FDA
21
CFR
PART 11

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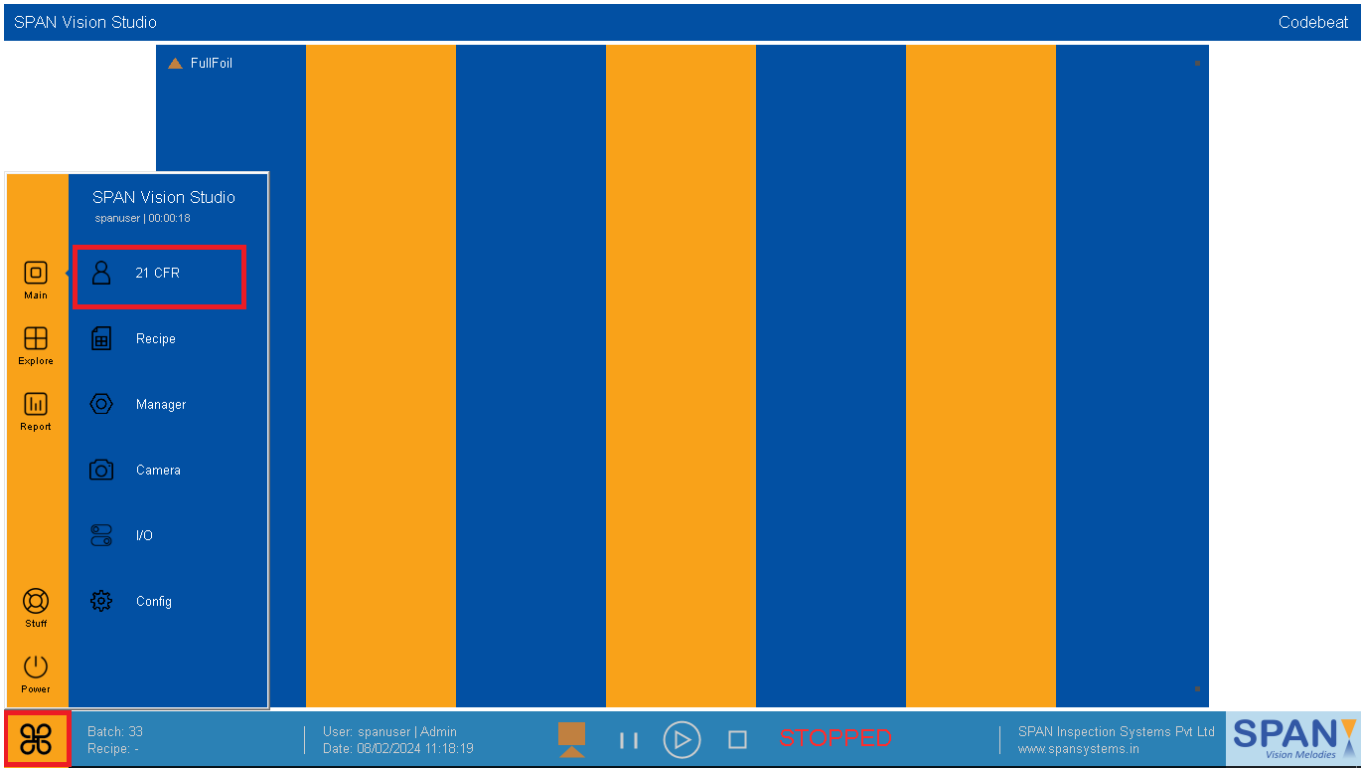
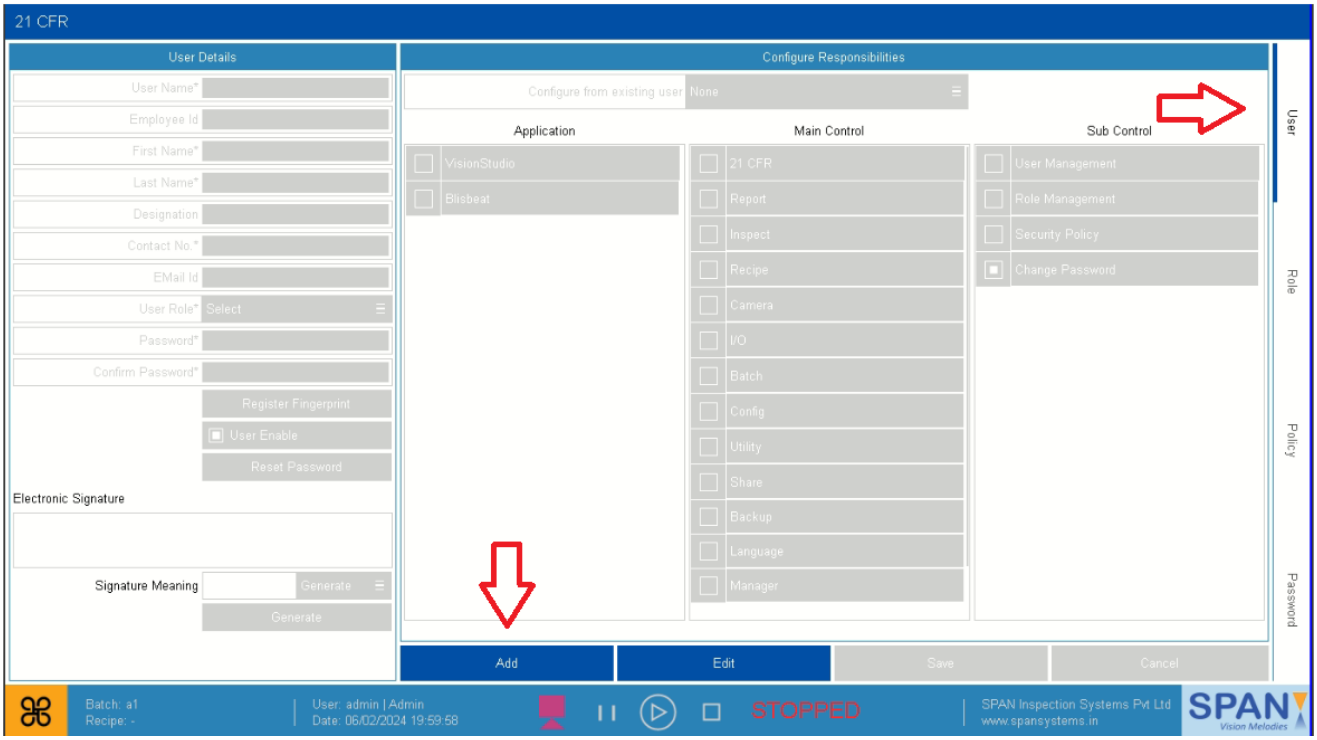
HOW TO ENTER 21CFR MODULE

- Start the SPAN Vision Studio Software. If it is operated for first time, login using
  Username: spanuser
  Password: Take password form the SPAN team
- Once logged in using spanuser - administrator has to create his / her own user to login next time.
- Click 21CFR button as displayed in below image to enter 21CFR.

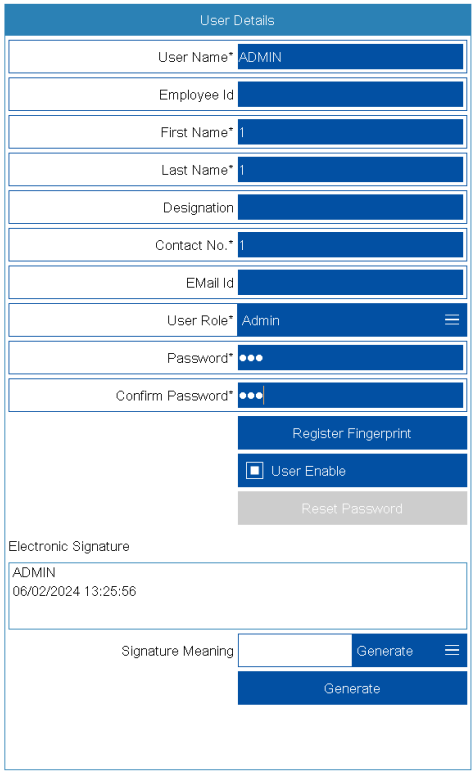


HOW TO ADD USER

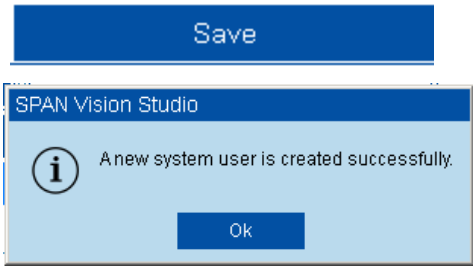
- On entering 21CFR, click on “User” tab on top right side of the screen.



- Click Add button on bottom side of the screen to add user.



