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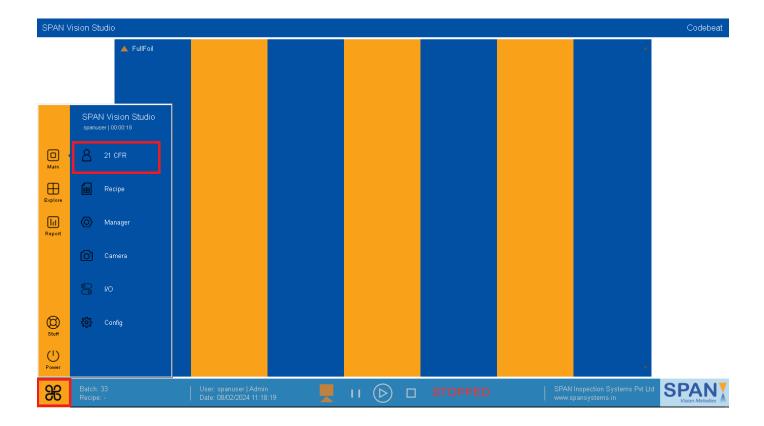


HOW TO ENTER 21CFR MODULE

• Start the SPAN Vision Studio Software. If it is operated for first time, login using Username: spanuser

Password: Take password form the SPAN team

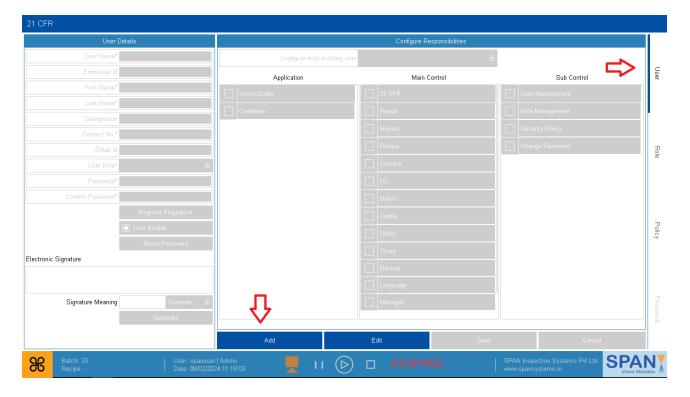
- Once logged in using spanuser administrator has to create his / her own user to login next time.
- Click 21CFR button as displayed in below image to enter 21CFR.

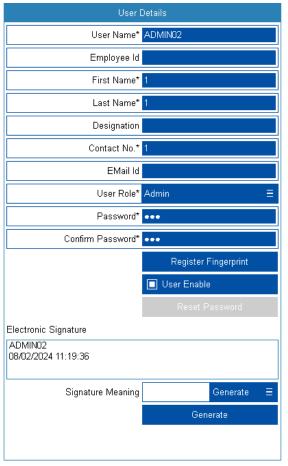




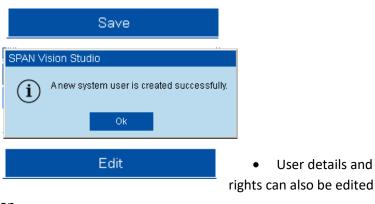
HOW TO ADD USER

- 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.

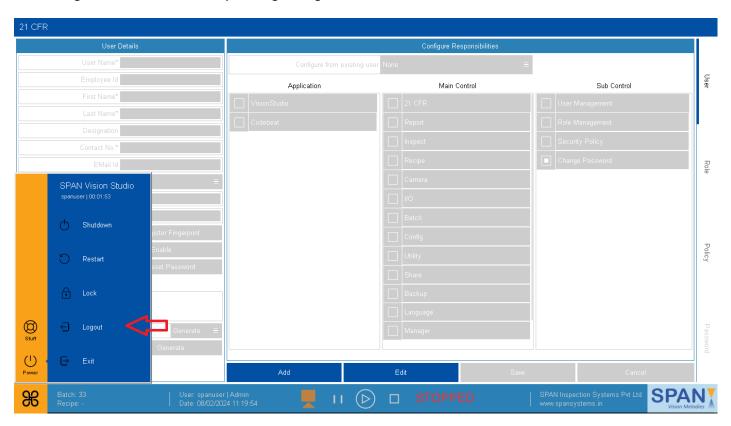


by click on.

