cytiva

Change control and regulatory documentation

Navigation and access

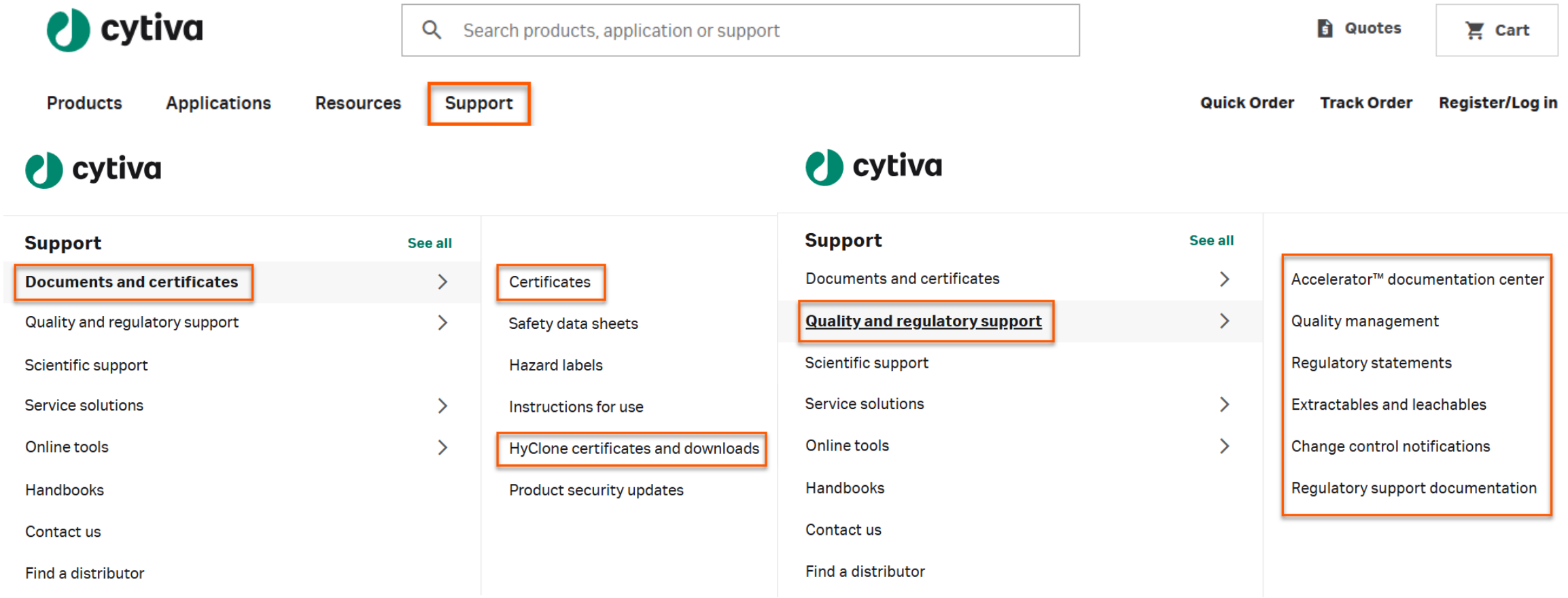
danaher

Regulatory support documentation is an invaluable starting point for process development and validation. It is also critical for preparing standard operating procedures (SOPs), quality control, and for supporting clinical and marketing applications to regulatory agencies.

Presentation overview and quick links

- Two separate online systems
  - Cytiva's regulatory support documentation – summary
- Accessing extractables information
- Locating your lot-specific product certificate
- Log in to the regulatory support website
  - Start your subscription
  - View your active subscriptions
- E-mail notifications
- Register and log in to the Accelerator™ documentation center
  - Help for the Accelerator documentation center
  - Document module
  - Drawing module
  - Claims and compliance reports

Navigating cytiva.com



Quality and Regulatory Support

With regulatory support accounts—available to Cytiva customers—you gain access to product documentation useful for process development and validation. The documentation is free of charge and is critical for preparing standard operating procedures (SOPs), quality control, and clinical and marketing applications for submission to regulatory agencies.

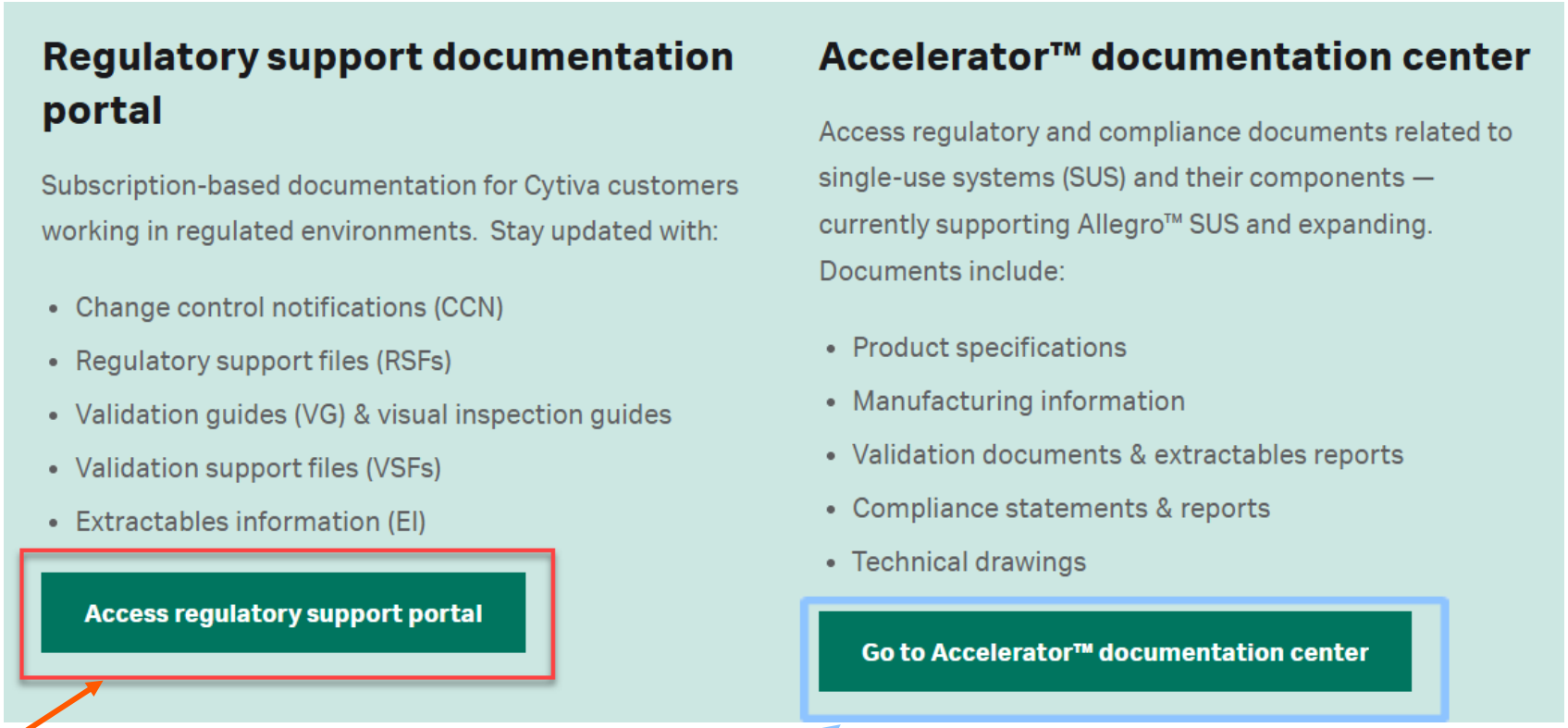
We offer change control notification (CCN), regulatory support files (RSF) for chromatography resins and cell culture media, validation guides (VG) for single-use products and bioprocess filters, validation support files (VSF) for software, and extractables information (EI) for supported products.