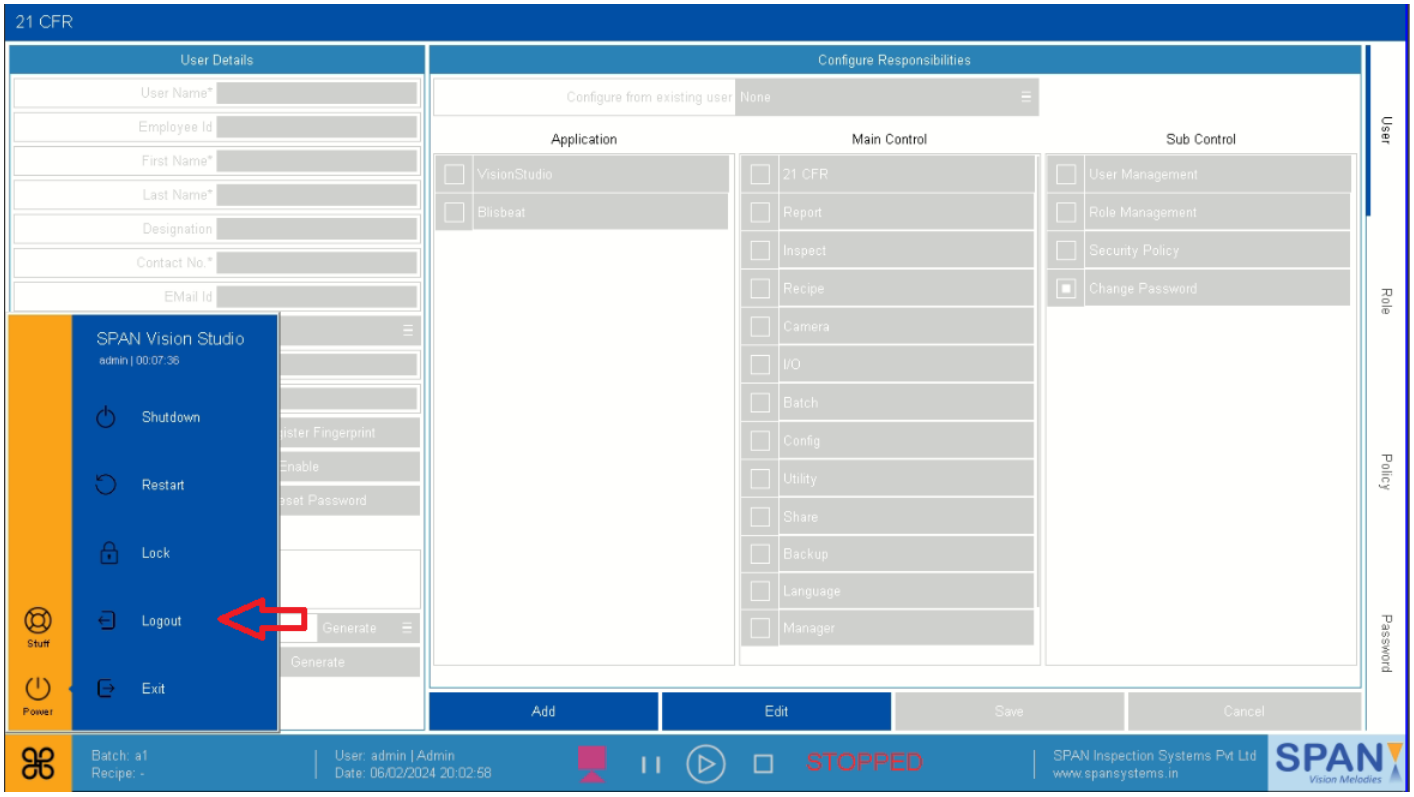
- Enter the required information in “User Details” section.
- All the fields marked with asterisk are compulsory.
- Select User Role as Admin for first user.
- After all the information is entered, click “Generate” button to Generate Electronic Signature.
- Click Save Button to save newly created User.



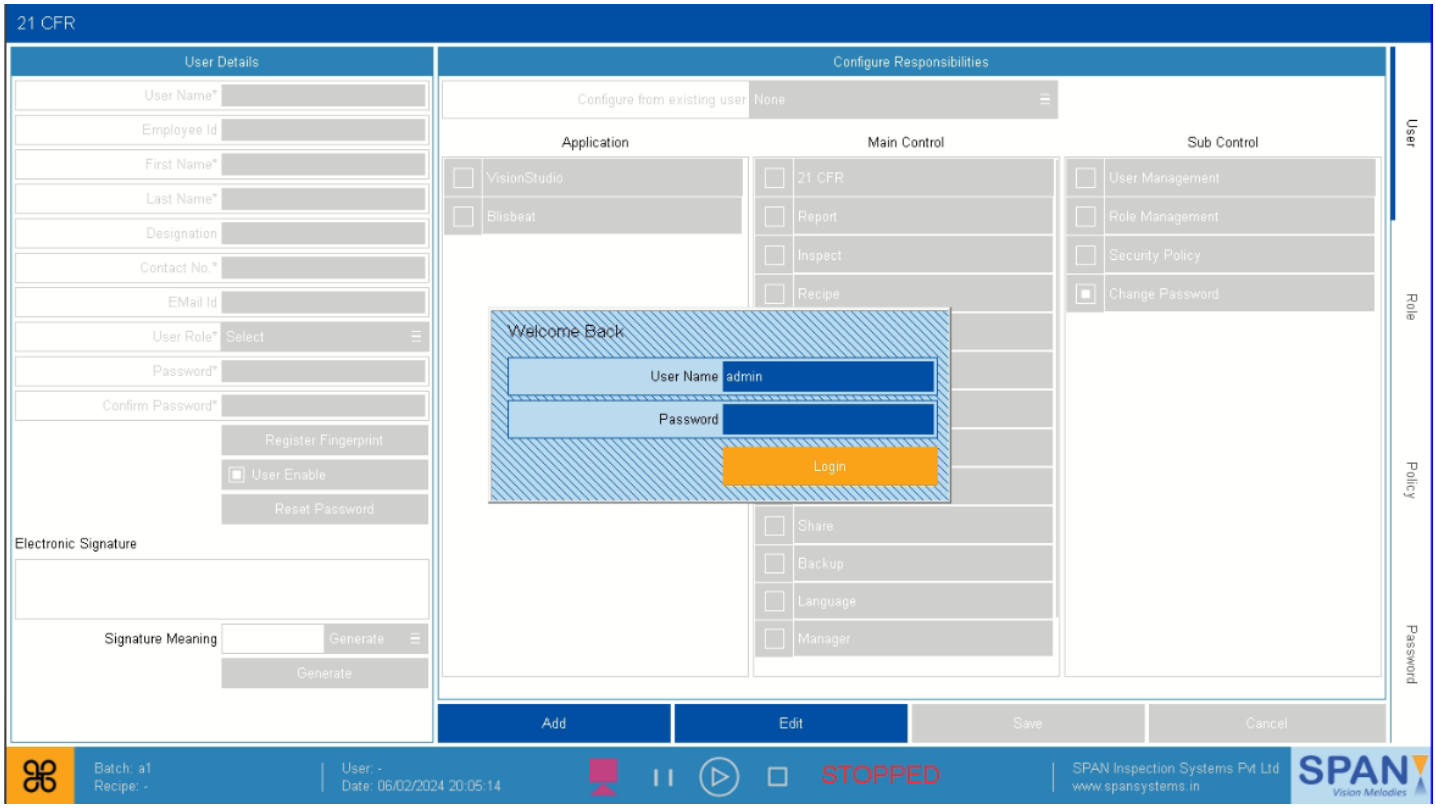
-
- User details and rights can also be edited by click on.
-

RELOGIN USING ADMIN USER

- Logout from current user, by clicking on Logout Button as shown below.

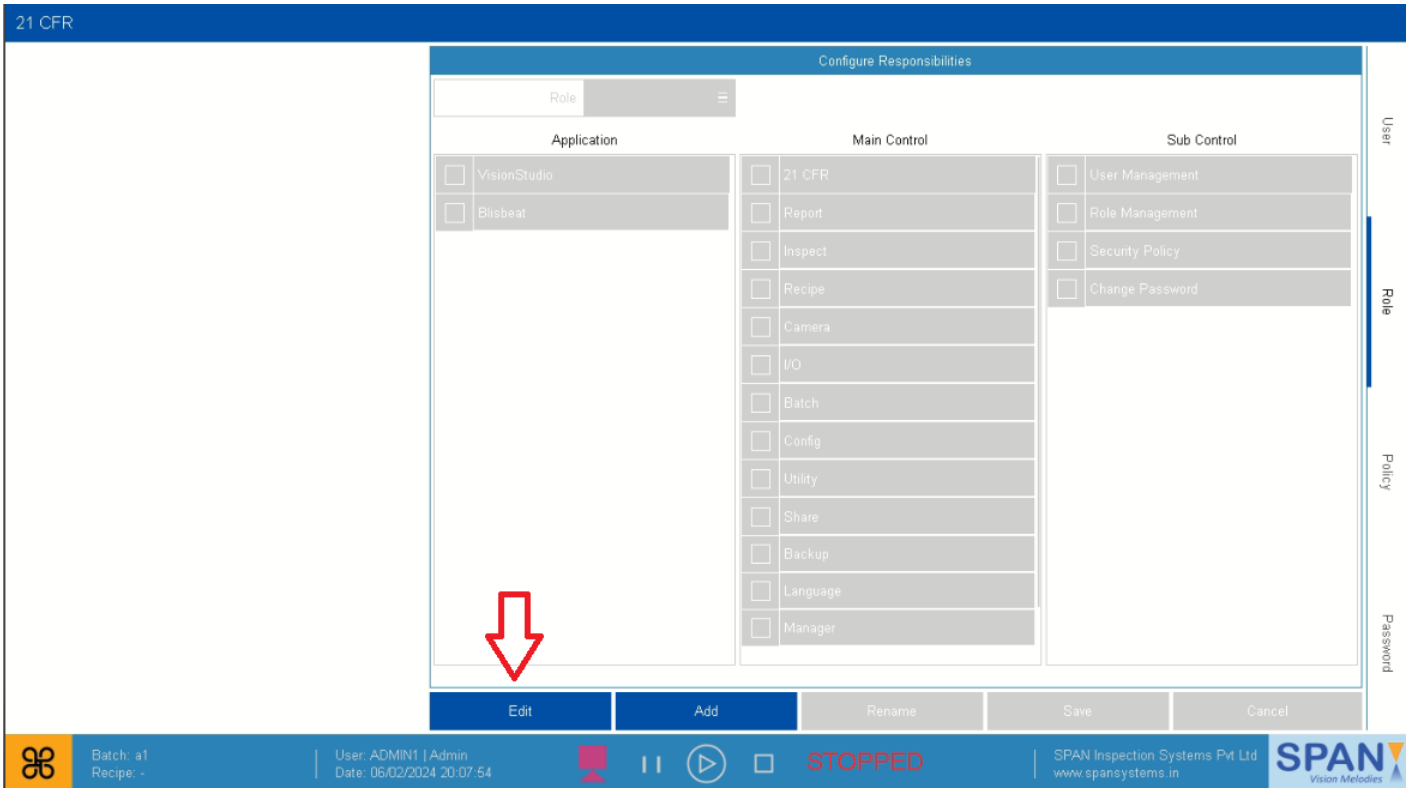


- Re-login with new user which you have created.

