



# Instructions for use of the GE Healthcare Life Sciences regulatory support web site

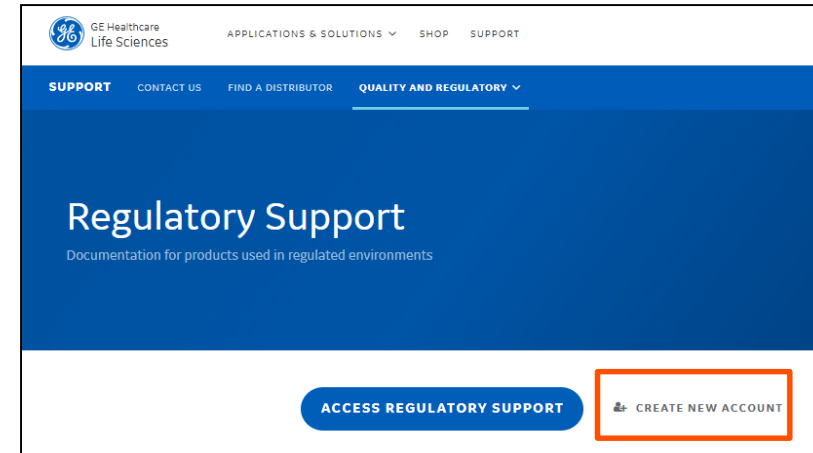
- Change control notifications
- Regulatory support documentation

May 30, 2018

# Step 1: Go to Regulatory Support Web site

[www.gelifesciences.com/rsf](http://www.gelifesciences.com/rsf)

Click **Create New Account**.

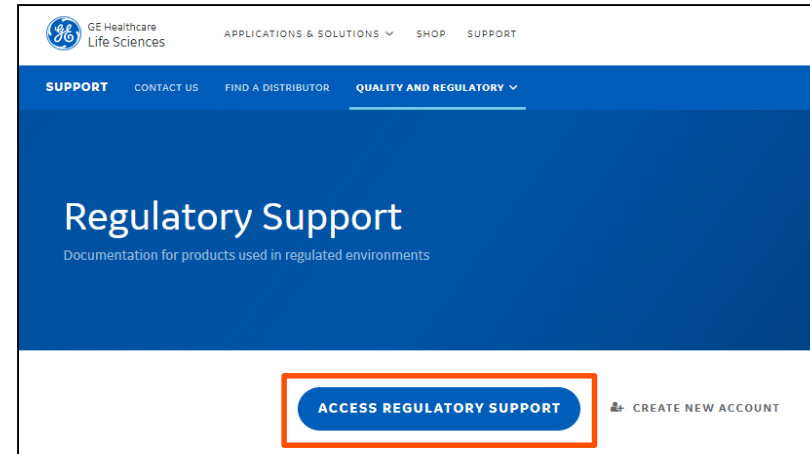


Fill out the **RS Registration Form** and click **Submit**.

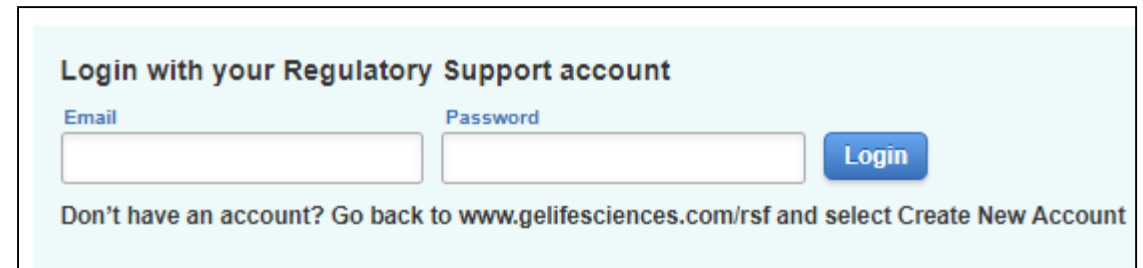


# Step 2: Access Regulatory Support

Click **Access Regulatory Support**.



**Login** with the email and password that you selected when you created the account (Step 1).

A screenshot of a login form on a light blue background. The title is 'Login with your Regulatory Support account'. Below the title are two input fields: 'Email' and 'Password'. To the right of the 'Password' field is a blue 'Login' button. Below the input fields is a link: 'Don't have an account? Go back to www.gelifesciences.com/rsf and select Create New Account'.

# Step 3: Complete My Profile

Complete your profile and click the **Update Profile** button.

You will **immediately** be able to subscribe to **Change Control Notifications** (CCN).