Regulatory documentation is provided via two separate online systems: Regulatory support and Accelerator documentation center.

Our subscription service notifies you when updated regulatory documents are available.

Two separate online systems

With different documents and different logins



1 **cytiva.com/rsf**
Login: Cytiva web account required

2 **cytiva.com/adc**
Login: Separate account required

Cytiva's regulatory support documentation – summary

Access without login	Access with login	Access via subscription with login + online CDA	Accelerator documentation center with login	On request only
• Quality management documents • Regulatory statements • Extractables testing/approach • Global site certificates such as ISO certificates	• Change control notifications (CCN) by subscription	• Regulatory support documentation by subscription • Regulatory support files, validation guides, and validation support files • Extractables reports • Visual inspection libraries	• Documents related to single-use systems (SUS) and their components — currently supporting Allegro™ SUS and expanding. • Drawings and bill of materials (BOMs) • Compliance documents and The claims and compliance report • Validation documents and technical reports • Extractables reports • Visual inspection library	• Drawings and BOMs for products not in the Accelerator documentation center • Qualification packages (for products not in the Accelerator documentation center) • Chain of custody

Note: Regulatory support and Accelerator documentation center require two separate login accounts.

**May require NDA to access some documents.*

Key available quality management documents

All documents on the right are readily available on the Cytiva web without creating an account.

- Cytiva Rx-360 general quality systems - Questionnaire responses
- Quality policy
- Quality management system
- Standard for Cytiva change control and notification process for designated products
- Cytiva change control and notification process for Pall Medical products

Accessing extractables information

Discover our approach to extractables and leachables testing on our website.
https://www.cytivalifesciences.com/en/ussupport/quality-and-regulatory-support/extractables-and-leachables

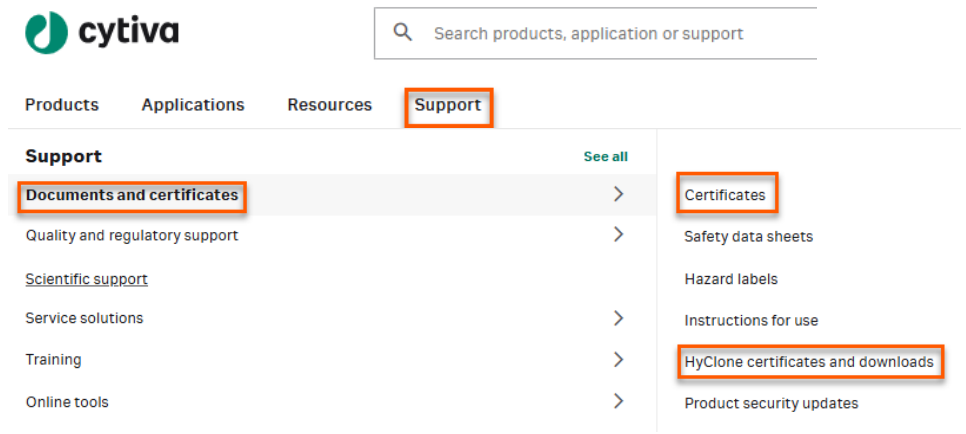
The actual information and reports are accessible on our two websites:

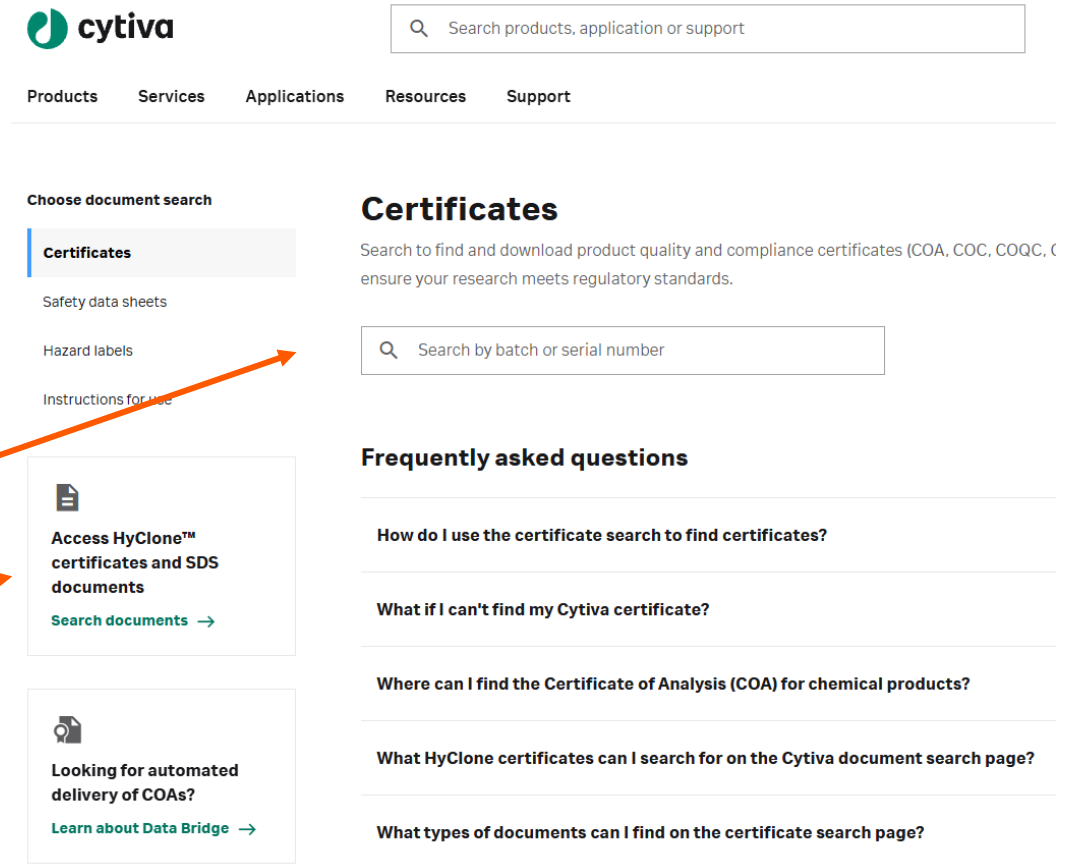
- Accelerator documentation center (Allegro single-use systems and associated filters and aseptic connectors)
- Regulatory support website (for all other product groups)

The webpage above guides you on where to locate extractables information and reports based on product type.

