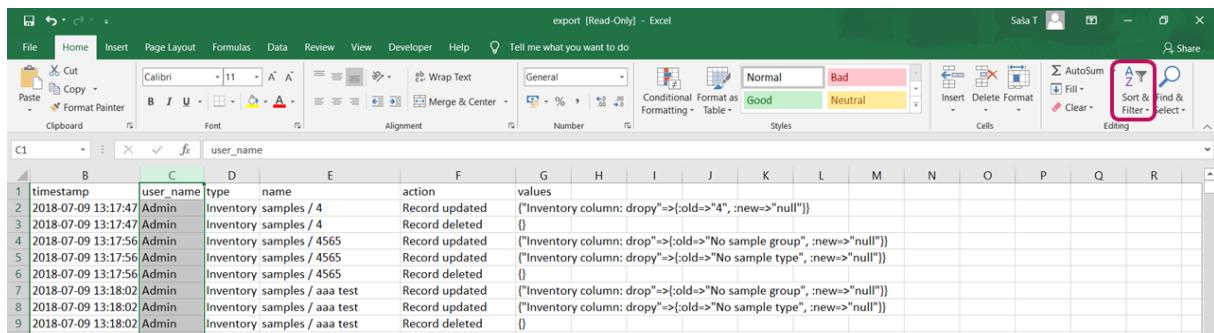
Show 10 entries  

Timestamp	User	Record name	Record id	Record type	Action	Values
11-Jun-2020 21:50 +0000	 Polly Ester	Sampling biological material	1DCC	Protocol	Record updated	
11-Jun-2020 21:23 +0000	 Polly Ester	Sampling biological material	1DA1	Protocol	Record updated	
11-Jun-2020 13:14 +0000	 Polly Ester	[NEW] Demo project by SciNote / Polymerase chain reaction (PCR) / Sampling biological material	1D4B	Protocol	Record updated	
11-Jun-2020 13:13 +0000	 Polly Ester	[NEW] Demo project by SciNote / Polymerase chain reaction (PCR) / Sampling biological material	1D41	Protocol	Record updated	
11-Jun-2020 13:12 +0000	 Polly Ester	[NEW] Demo project by SciNote / Polymerase chain reaction (PCR) / Sampling biological material	1D38	Protocol	Record updated	
11-Jun-2020 10:18 +0000	 Polly Ester	Production of Pr0 Te1_n / 1 Cloning Construct_2 / 2019-Nov / 2019-Nov-12 Sequencing	1D1D	Protocol	Record updated	
Changed field		Old value	New value			
Protocol type		Linked	Unlinked			
Parent updated at		16-Apr-2020 10:38 +0000	null			
Parent		Sequencing prep	null			

You can easily export the audit trail as a comma-separated values (.csv) file.



After you download the .csv file, you can reopen it in Excel as a spreadsheet table and use *Sort & Filter* option to filter the audit trail records, for example, by a user name.