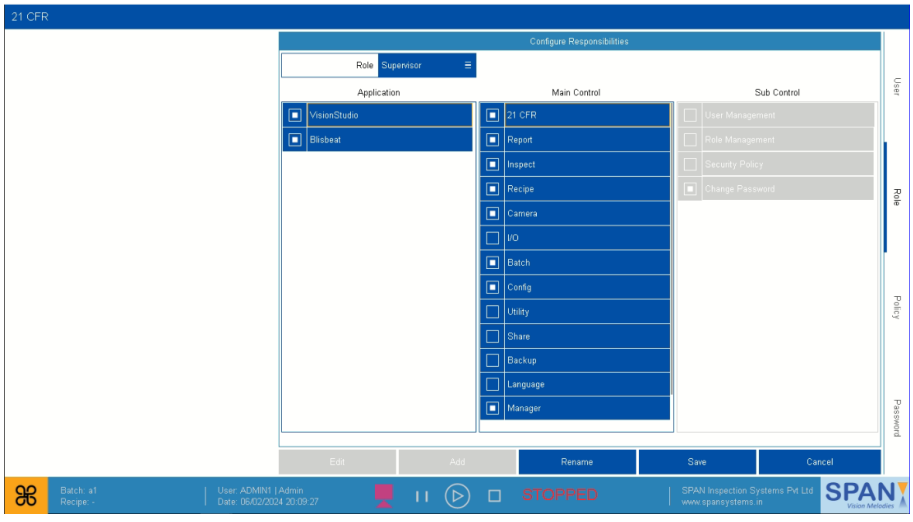


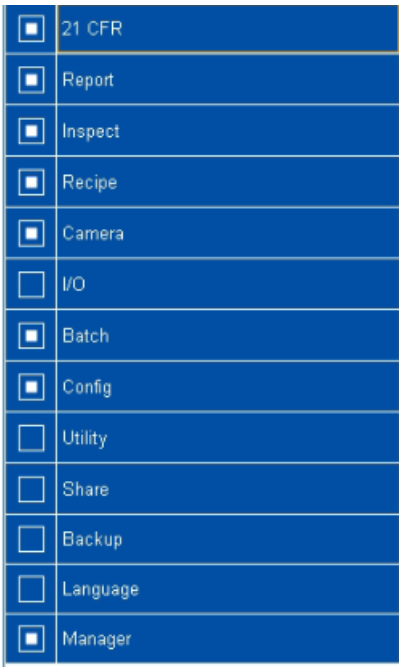
HOW TO EDIT DEFAULT RIGHTS TO VARIOUS USER ROLES

- Again, go to 21CFR, click on Role tab.
- Click “Edit” button for role editing.

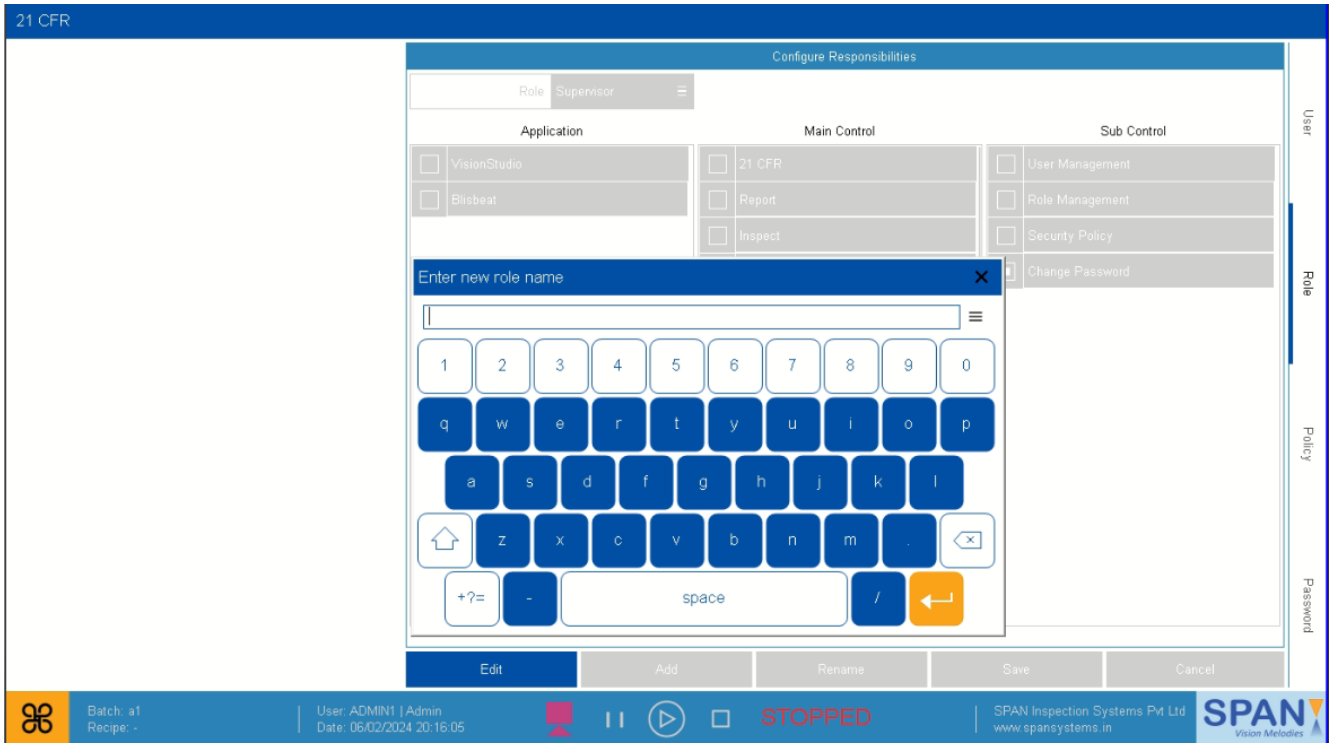


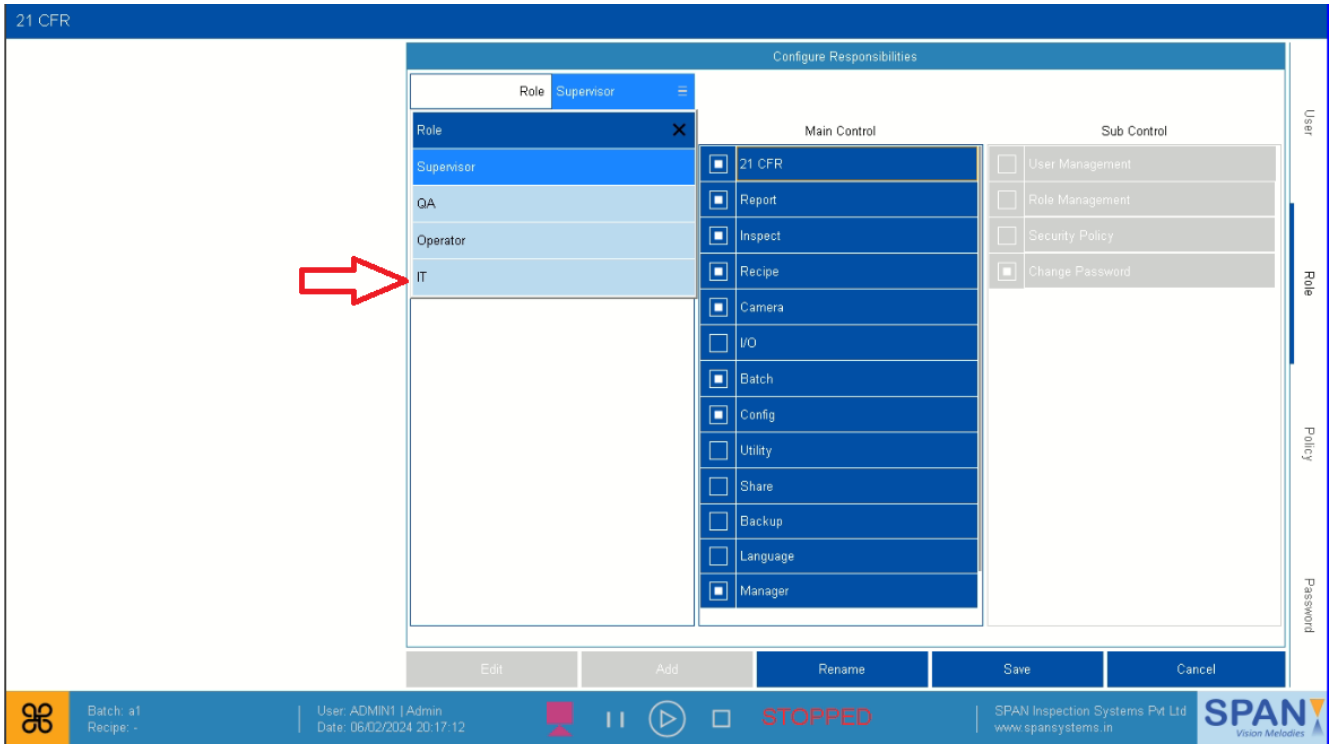
- Select Role to be edited.
- Select / Deselect the desired rights to the selected role of user.
- Click save button once finished selecting rights. Now, whenever new user is created here after these new roles will be applied by default (however customization of rights is even possible during user management).