**If you would also like** to subscribe to Regulatory Support Files (RSF), Validation Guides (VG), and Validation Support Files (VSF), you will need to sign the online **Confidentiality Agreement** by ticking a box.

Your account will then go through manual approval, and you will be notified by email when approval is completed.

My Profile Search Subscriptions My Subscriptions Logout from Regulatory Support

Information missing. Make sure to fill in all needed information before submitting your registration!  
- Missing Fields : Company/Institution, State/Province, City, Address Line 1, Zip/Postal Code

### Welcome to Regulatory Support!

You find more information about [Regulatory Support](#) in [brochures and datafiles](#), [frequently asked questions](#) and [contact](#)

#### Contact Information

First Name *	Address Line 1 *	Zip/Postal Code *
<input type="text" value="Fonster"/>	<input type="text"/>	<input type="text"/>
Last Name *	Address Line 2	State/Province *
<input type="text" value="Tvatt"/>	<input type="text"/>	<input type="text"/>
Email	City *	Country *
<input type="text" value="fonster@tvatt.se"/>	<input type="text"/>	<input type="text" value="Sweden"/>
Company/Institution *	<input checked="" type="checkbox"/> I have read and agree to the websites <a href="#">privacy policy</a> , including the terms of use of this website.	
<input type="text"/>		

#### Subscription Category

By submitting your profile you will be able to subscribe to Change Control Notifications.

Please note that you may only subscribe to Change Control Notifications that apply to products that you have purchased and that your access to this site may be suspended if you misuse the site to gain access to information about other products than purchased.

If you would also like to subscribe to other Regulatory Support documentation (RSF, VG, VSF), please tick the box below before submitting your profile.

I want to subscribe to Regulatory Support Files (RSF), Validation Guides (VG) and Validation Support Files (VSF)

#### Confidentiality Agreement

GEHC CONFIDENTIALITY AGREEMENT – Regulatory Support – terms and conditions

IMPORTANT - PLEASE READ CAREFULLY  
THIS IS THE CONFIDENTIALITY AGREEMENT THAT END-USER (HEREINAFTER "END-USER") IS REQUIRED TO ACCEPT BEFORE USING THE GEHC REGULATORY SUPPORT WEB SITE. CAREFULLY READ ALL OF THE TERMS AND CONDITIONS OF THIS CONFIDENTIALITY AGREEMENT BEFORE SUBMITTING YOUR APPLICATION FOR A PROFILE ACCOUNT ON THE REGULATORY SUPPORT WEB SITE (HEREINAFTER "PROFILE ACCOUNT"). CLICKING THE APPLICABLE "ACCEPT" OR EQUIVALENT BUTTON ON THIS MESSAGE INDICATES END-USER'S

I agree to the Confidentiality Agreement



# Step 4: Select subscriptions

Click **Search Subscriptions** tab.

Press button **Show Available Subscriptions**.

For example, to choose the ÄKTA readyflux Flow Kit, select **ReadyToProcess** radio button.

Select **ÄKTA readyflux Flow Kit** (multiple product line categories may be added here [e.g., ÄKTA ready Flow Kit]).

Click **Add** button.

The screenshot shows the 'Search Subscriptions' interface. At the top, there are navigation tabs: 'My Profile', 'Search Subscriptions' (highlighted with a red box), and 'My Subscriptions'. A 'Logout from Regulatory Support' link is in the top right. Below the tabs is a message: 'Please select a subscription type.' with a close button. The main content area has two sections: '1. Subscription category' and '2. Subscription type'. In the 'Subscription category' section, the 'Show Available Subscriptions' button is highlighted with a red box. Below it is a list of radio buttons. The 'Change Control Notification - ReadyToProcess' option is selected, indicated by a red arrow. In the 'Subscription type' section, there is a list of checkboxes. The 'ÄKTA readyflux Flow Kit' checkbox is checked, also indicated by a red arrow. At the bottom of the list, there is an 'Add' button highlighted with a red box. Navigation links 'Previous', '1', '2', '3', '4', and 'Next' are visible between the two sections.



# Step 5: View subscriptions

Click **My Subscriptions** tab.

Click button **Refresh**.

For ÄKTA Flow Kit CCNs, select **ReadyToProcess**.

Select **ÄKTA readyflux Flow Kit** (click on hyperlink name of product line, **NOT** the checkbox located to the right).

You will see **all previously published** CCNs for the subscription.

To view a specific CCN, click on **hyperlink** name of document.