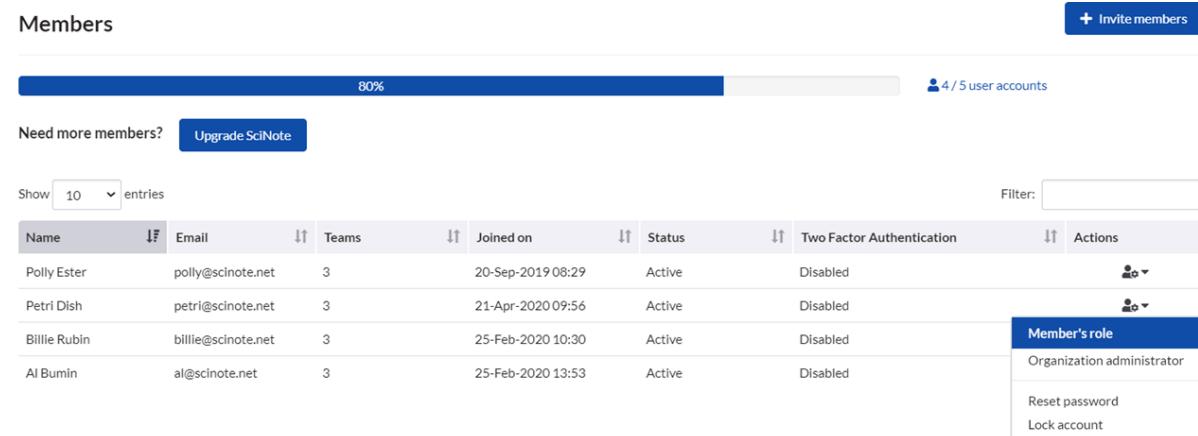
1	timestamp	user_name	type	name	action	values	G	H	I	J	K	L	M	N	O	P	Q	R
2	2018-07-09 13:17:47	Admin	Inventory samples / 4		Record updated	{"Inventory column: dropy"=>{old=>"4", :new=>"null"}}												
3	2018-07-09 13:17:47	Admin	Inventory samples / 4		Record deleted	{}												
4	2018-07-09 13:17:56	Admin	Inventory samples / 4565		Record updated	{"Inventory column: dropy"=>{old=>"No sample group", :new=>"null"}}												
5	2018-07-09 13:17:56	Admin	Inventory samples / 4565		Record updated	{"Inventory column: dropy"=>{old=>"No sample type", :new=>"null"}}												
6	2018-07-09 13:17:56	Admin	Inventory samples / 4565		Record deleted	{}												
7	2018-07-09 13:18:02	Admin	Inventory samples / aaa test		Record updated	{"Inventory column: dropy"=>{old=>"No sample group", :new=>"null"}}												
8	2018-07-09 13:18:02	Admin	Inventory samples / aaa test		Record updated	{"Inventory column: dropy"=>{old=>"No sample type", :new=>"null"}}												
9	2018-07-09 13:18:02	Admin	Inventory samples / aaa test		Record deleted	{}												

Advanced team management - Organization administrator

Organization administrators can see all teams within the organization and have full access to manage individual teams and their members.

All team members are alphabetically organized in a list under the *Members* in the Settings.

New users can be invited only by the Organization administrator, either in *Members* or directly within the individual team in *Teams* in the Settings. Team administrators, on the other hand, can add only existing users to a team.



Name	Email	Teams	Joined on	Status	Two Factor Authentication	Actions
Polly Ester	polly@scinote.net	3	20-Sep-2019 08:29	Active	Disabled	
Petri Dish	petri@scinote.net	3	21-Apr-2020 09:56	Active	Disabled	
Billie Rubin	billie@scinote.net	3	25-Feb-2020 10:30	Active	Disabled	
Al Bumin	al@scinote.net	3	25-Feb-2020 13:53	Active	Disabled	

Member's role
Organization administrator

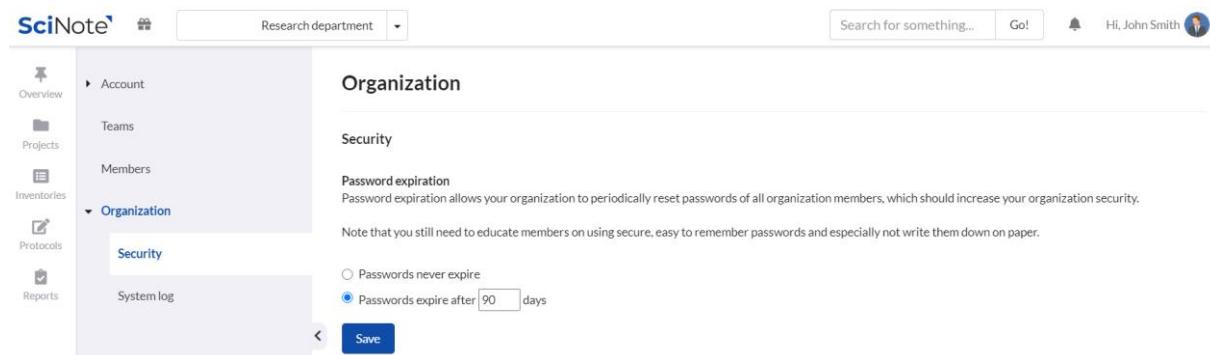
[Reset password](#)
[Lock account](#)

Security

1. Password expiration

Password expiration is also a part of 21 CFR Part 11 requirements. Password expiration allows your organization to periodically reset passwords of all members, which will increase your organization's security if used properly.