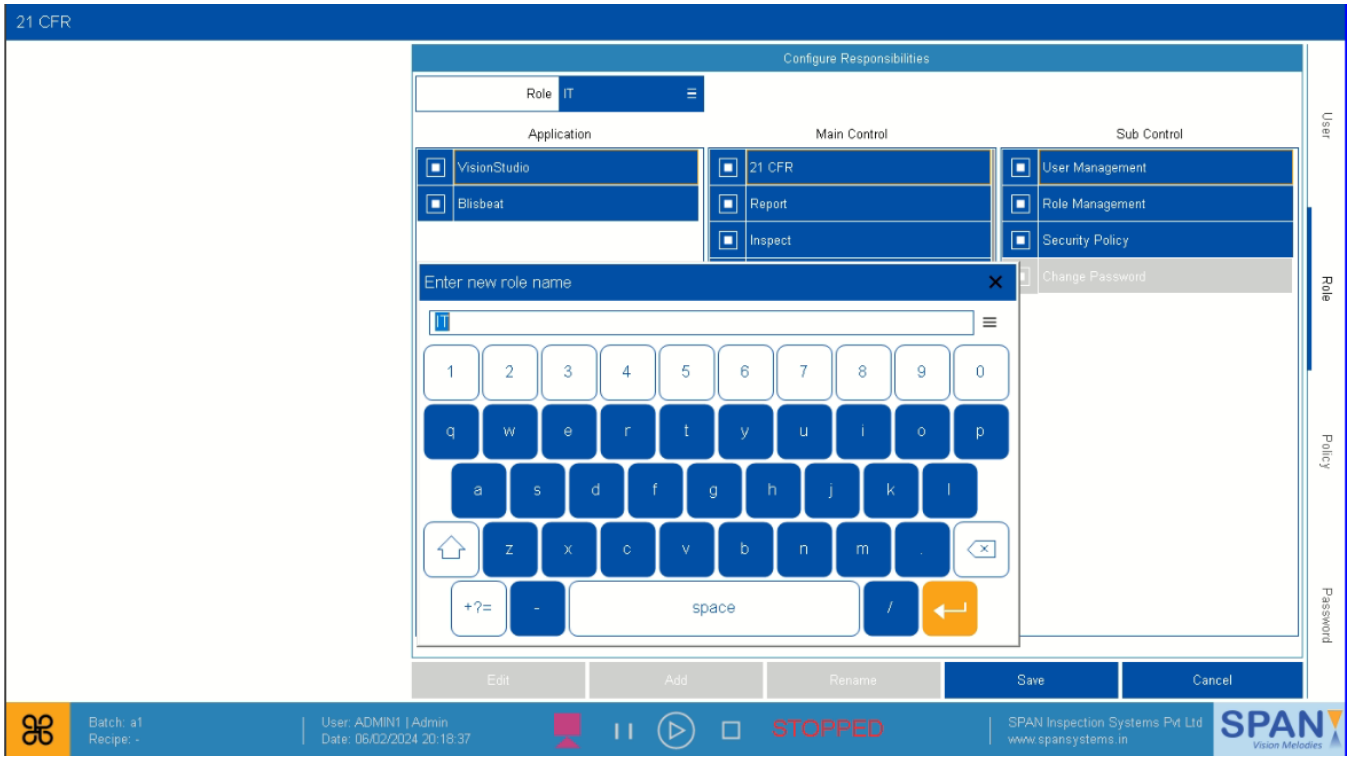


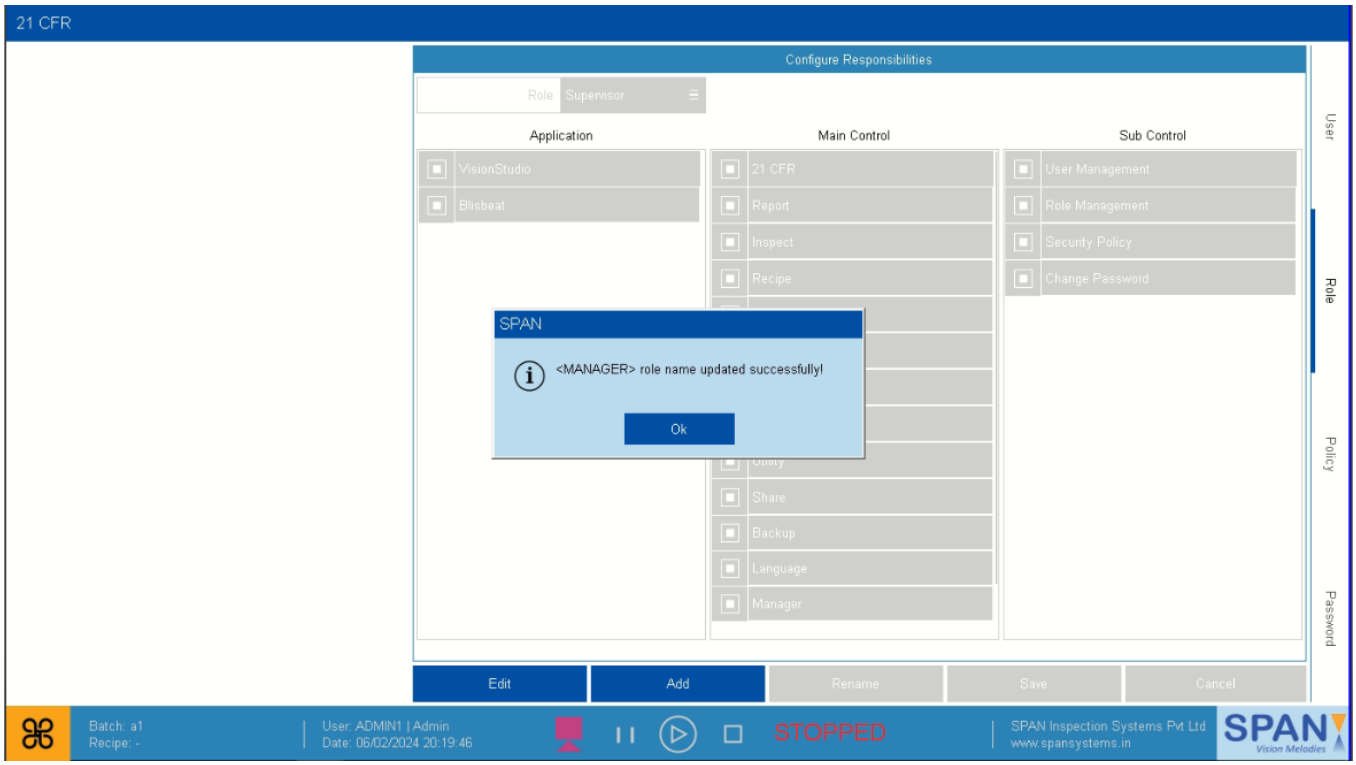
- Add: Click on add to create another user role with customize rights.





- Rename: click on Rename button to change the role name.


21 CFR
Configure Responsibilities
Role IT
Application
Main Control
Sub Control
VisionStudio
Blisbeat
21 CFR
Report
Inspect
User Management
Role Management
Security Policy
Change Password
Enter new role name
IT
User
Role
Policy
Password
Edit
Add
Rename
Save
Cancel
Batch: a1
Recipe: -
User: ADMIN1 | Admin
Date: 06/02/2024 20:18:37
STOPPED
SPAN Inspection Systems Pvt Ltd
www.spansystems.in


21 CFR
Configure Responsibilities
Role Supervisor
Application
Main Control
Sub Control
VisionStudio
Blisbeat
21 CFR
Report
Inspect
Recipe
Share
Backup
Language
Manager
User Management
Role Management
Security Policy
Change Password
SPAN
<MANAGER> role name updated successfully!
Ok
User
Role
Policy
Password
Edit
Add
Rename
Save
Cancel
Batch: a1
Recipe: -
User: ADMIN1 | Admin
Date: 06/02/2024 20:19:46
STOPPED
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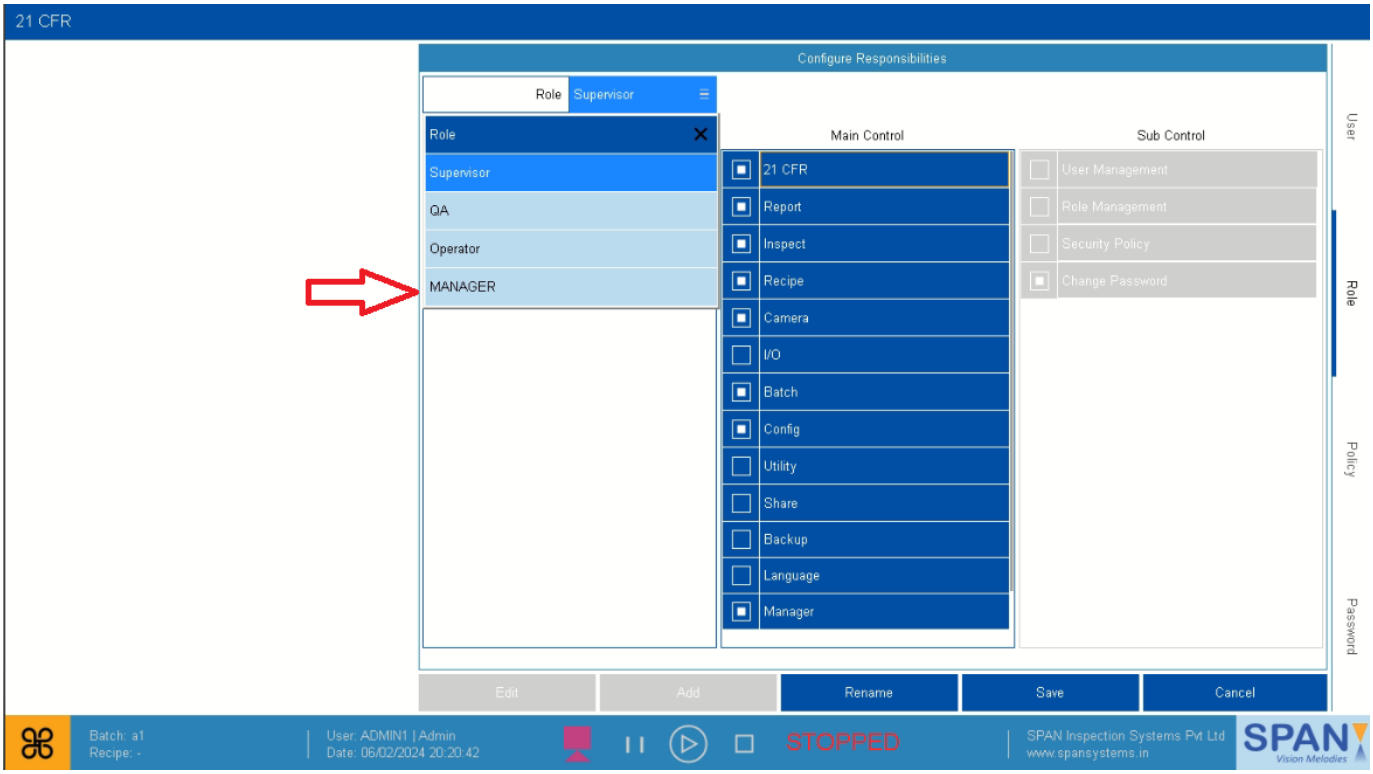
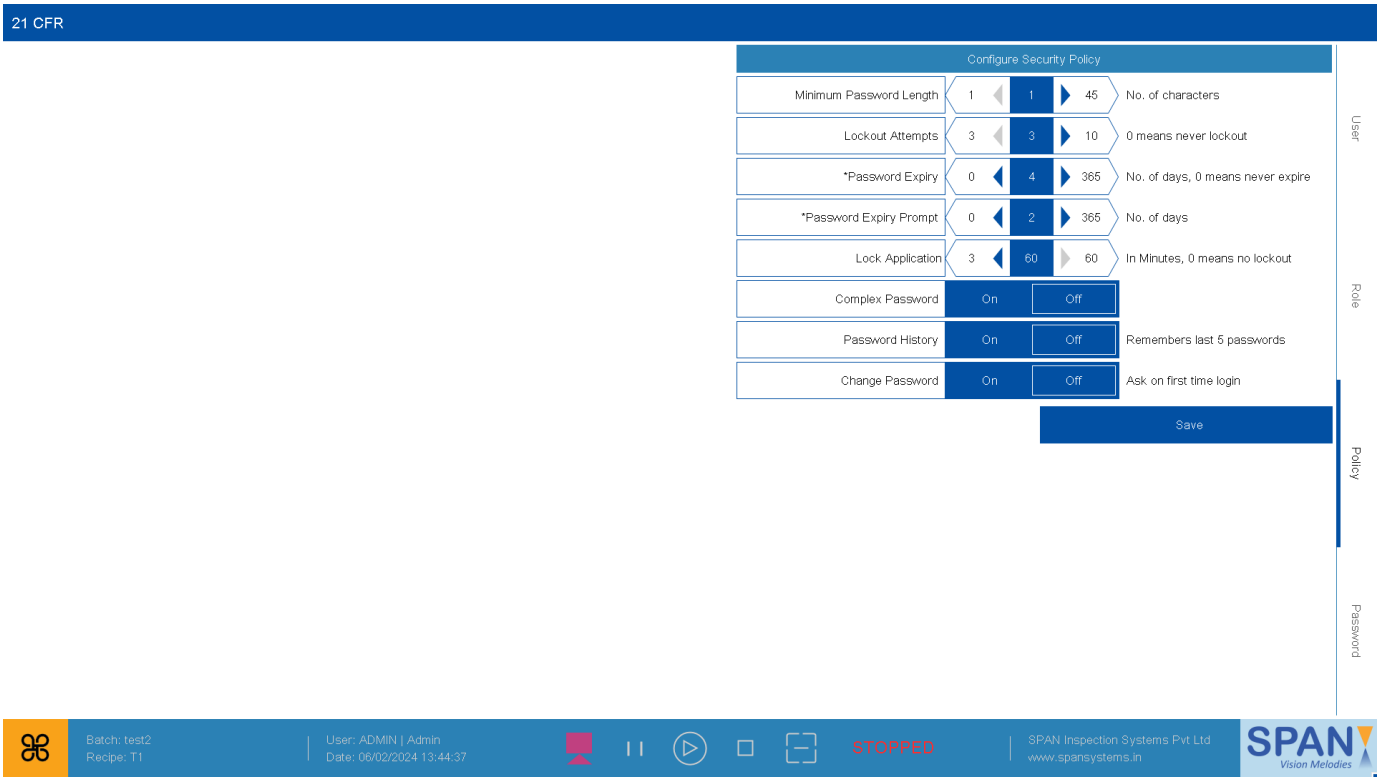