Product Type	Product description	Representative part number	Primary MOC [1]	Pretreatment[2]	Extractables study design			Comment	Applicable extractables reports	Report portal[5]
					USP<665>[3]	BioPhorum	Legacy[4]			
Aseptic connector	ReadyMate™ DAC	28936688	PC	Gamma & Autoclave	H	X		Cytiva manufactuted component	Component family file: ReadyMate DAC. Extractables study: 17-002	Regulatory support portal
	Kleenpak® sterile connector	KPCHT02F11 KPCHT02M11	PC	Irradiation and autoclave	H	X		Cytiva manufactuted component	USTR 3946 (Comprehensive summary)	Accelerator™ documentation center

Locating your lot-specific product certificate





- www.cytiva.com/certs
- Search by batch or serial number
- Additional link for Hyclone™

Regulatory support documentation: on request only

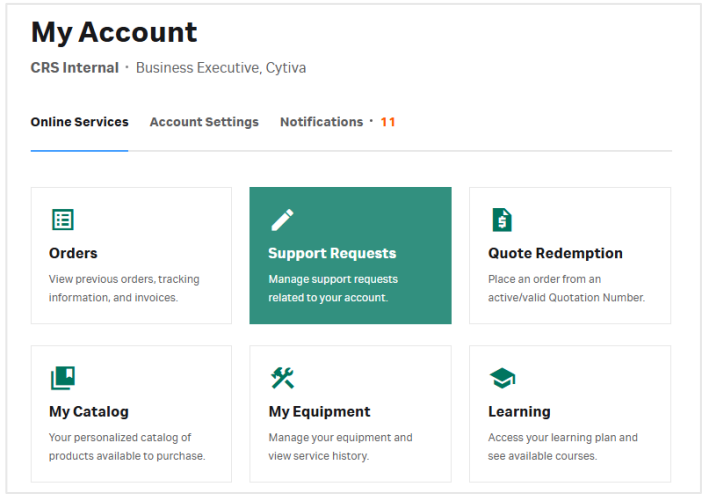
For inquiries or requests not addressed by the Cytiva information platforms

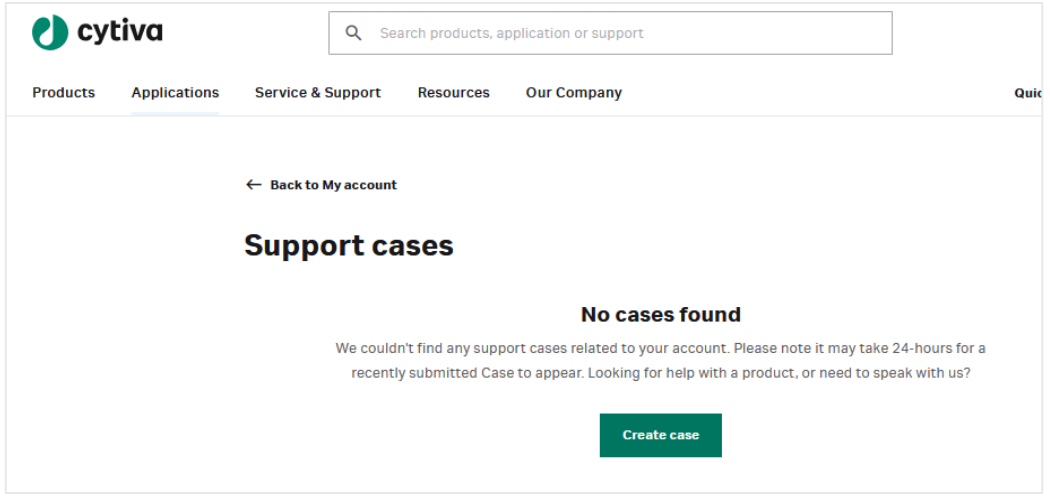
1. Go to www.cytiva.com/account

2. Select 'Support requests'

3. Create case

4. Follow the Help & Support prompt for:
- Invoice query
- Order status
- Price and availability
- Scientific support





You can also create cases by emailing your regional support team.

1 Regulatory support

Change control notification (CCN) service

- Our quality management system ensures our processes adapt to change.
- The service covers the following products used in regulated environments: bioprocess hardware, software, single-use disposables, filtration products, chromatography resins, cell culture products, cell and gene therapy products, and Biacore™ products.
- Our web-based change control notification service alerts you to changes that may impact your product or process.
- What the CCN service offers:
  - Email notifications when a new CCN is published
  - Access to history of all previously published CCNs for a specific product
  - Download files in pdf format

Log in to the regulatory support website

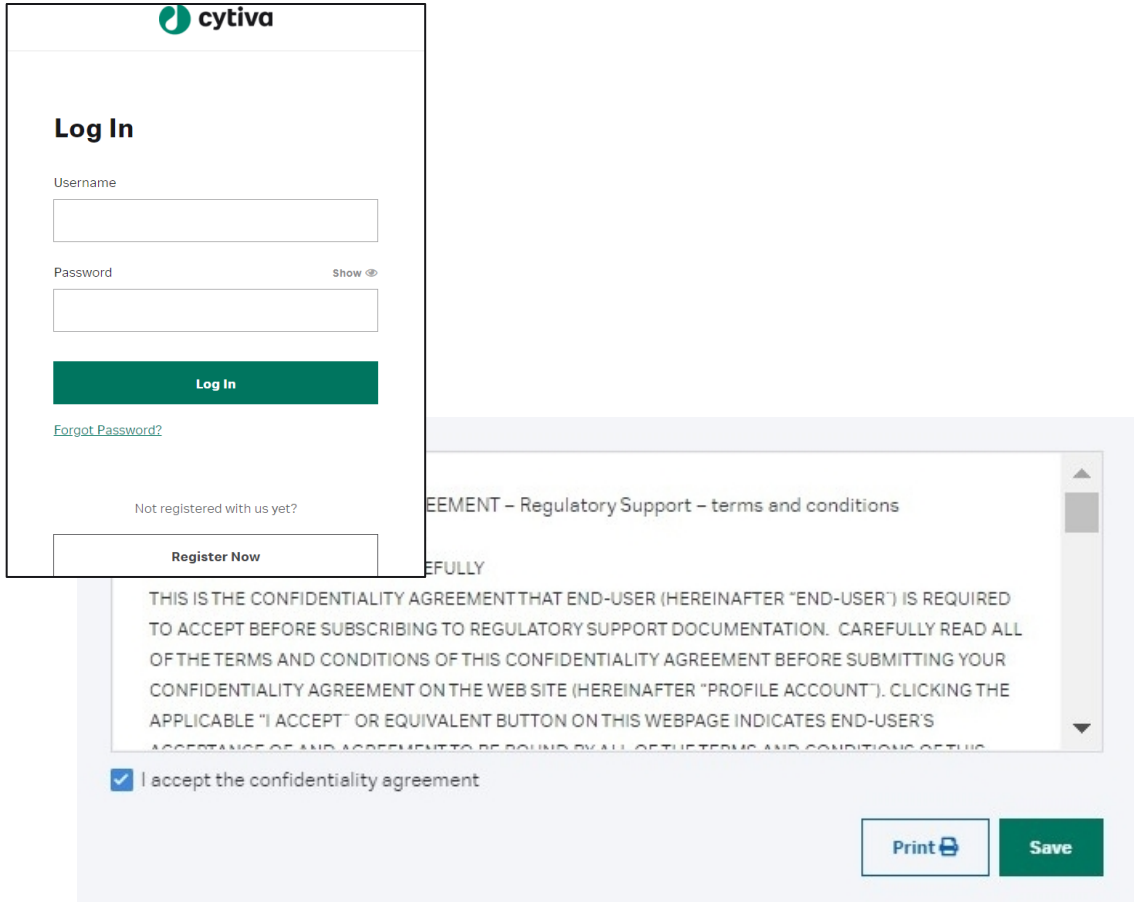
If you already have a cytiva.com account, log in to www.cytiva.com/rsf, with your e-mail address and password.

If you do not have an account, click '**Register now**' and follow the instructions to create one.