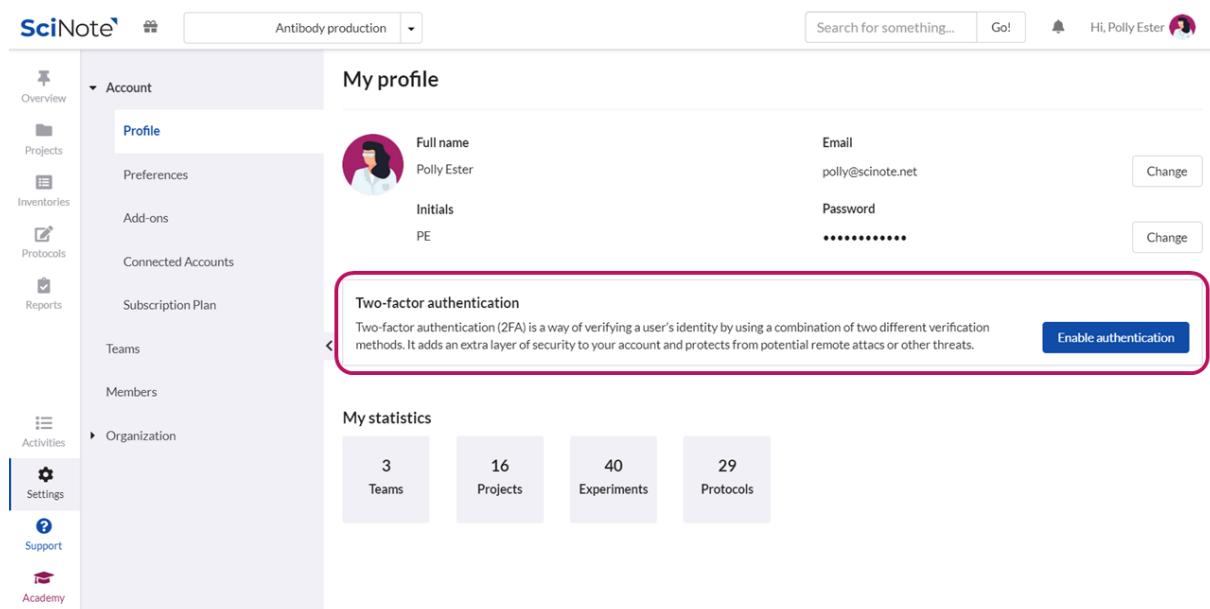
Passwords can be reset on demand for individual users in *Members* (see the image above) or in *Organization* under the *Security* in the *Settings* (see the image below).



The screenshot shows the SciNote interface with the 'Organization' settings. Under the 'Security' section, there is a note: 'Password expiration allows your organization to periodically reset passwords of all organization members, which should increase your organization security.' Below this, it says 'Note that you still need to educate members on using secure, easy to remember passwords and especially not write them down on paper.' There are two radio buttons: 'Passwords never expire' (unchecked) and 'Passwords expire after 90 days' (checked). A 'Save' button is at the bottom.

2. Two-factor authentication

You can enable two-factor authentication (2FA) for your account to have an extra layer of security by using a combination of two different verification methods. By enabling 2FA you will have to install the preferred Authenticator App on your mobile device.