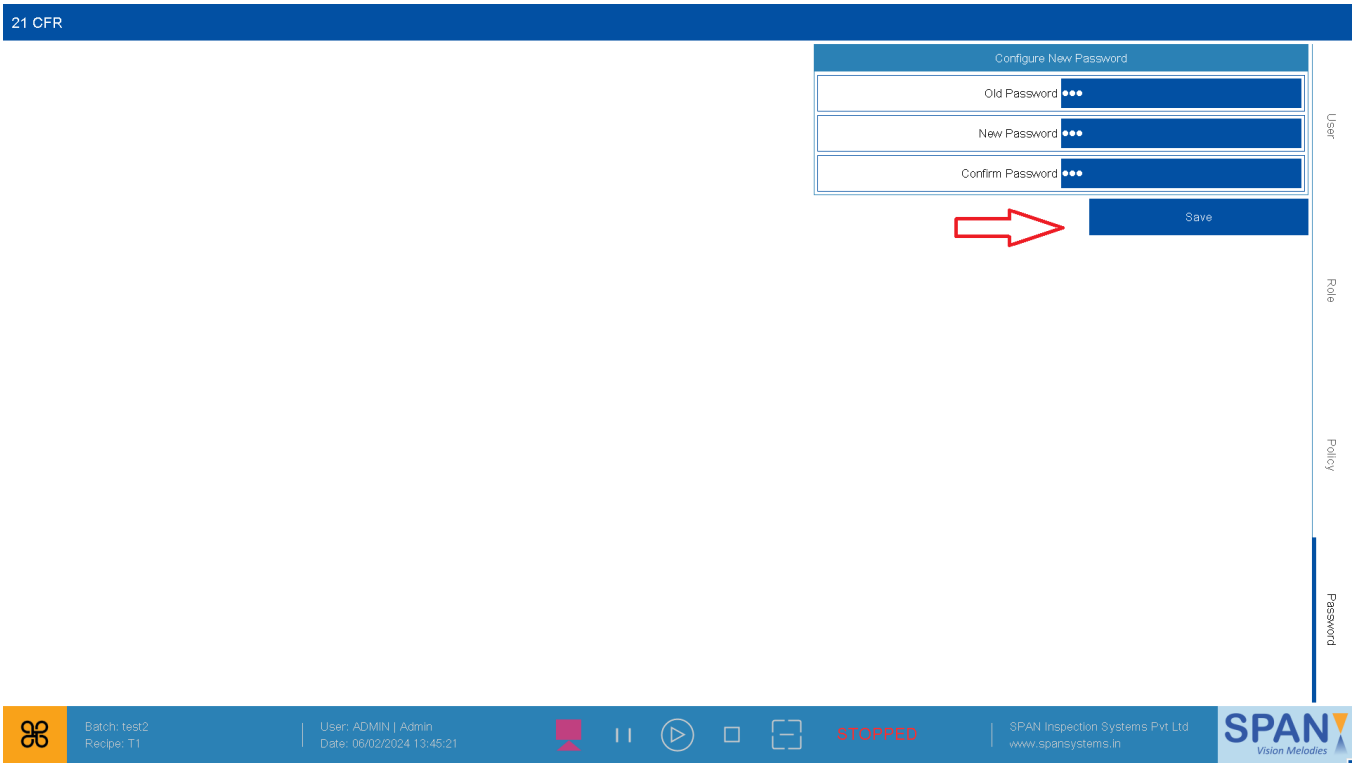
HOW TO EDIT SECURITY POLICY

- Click on Security Policy tab.
- Edit the required fields and click “Save”.
- Note that this setting will be applicable to all the users.



HOW TO CHANGE PASSWORD

- Click Change Password tab.
- Enter Old Password and New Password.
- Note that the new password complies with the password property set in security policy.


21 CFR
Configure New Password
Old Password
New Password
Confirm Password
Save
User
Role
Policy
Password
Batch: test2
Recipe: T1
User: ADMIN | Admin
Date: 06/02/2024 13:45:21
STOPPED
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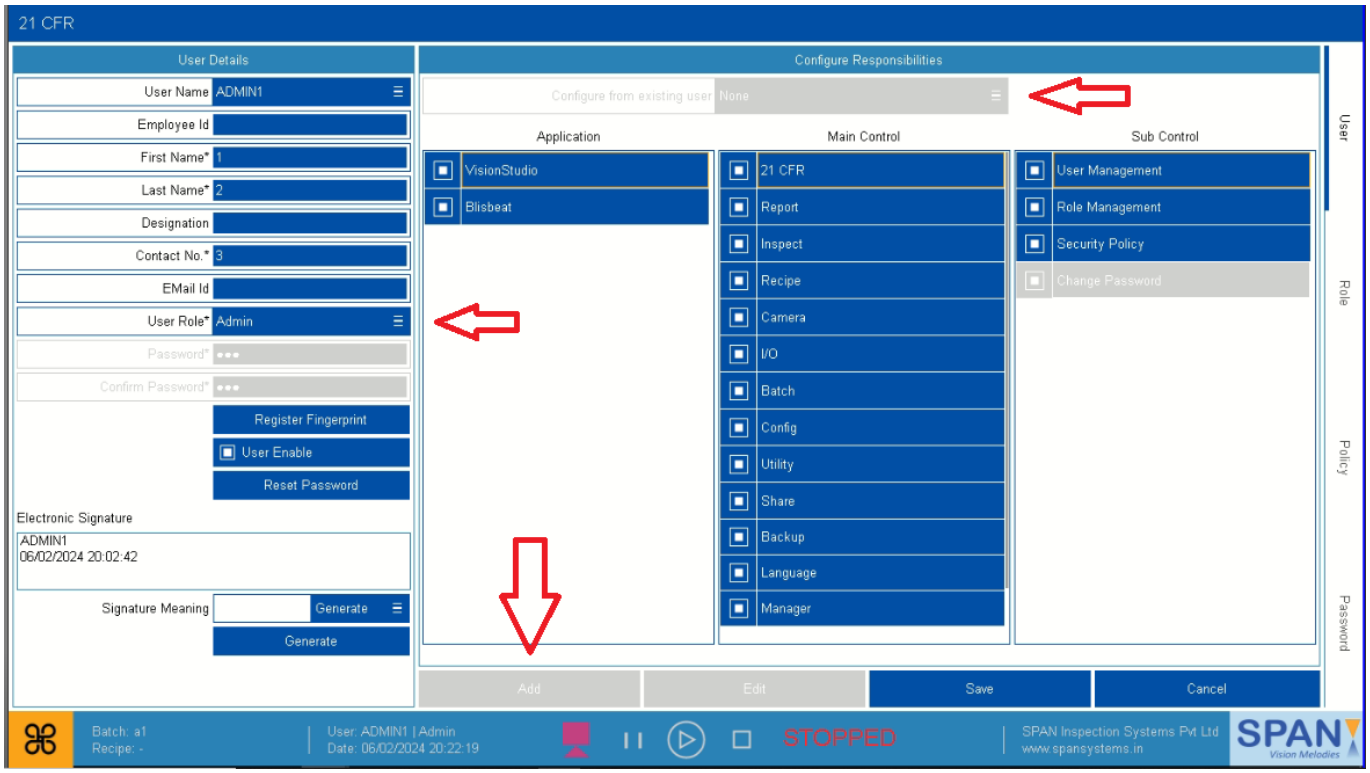
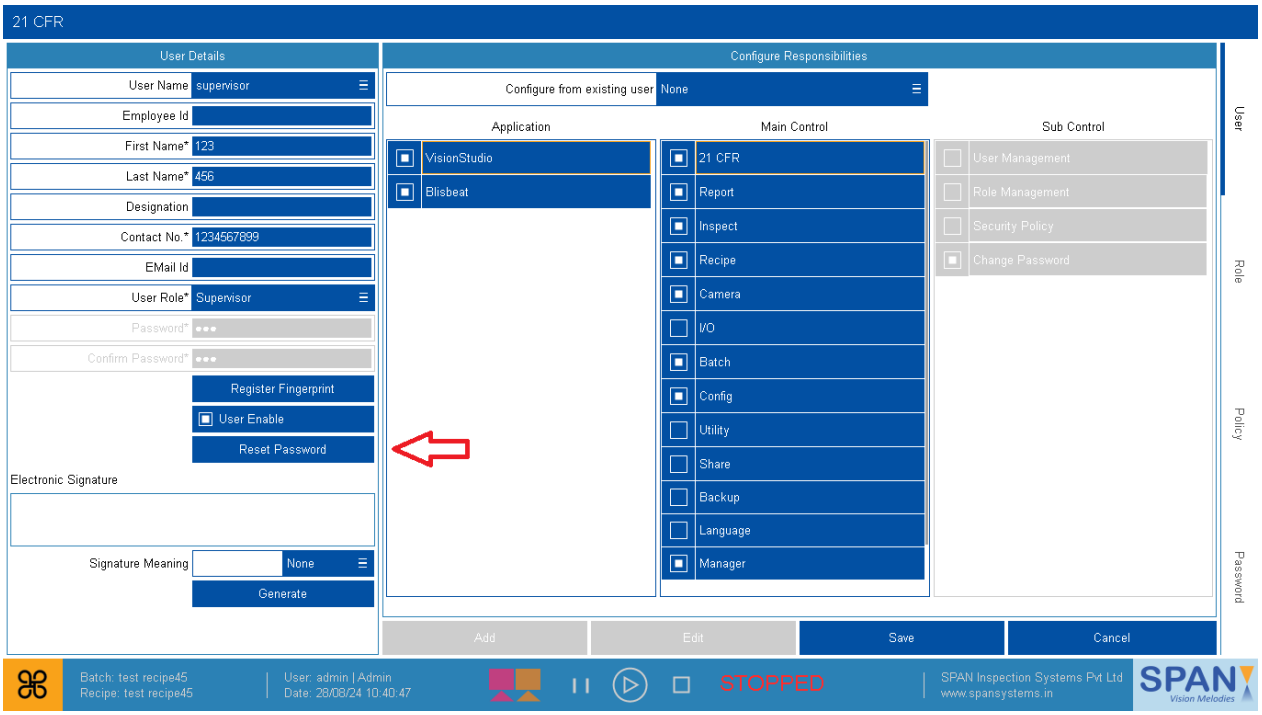
ADD SUPERVISOR / OPERATOR / QA USER