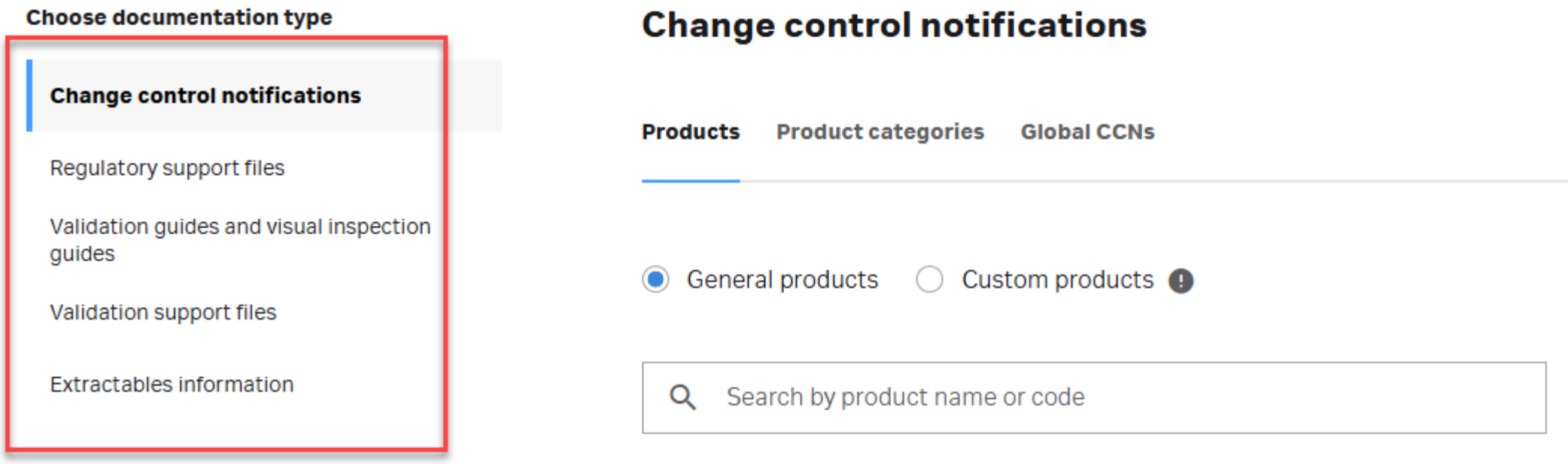
Please remember to register with your company e-mail address.

Consider using a shared mailbox when subscribing to change control notifications (CCNs) to minimize communication gaps that can arise from personnel changes.

If you wish to access confidential files, i.e., validation guides, extractables studies, etc., you can accept the online CDA during registration. Otherwise, you will be prompted when you request access to these documents.



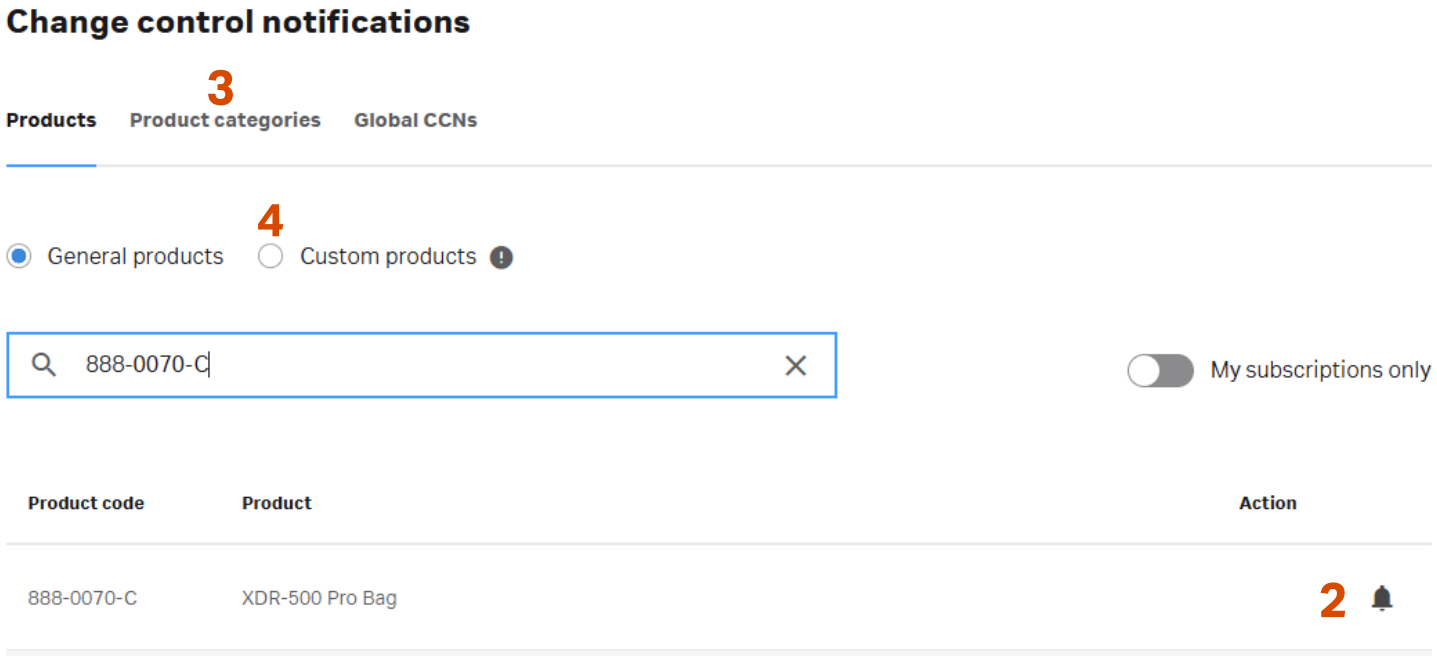
Start your subscription



After logging in to www.cytiva.com/rsf, you will be redirected to Regulatory documentation where you can search and subscribe.

Select the document type you want to subscribe to by navigating the options to your right.

Subscribe to change control notifications (CCNs)



1. Search for a product code (e.g., 888-0070-C) to generate a list of search results.
2. Click the bell icon to subscribe to a product in the search results.
3. For equipment and software, switch tab and search by category.
4. For custom products, ensure Custom products is selected. For custom Hyclone products, please email: changenotice@cytiva.com

Note: Customers should subscribe to both equipment and consumables separately.
For ReadyToProcess™ columns packed with resins, both column and resin require subscriptions.

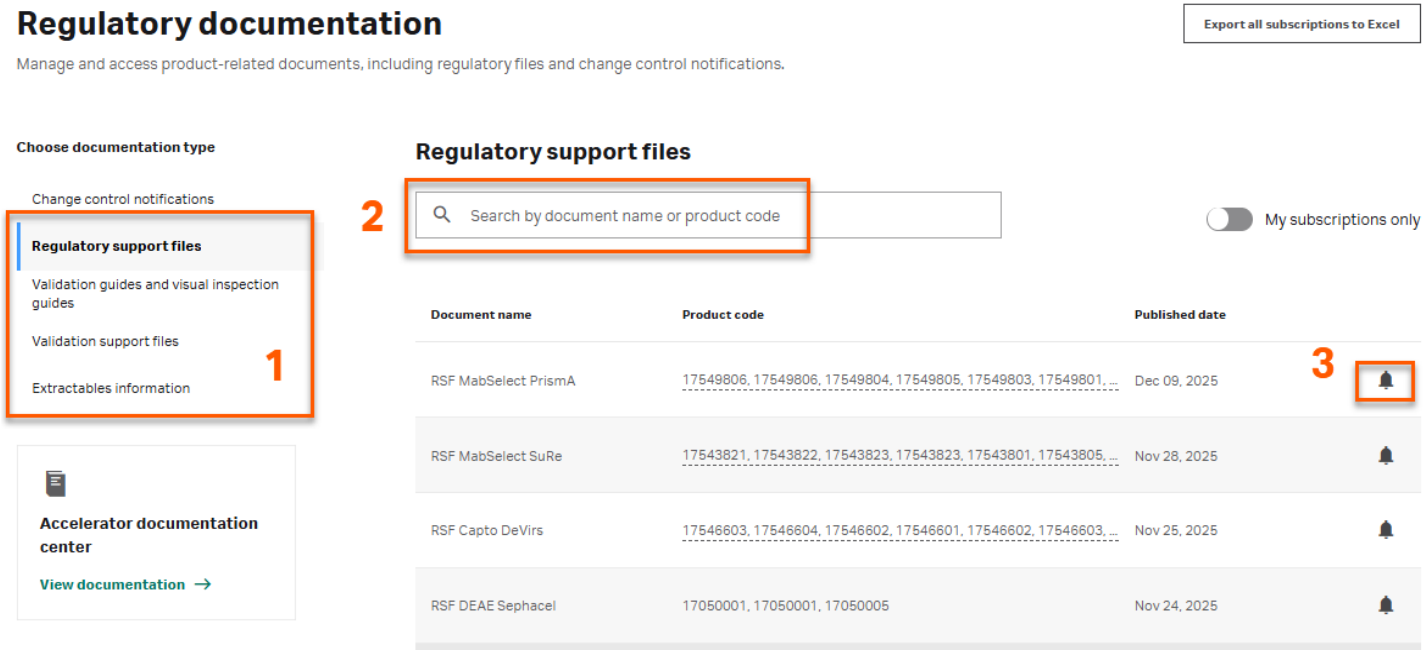
Subscribe to confidential regulatory support documentation