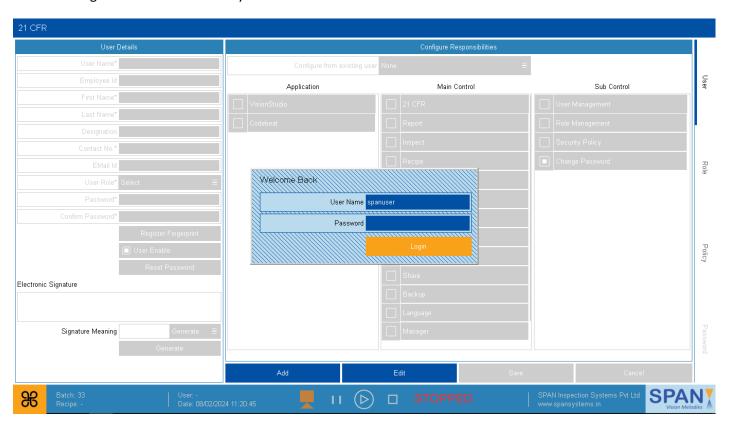


RELOGIN USING ADMIN USER

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



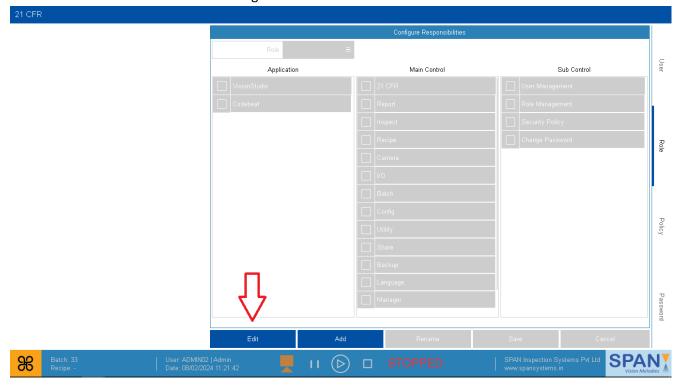
• Re-login with new user which you have created.



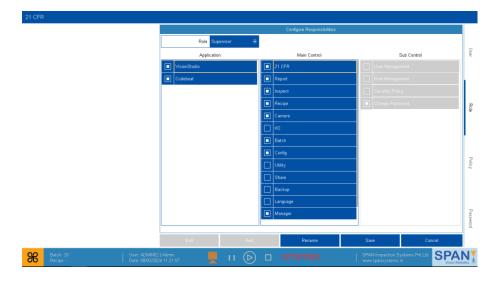


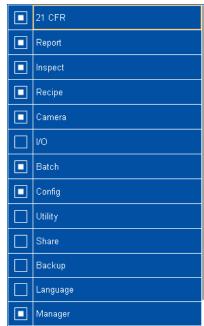
HOW TO EDIT DEFAULT RIGHTS TO VARIOUS USER ROLES

- 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.

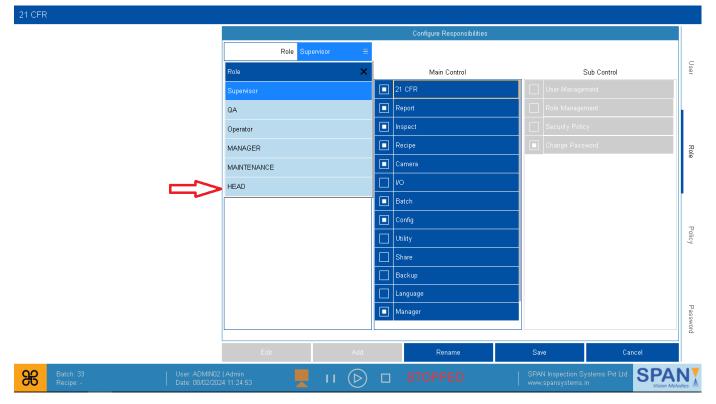
Main Control Application Sub Control Role \equiv 3 4 6 8 9 0 X space **SPAN** Configure Responsibilities User Main Control Sub Control 21 CFR Report QA Inspect Operator Recipe MANAGER Role MAINTENANCE □ | I/O ADMINISTRATOR ■ Batch Utility Backup Language Manager **SPAN**