- Click User Management tab.
- Click “Add” button.
- Enter all the information in User Details.
- Select User Role as Supervisor / Operator / QA from drop down list.
- Click “Generate” button to generate Electronic Signature. This is allowed only to supervisor, QA and Admin users only.
- You can select any of the previous users from “Configure from existing user”, this will help you to exactly assign rights as selected user.
  USER B = USER A (Can be easily done, you don’t need to remember the rights given to USER A)

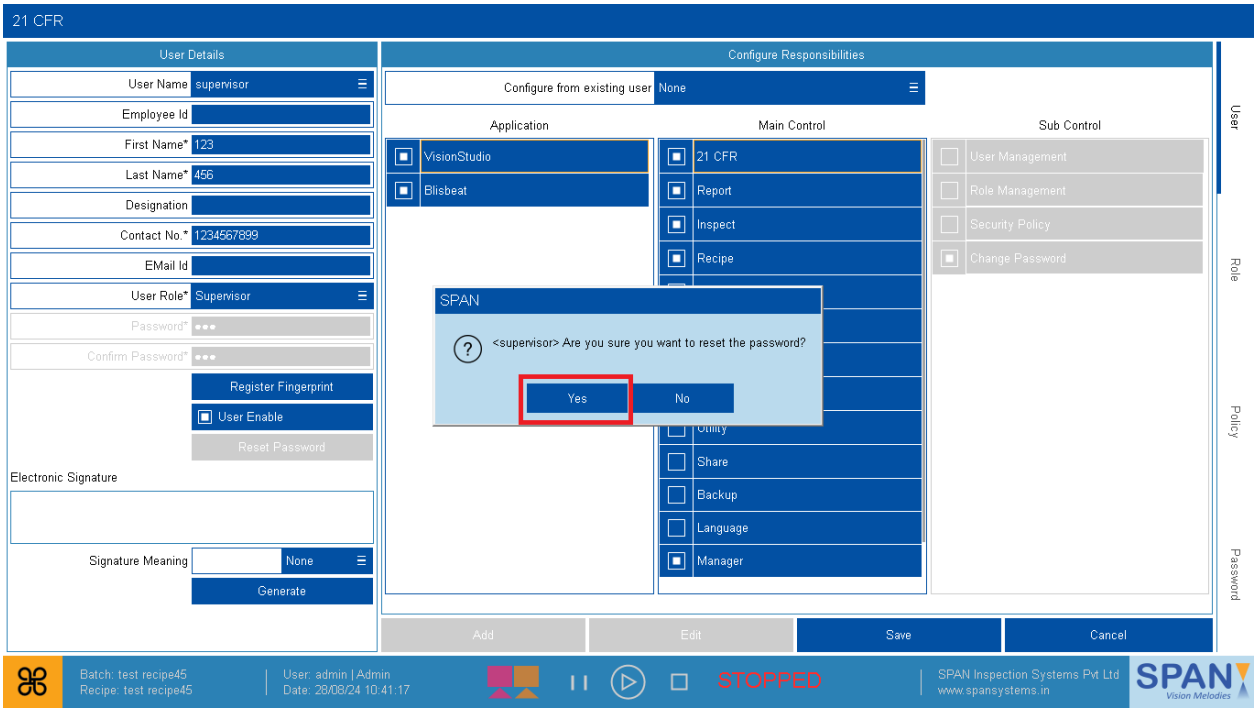


HOW TO RESET PASSWORD?

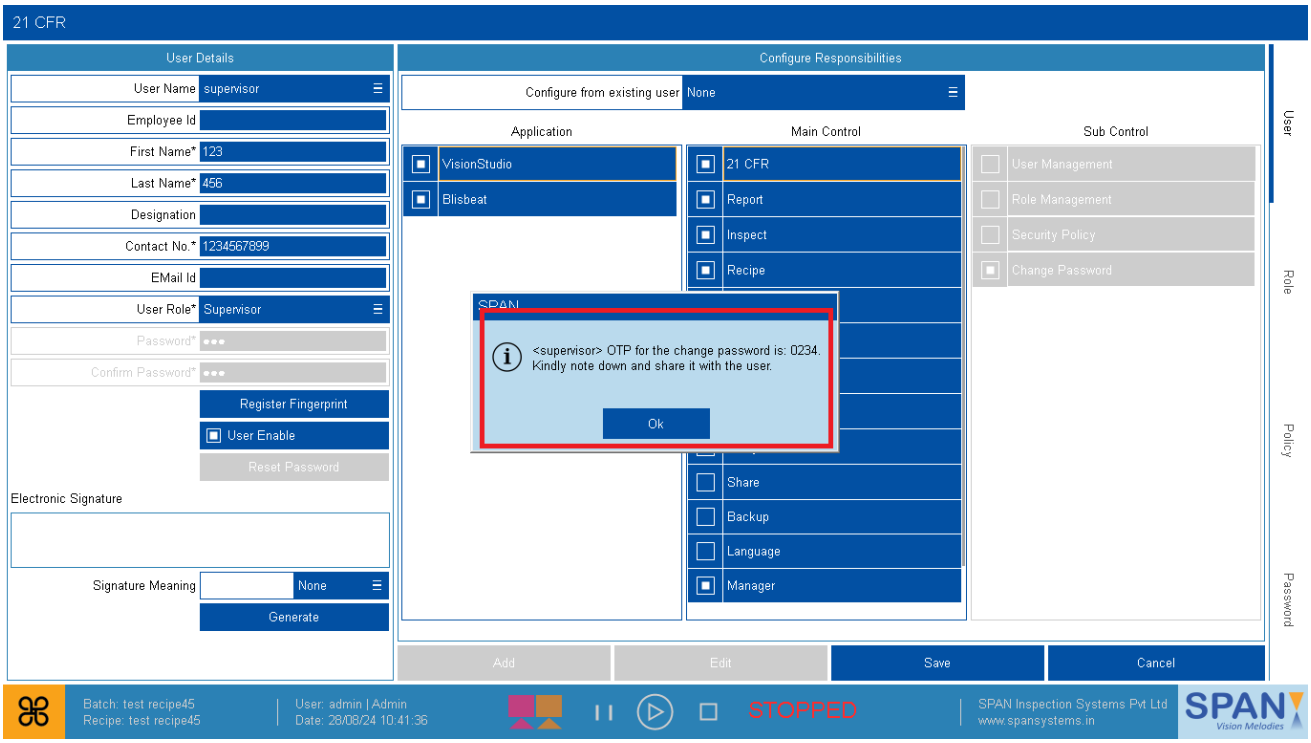
- Click on Rest Password.



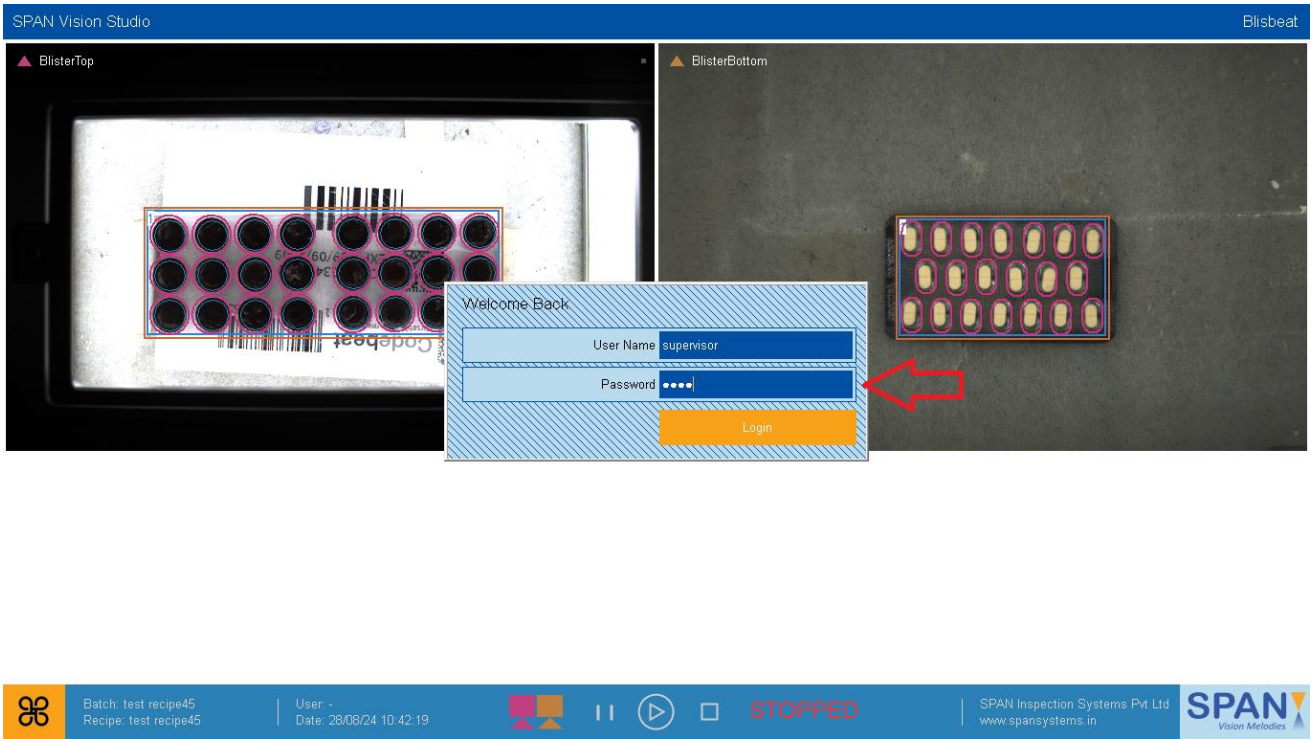
- Click on Yes.