When you subscribe to confidential regulatory support documentation for the first time, our support team will review and approve your request—usually within two business days. While your request is under review, you'll see an online notification, and you'll receive an email once you're approved.

After first approval, you can access most regulatory support documents immediately after adding them.

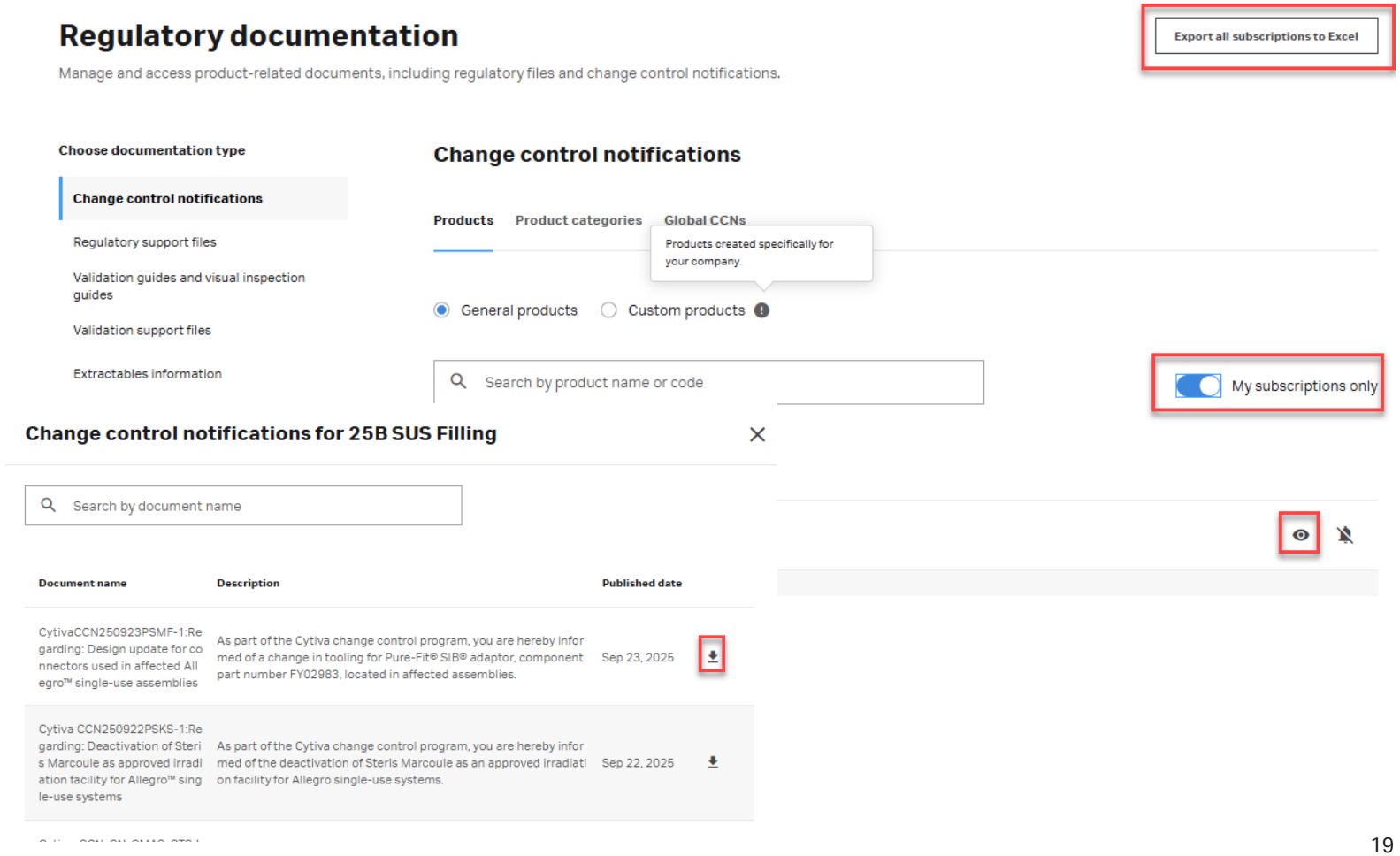
Note: Some subscriptions require an extra approval step due to the sensitivity of the information. If this applies to your request, you'll be notified online. Our support team will handle the additional review, and you'll receive a confirmation email once it's complete.

1. Select document type
2. Search for the product in question
3. Press the bell icon to add it to your subscriptions



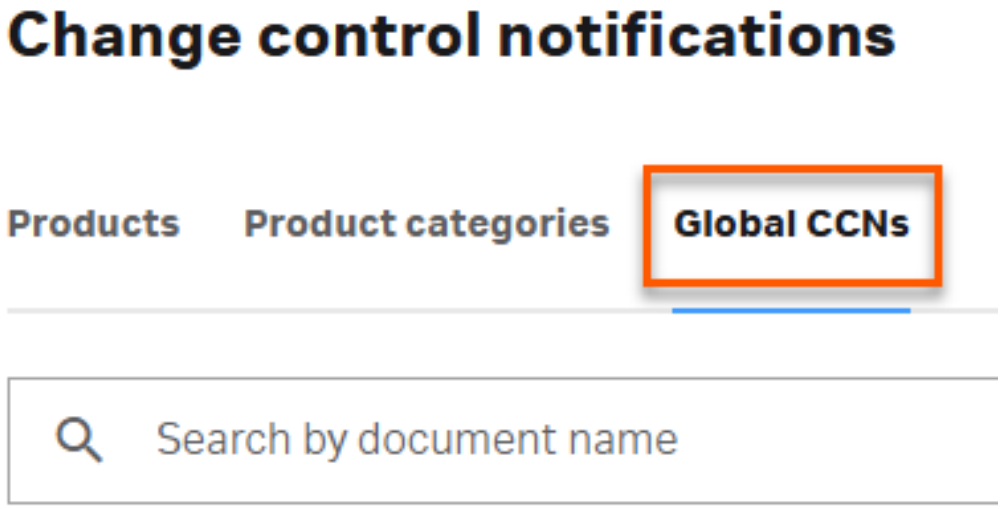
View your active subscriptions for change control notifications

- Select documentation type ‘Change control notifications’ and makes sure you also activate **'My subscriptions only**’.
- Select the part number of interest.
- Press the eye icon and a pop-up window will show you all related CCNs published.
- From this page you can also unsubscribe to any product/CCN category by pressing the crossed over bell icon.
- You can also export a list of your current subscriptions.