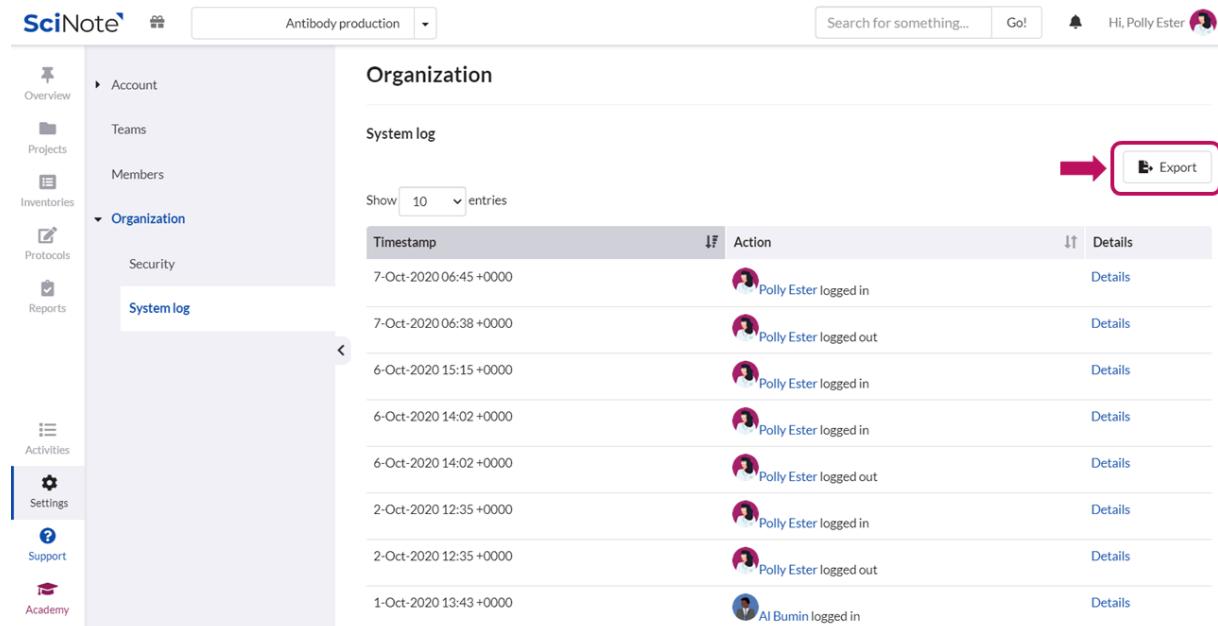
The screenshot shows the SciNote 'My profile' page under the 'Account' tab. In the 'Profile' section, there is a 'Two-factor authentication' section with the following text: 'Two-factor authentication (2FA) is a way of verifying a user's identity by using a combination of two different verification methods. It adds an extra layer of security to your account and protects from potential remote attacks or other threats.' A blue 'Enable authentication' button is located at the bottom right of this section. The sidebar on the left shows various account management options like Overview, Projects, Inventories, etc.

3. System log records

This functionality automatically records system activities and detects potential unauthorized access to SciNote. It gives you a detailed overview over invalid and valid user logins, user logouts and system errors.

System log records can be viewed only by Organization administrators. They can access system logs on a separate page, located under *Settings*, within the *Organization*.

System log records can be exported as a comma-separated values (.csv) file that can be re-opened in Excel as a spreadsheet table.



The screenshot shows the SciNote interface with the 'Organization' tab selected in the sidebar. The 'System log' section is displayed, showing a table of log entries. The table has columns for 'Timestamp', 'Action', and 'Details'. The 'Action' column shows logins and logouts for users 'Polly Ester' and 'Al Bumin'. The 'Details' column for each entry is a link. An 'Export' button is highlighted with a red arrow.

Timestamp	Action	Details
7-Oct-2020 06:45 +0000	Polly Ester logged in	Details
7-Oct-2020 06:38 +0000	Polly Ester logged out	Details
6-Oct-2020 15:15 +0000	Polly Ester logged in	Details
6-Oct-2020 14:02 +0000	Polly Ester logged in	Details
6-Oct-2020 14:02 +0000	Polly Ester logged out	Details
2-Oct-2020 12:35 +0000	Polly Ester logged in	Details
2-Oct-2020 12:35 +0000	Polly Ester logged out	Details
1-Oct-2020 13:43 +0000	Al Bumin logged in	Details

If you need more information about CFR 21 Part 11 in SciNote, schedule a Q&A session below:

[Schedule a demo](#)