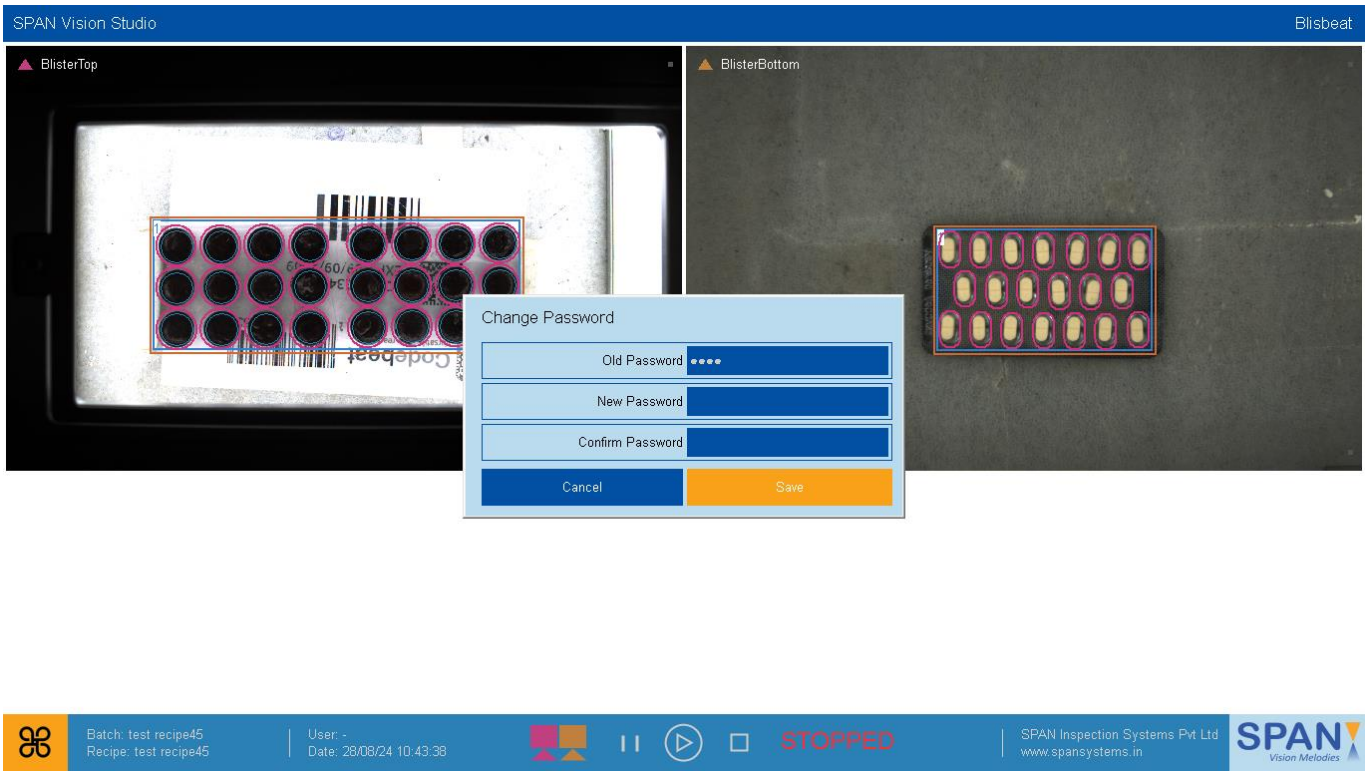
- Remember the OTP shown on the screen and then click on OK.



- Log-out the Admin user and log in the user which we had currently done the rest password using OTP .



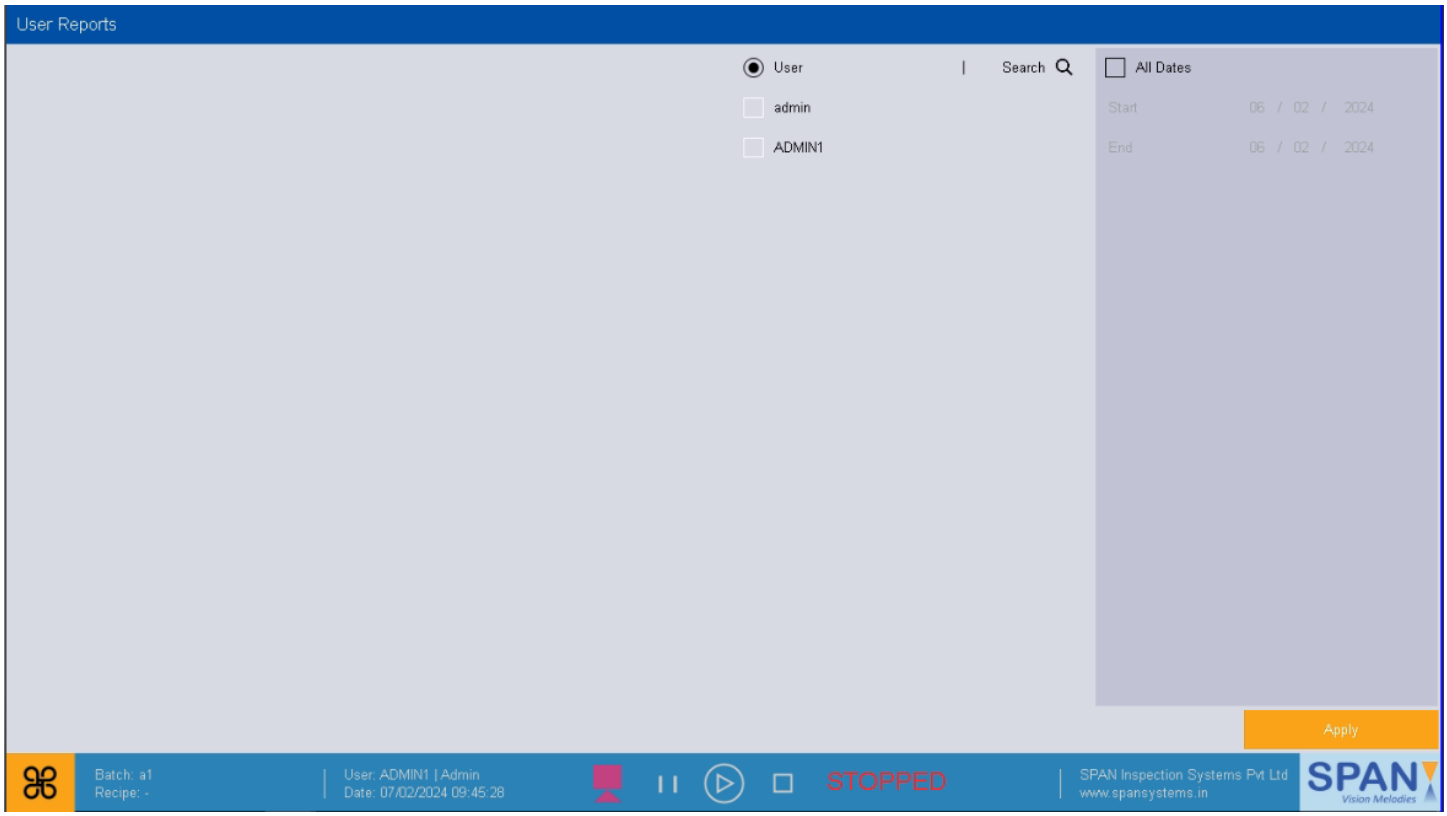
- Now enter the password user wants to set in the New Password and Confirm Password.



REPORTS

- There are two types of 21cfr related reports which user can generate.
- Default accesses to these reports are given to Admin, QA, and Supervisor. If required operator can be given rights to access these reports during user creation.
- Click on “Report” tab.
- Click on “User” to generate the User Responsibility Report.

- Select user for which you want to see his/ her assigned responsibilities and click “Apply”.



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Ahmedabad, Gujarat, India

User Responsibility Report

Machine Id	01	**Generated By**	admin
Machine Type	02	**Generated Date & Time**	07/10/2024 11:24:50

User Details

User Name	admin
Employee Id	001
First Name	adm
Last Name	adm
Designation	admin
Contact Number	8781234356
Email Id	admin@gmail.com
User Role	Admin
Signature Name	None
User Creation Date	07/10/2024 11:23:46
Is Enable	True
Created By	b1
Last Password Update Date	07/10/2024 11:23:46
Is Password Expired	False

Blisbeat

Inspect		
☑ Alarm		
☑ Machine		
☑ Learn		
☑ Segment		
☑ Tolerances		
☑ Blister		
☑ Grid Shift		

Reviewed By	Approved By	Authorised By

1 of 2

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Ahmedabad, Gujarat, India

User Responsibility Report

Machine Id	01	**Generated By**	admin
Machine Type	02	**Generated Date & Time**	07/10/2024 11:24:50