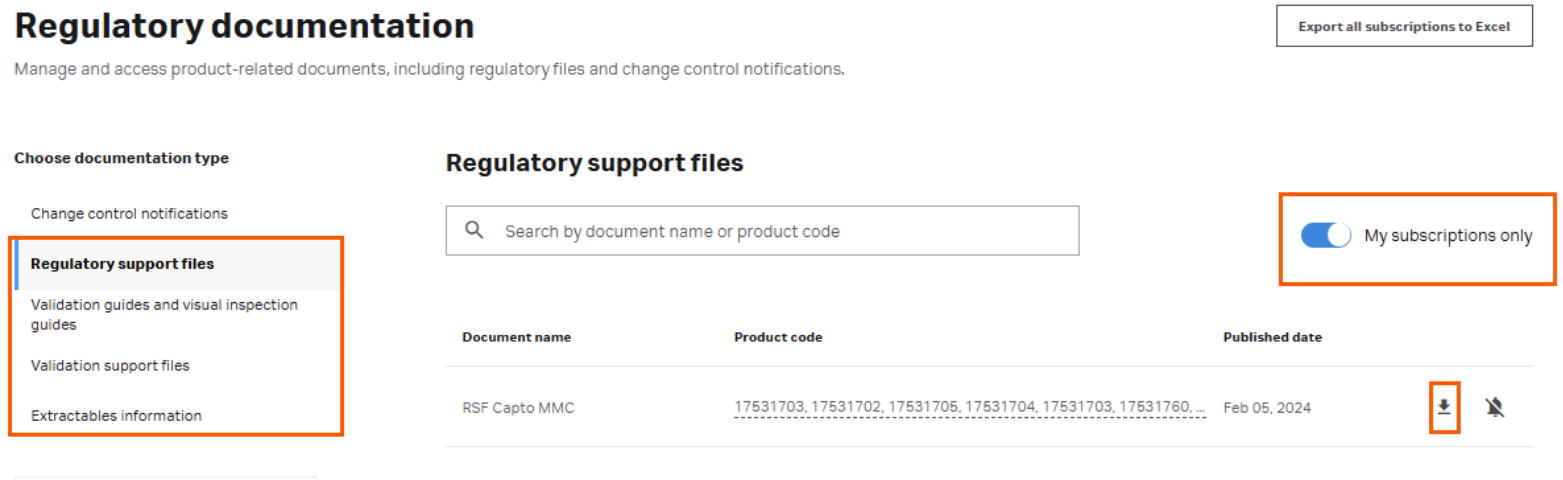
View your active subscriptions for change control notifications

- Global CCNs impact all products, and you are automatically subscribed to global CCNs upon subscription to any product.
- You will find these under the tab '**Global CCNs**'



View your active subscriptions for regulatory support documentation

- Select documentation type e.g. '**Regulatory support files**'
- Makes sure you activate '**My subscriptions only**'.
- Press the download button.
- From this page you can also unsubscribe to any document by pressing the crossed-out bell icon.



E-mail notifications

Change control notifications

You will receive a single e-mail when a CCN is published to your product subscription, even if the CCN covers multiple products. Each e-mail lists all the affected products that you subscribe to.

Regulatory support documentation

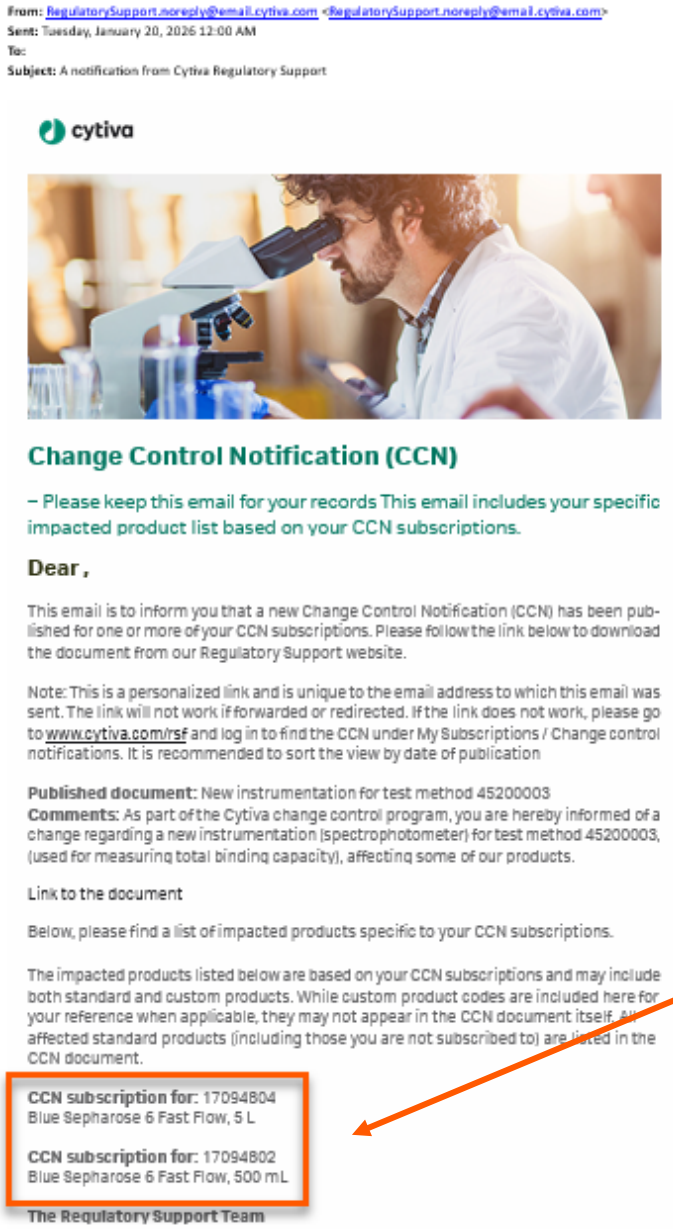
You will receive an e-mail when a document that you subscribe to is updated.

We recommend that you retain your notification email with the CCN for your records.

E-mail notifications: How to read your CCN email

The registered subscriber receives our email.

Click on this link to open the change control notification document.



From: RegulatorySupport.noreply@email.cytiva.com <RegulatorySupport.noreply@email.cytiva.com>
Sent: Tuesday, January 20, 2026 12:00 AM
To:
Subject: A notification from Cytiva Regulatory Support

cytiva

Change Control Notification (CCN)

– Please keep this email for your records This email includes your specific impacted product list based on your CCN subscriptions.

Dear ,

This email is to inform you that a new Change Control Notification (CCN) has been published for one or more of your CCN subscriptions. Please follow the link below to download the document from our Regulatory Support website.

Note: This is a personalized link and is unique to the email address to which this email was sent. The link will not work if forwarded or redirected. If the link does not work, please go to www.cytiva.com/rsf and log in to find the CCN under My Subscriptions / Change control notifications. It is recommended to sort the view by date of publication

Published document: New instrumentation for test method 45200003
Comments: As part of the Cytiva change control program, you are hereby informed of a change regarding a new instrumentation (spectrophotometer) for test method 45200003, (used for measuring total binding capacity), affecting some of our products.