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









HOW TO EDIT SECURITY POLICY

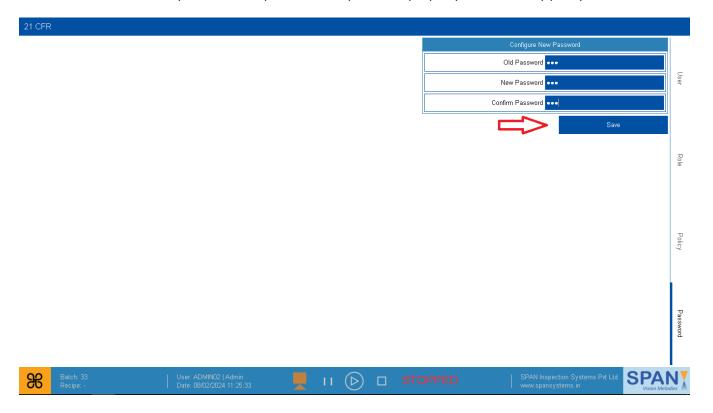
- Click on Security Policy tab.
- Edit the required fields and click "Save".
- Note that this setting will be applicable to all the users.





HOW TO CHANGE PASSWORD

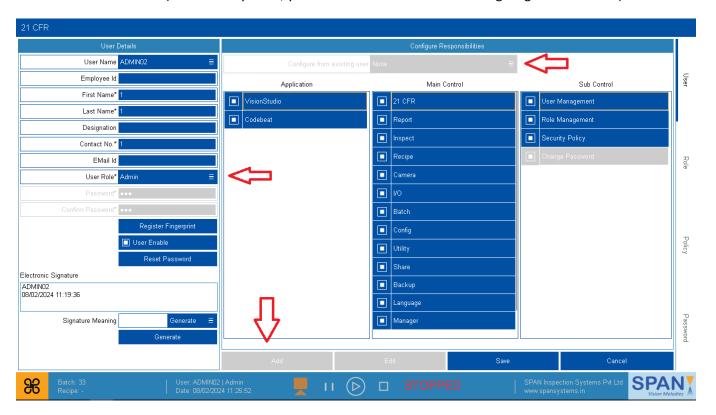
- Click Change Password tab.
- Enter Old Password and New Password.
- Note that the new password complies with the password property set in security policy.





ADD SUPERVISOR / OPERATOR / QA USER

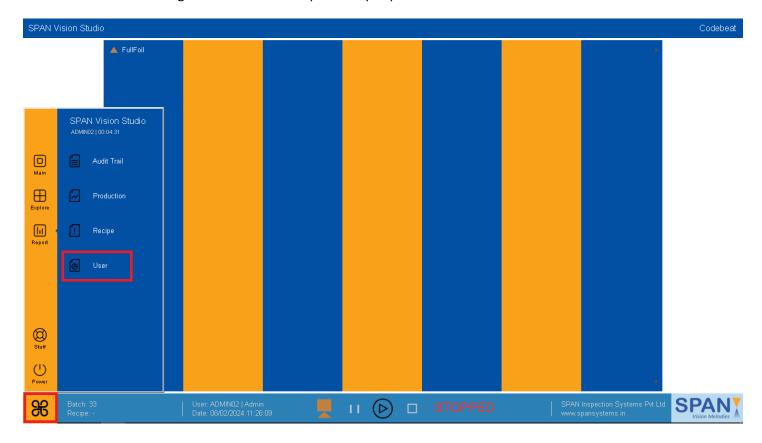
- Click User Management tab.
- Click "Add" button.
- Enter all the information in User Details.
- Select User Role as Supervisor / Operator / QA from drop down list.
- Click "Generate" button to generate Electronic Signature. This is allowed only to supervisor, QA and Admin users only.
- You can select 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)