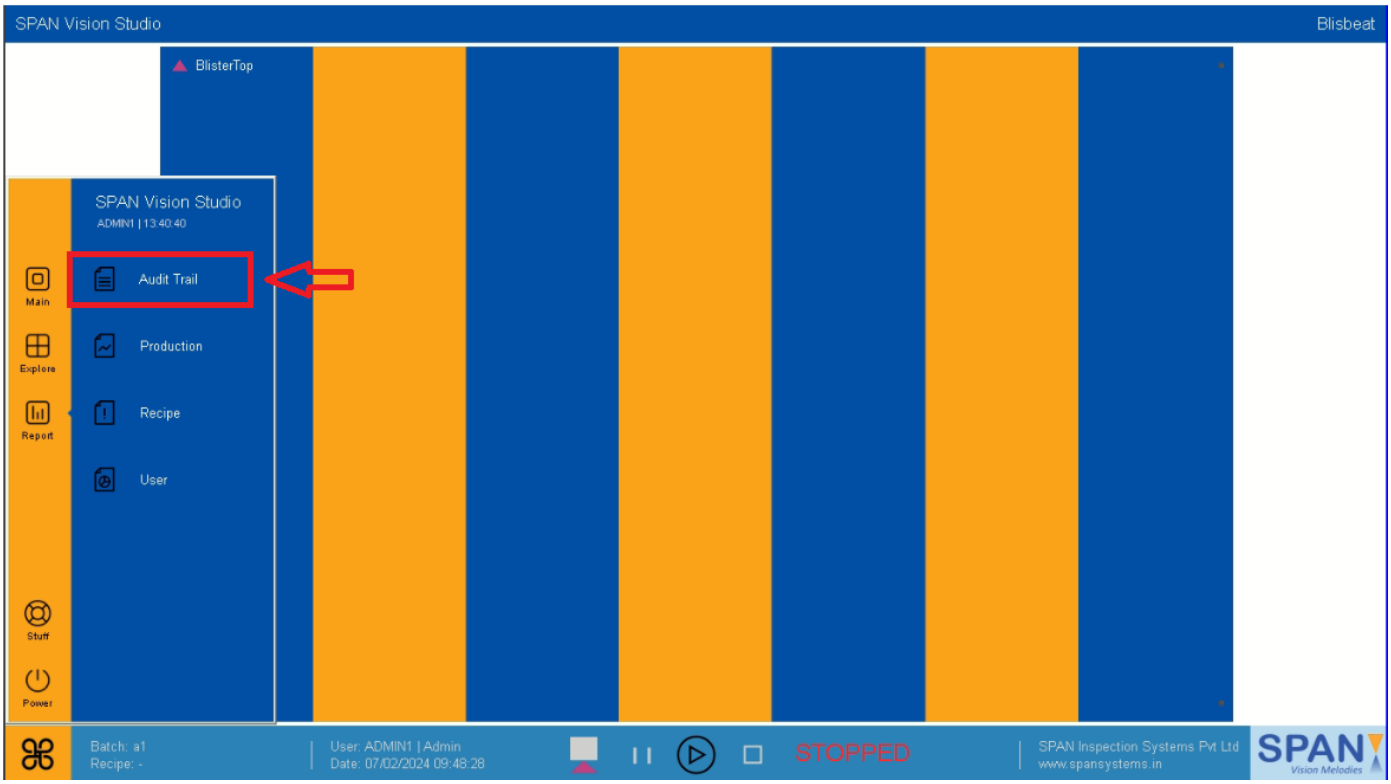
VisionStudio

21CFR	Recipe	Inspect
☑ User Management	☑ Load	☑ Start Stop
☑ Role Management	☑ Rename	☑ Reset Counters
☑ Security Policy	☑ Delete	☑ Batch Number
☑ Change Password	☑ New	☑ Image Bank
	☑ Edit	☑ Analysis
	☑ Copy	
Manager	**Camera**	**I/O**
☑ Manager	☑ Camera Settings	☑ I/O Settings
	☑ Camera Utility	☑ I/O Troubleshoot
Config	**Batch**	**Backup**
☑ Config	☑ Batch	☑ Backup
Share	**Utility**	**Language**
☑ Share	☑ Process	☑ Language
	☑ Company	
Print Screen	**Power**	
☑ Print Screen	☑ Shutdown	
	☑ Restart	
	☑ Unlock	
Report		
☑ Audit Trail		
☑ Production		
☑ Recipe		
☑ User		

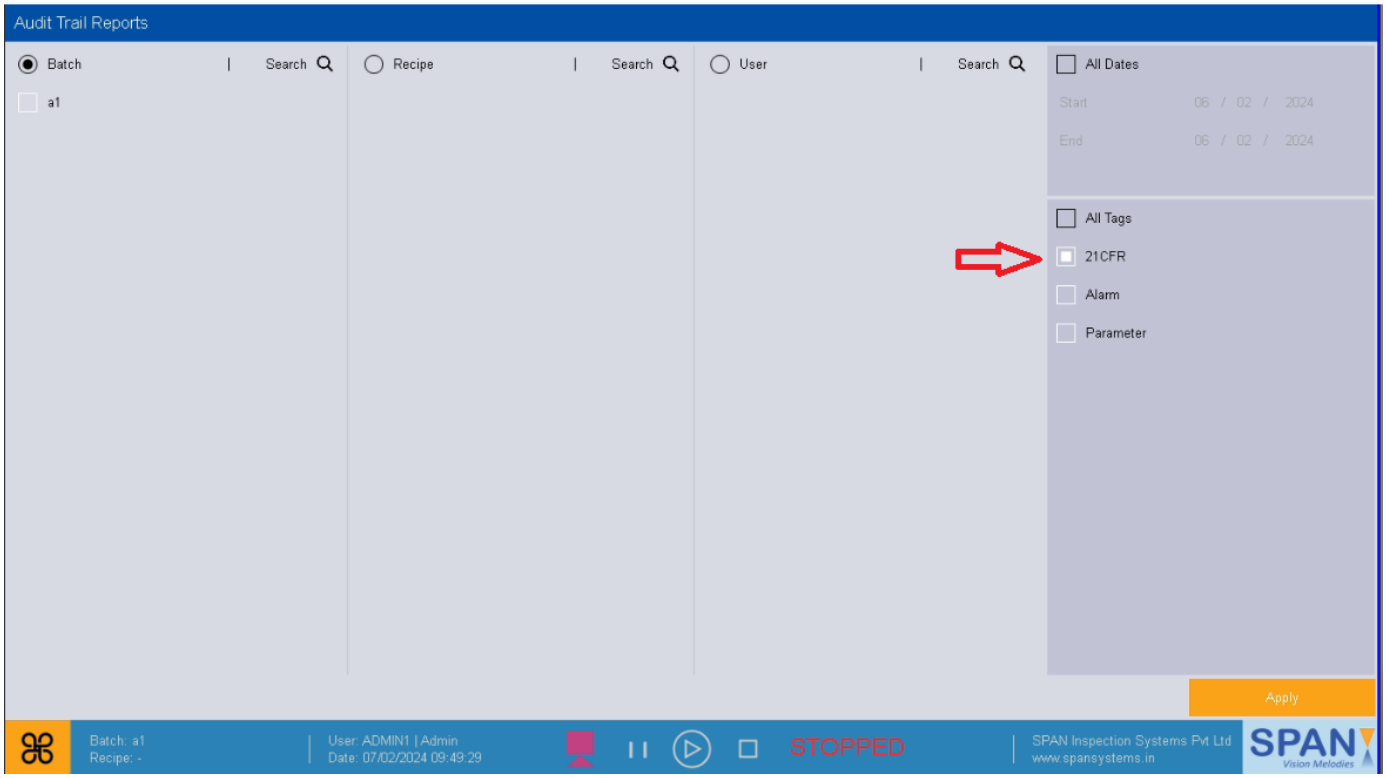
Reviewed By	Approved By	Authorised By

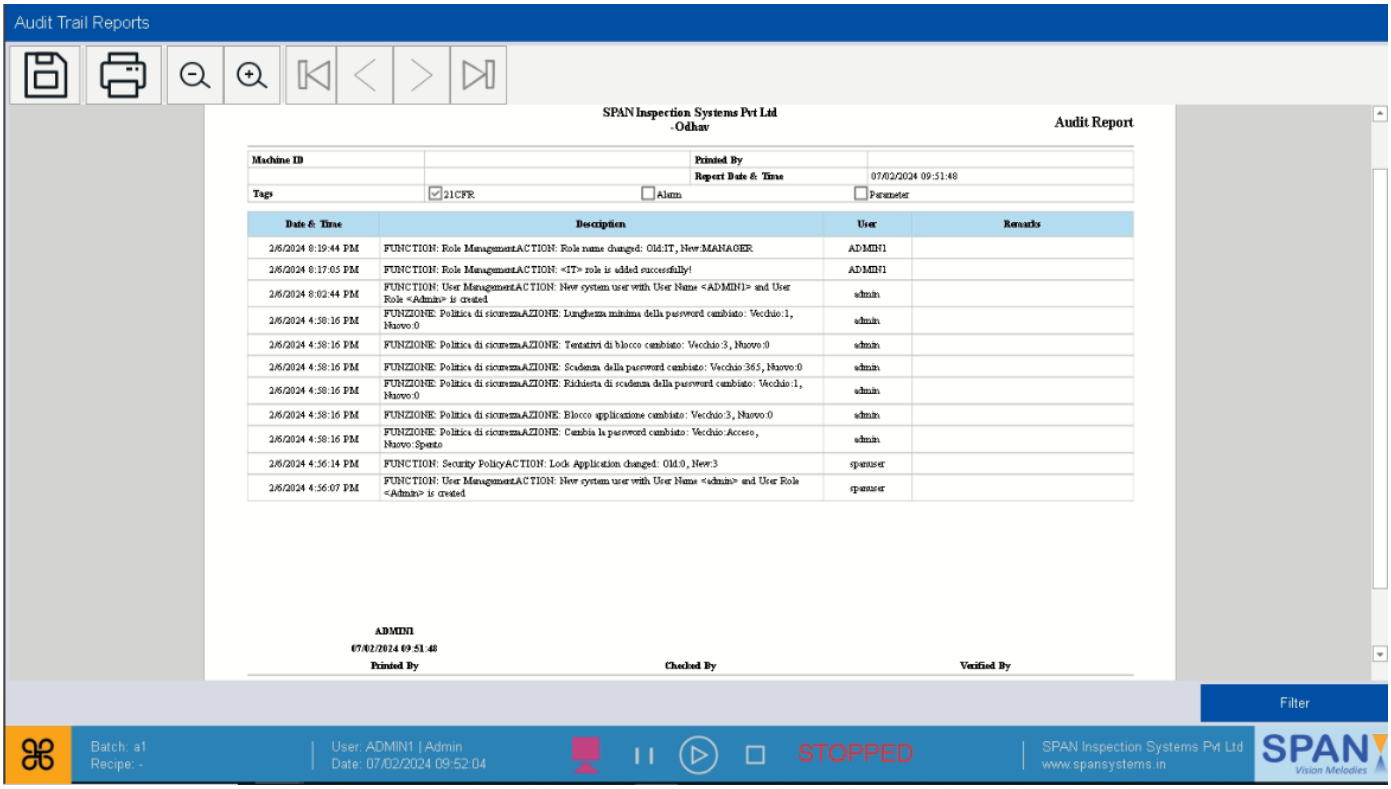
2 of 2

- To see the audits of user creation and the changes done in security policy in the above steps, user has to generate the Audit Trial report.



- Click on 21CFR to check the audits of 21CFR.





- You can select the user to generate audit report for only that particular user; also, it is possible to generate audit report from specified Start Date to End Date.
- Click “Generate Report” button.