Link to the document

Below, please find a list of impacted products specific to your CCN subscriptions.

The impacted products listed below are based on your CCN subscriptions and may include both standard and custom products. While custom product codes are included here for your reference when applicable, they may not appear in the CCN document itself. All affected standard products (including those you are not subscribed to) are listed in the CCN document.

CCN subscription for: 17094804
Blue Sepharose 6 Fast Flow, 5 L

CCN subscription for: 17094802
Blue Sepharose 6 Fast Flow, 500 mL

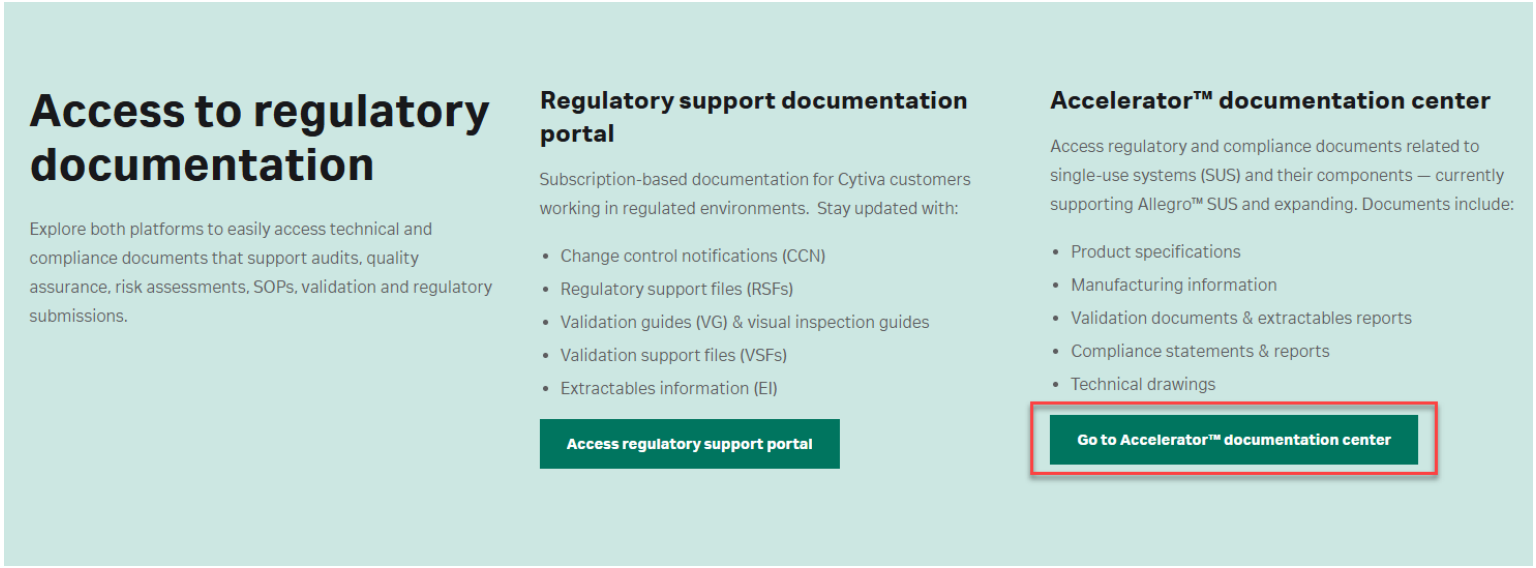
The Regulatory Support Team

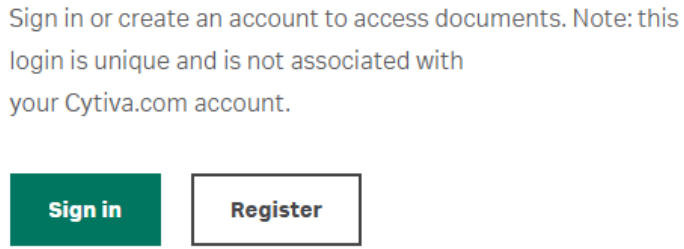
You must be logged in as the subscriber to access the document. Once downloaded, the CCN can be distributed internally.

This section shows which of the products you subscribe to are affected by the change.
We recommend keeping this email with the CCN for your records.

2 Accelerator documentation center

Accelerator documentation center





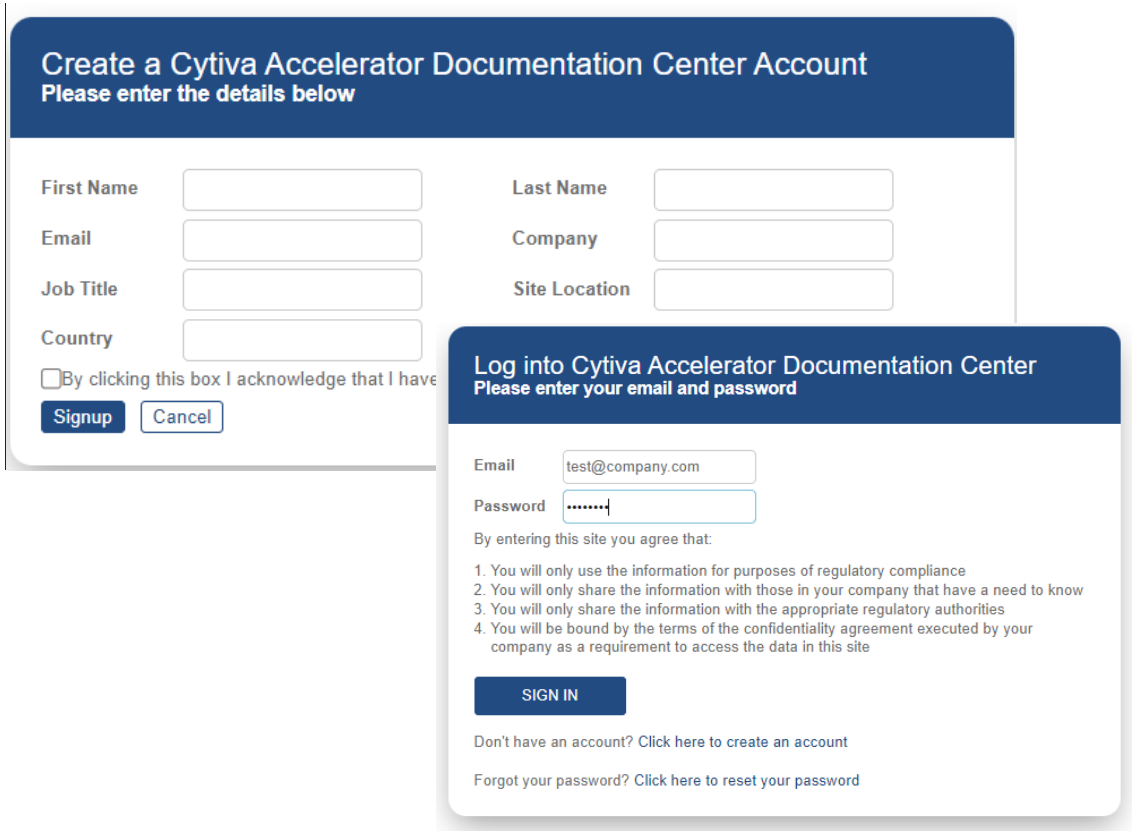
Register and log in to the Accelerator documentation center

If you already have an account, log in to cytiva.com/adc, with your e-mail address and password.

If you do not have an account, click '**Register**' and follow the instructions to create one. This platform does not allow shared user accounts.

Once the account is approved, click '**Sign in**'.

We recommend using Google Chrome to access the Accelerator documentation center.