My Profile Search Subscriptions **My Subscriptions** Logout from Regulatory Support

Collapse Expand **Refresh**

Previous 1 | 2 | 3 | 4 Next

- ▶ BioProcess Hardware - Extractables Summary
- ▶ Change Control Notification - Biacore
- ▶ Change Control Notification - Bioprocess Hardware
- ▶ Change Control Notification - BioProcess Software
- ▶ Change Control Notification - Cell Therapy
- ▶ Change Control Notification - Chromatography Resins
- ▶ Change Control Notification - Density Gradient Media
- ▶ Change Control Notification - Filtration
- ▶ Change Control Notification - HyClone
- ▼ **Change Control Notification - ReadyToProcess**
  - Global Notifications
  - ÄKTA ready Flow Kit
  - ÄKTA readyflux Flow Kit** 
    - Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
    - Published on: 11/16/2017 Addition of UV Sensor to ÄKTA™ readyflux Flow Kit Plus Section
  - ReadyCircuit Bags
  - ReadyCircuit NFF Assemblies

Previous 1 | 2 | 3 | 4 Next

Cancel



# Step 6: Open file

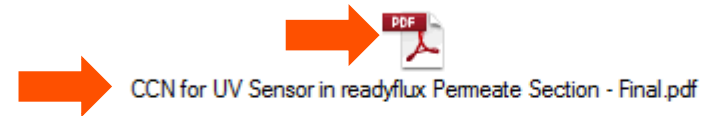
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Click on **PDF Icon** or **hyperlink name** to open document.



## Regulatory Support

Title: **Addition of UV Sensor to ÄKTA™ readyflux Flow Kit Plus Section**  
Published on: **11/16/2017**



# Step 7: Cancel a subscription

**Tick the box** next to the subscription you wish to cancel.  
Click button **Cancel**.

The screenshot shows the 'My Subscriptions' page in a web application. At the top, there are navigation tabs for 'My Profile', 'Search Subscriptions', and 'My Subscriptions', along with a 'Logout from Regulatory Support' link. Below the tabs are buttons for 'Collapse', 'Expand', and 'Refresh'. A pagination bar shows 'Previous 1 | 2 | 3 | 4 | Next'. The main content area lists several subscription categories, each with a checkbox on the right. The categories are: 'BioProcess Hardware - Extractables Summary', 'Change Control Notification - Biacore', 'Change Control Notification - Bioprocess Hardware', 'Change Control Notification - BioProcess Software', 'Change Control Notification - Cell Therapy', 'Change Control Notification - Chromatography Resins', 'Change Control Notification - Density Gradient Media', 'Change Control Notification - Filtration', 'Change Control Notification - HyClone', and 'Change Control Notification - ReadyToProcess'. Under 'Change Control Notification - ReadyToProcess', there are sub-items: 'Global Notifications', 'ÄKTA ready Flow Kit', 'ÄKTA readyflux Flow Kit', 'ReadyCircuit Bags', and 'ReadyCircuit NFF Assemblies'. The 'ReadyCircuit Bags' checkbox is checked and highlighted with a red box. At the bottom of the page, a blue 'Cancel' button is also highlighted with a red box. A second pagination bar at the bottom shows 'Previous 1 | 2 | 3 | 4 | Next'.





# Step 8: Renewal of Confidentiality Agreement

If you selected to subscribe to RFS/VG/VSF in Step 3, and you have received the email confirming that the **Confidentiality Agreement** has been approved, you will see the **expiration date** of the Confidentiality Agreement on the tab My Profile.

When the agreement expires, you will receive a reminder by email to renew it.

Even if your agreement has expired, you will still receive emails about new CCNs and updates of RSF/VG/VSF, but you will not be able to access RSF/VG/VSF until the agreement is renewed.

My Profile Search Subscriptions My Subscriptions [Logout from Regulatory Support](#)

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#### Contact Information

First Name *	Address Line 1 *	Zip/Postal Code *
<input type="text" value="Test"/>	<input type="text" value="Test street 1"/>	<input type="text" value="12345"/>
Last Name *	Address Line 2	State/Province *
<input type="text" value="Test"/>	<input type="text"/>	<input type="text" value="Test"/>
Email	City *	Country *
<input type="text" value="test@test.se"/>	<input type="text" value="Test City"/>	<input type="text" value="Sweden"/>
Company/Institution *	<input checked="" type="checkbox"/> I have read and agree to the websites <a href="#">privacy policy</a> , including the terms of use of this website.	
<input type="text" value="Test Company"/>		

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I agree to the Confidentiality Agreement.

**Agreement expires: 01/23/2022** 



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GE Healthcare is audited and certified according to ISO 9001.

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