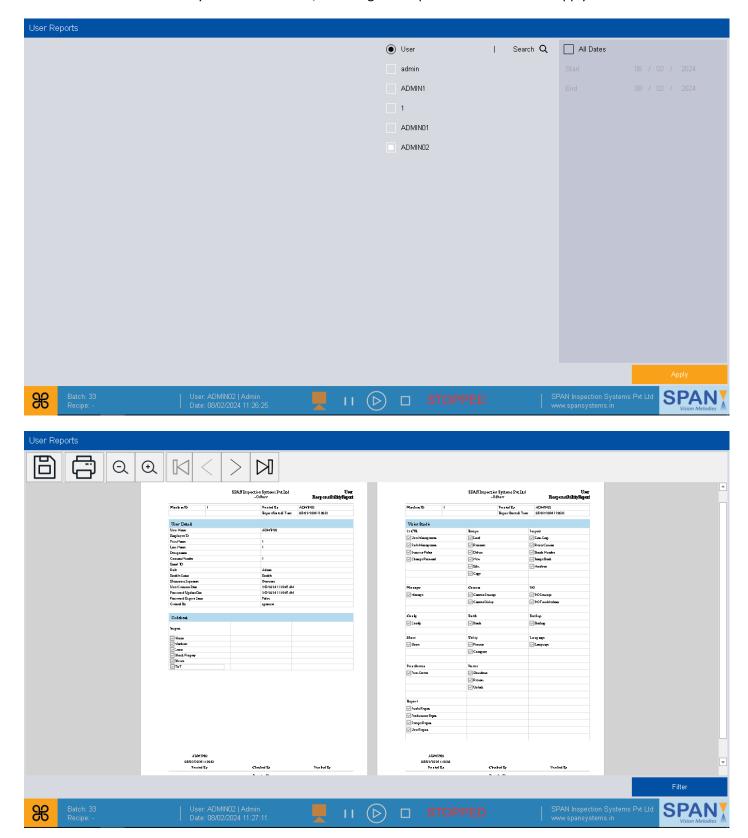
REPORTS

- 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.



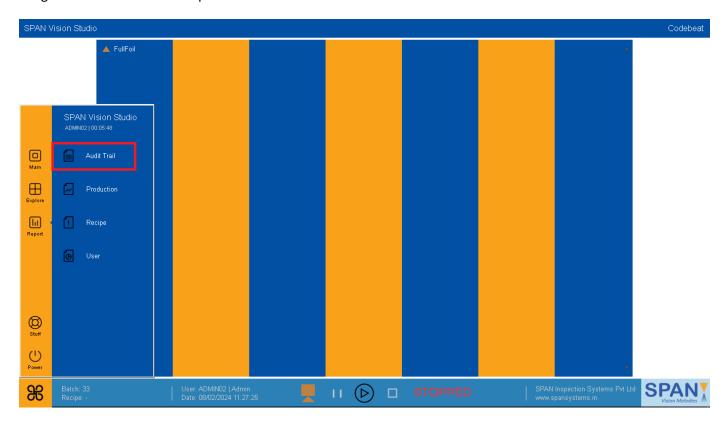


• Select user for which you want to see his/ her assigned responsibilities and click "Apply".

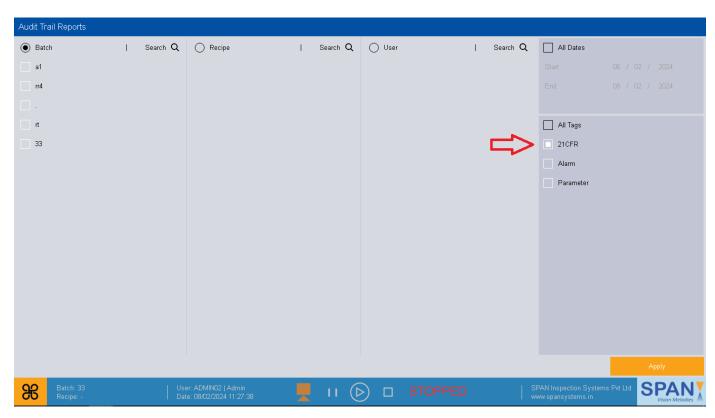




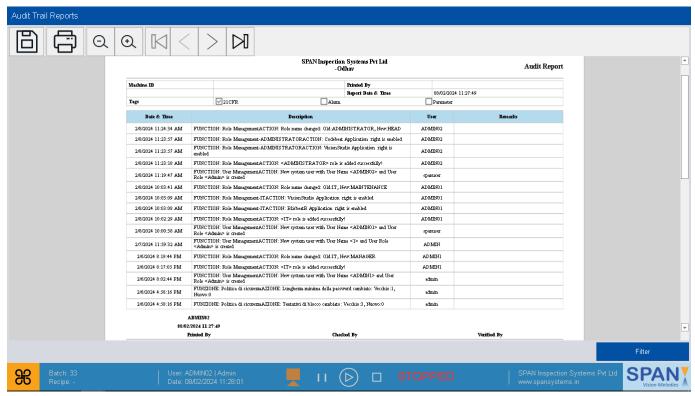
• To see the audits of user creation and the changes done in security policy in the above steps, user has to generate the Audit Trial report.



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.