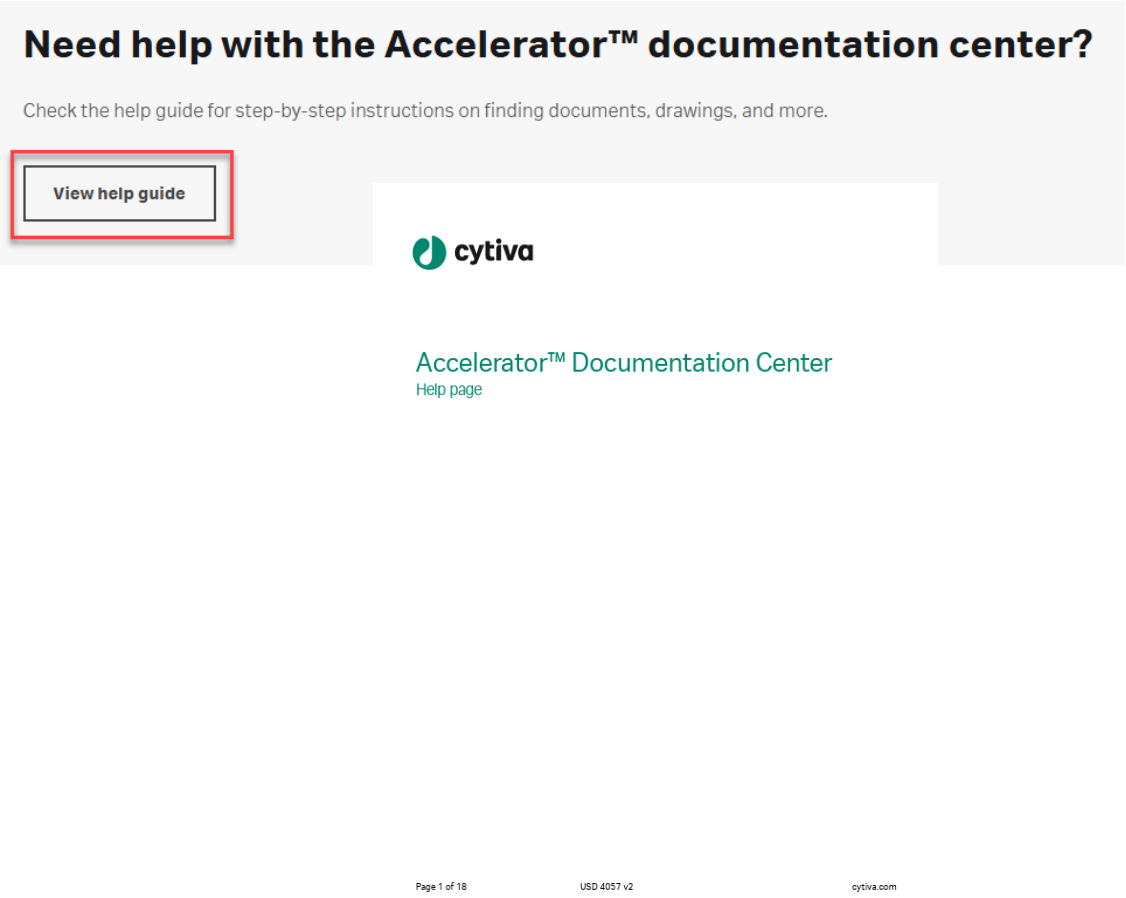


Note: Regulatory support and Accelerator documentation center require two separate login accounts.

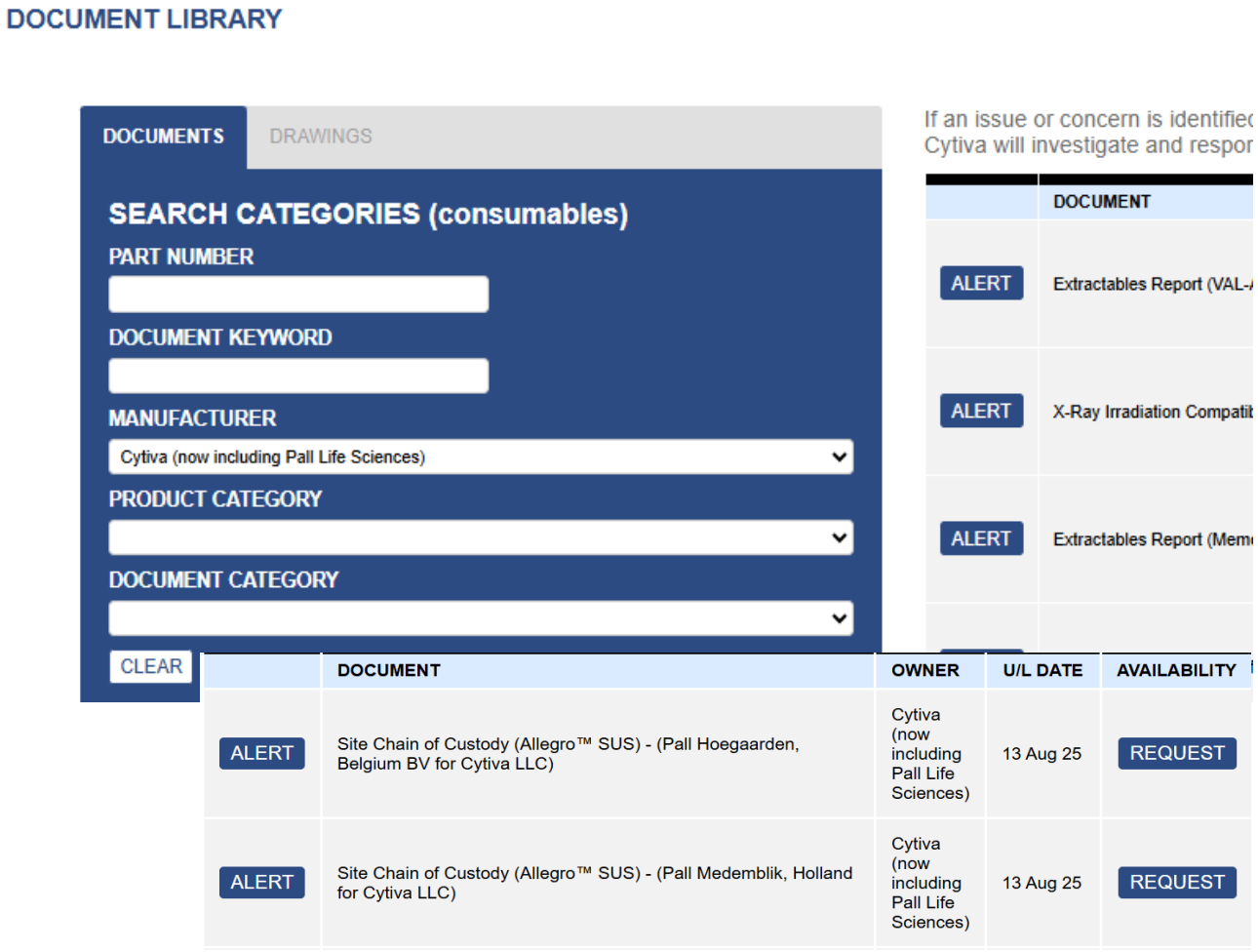
Help for the Accelerator documentation center

Under the Accelerator documentation center sign in and registration page, you will find an extensive help guide.

This guide provides detailed information around the extractable documents, document categories, and drawings that are in the Accelerator documentation center.



Document module in the Accelerator documentation center



Once logged in to the Accelerator documentation center, you'll have multiple ways to access the information:

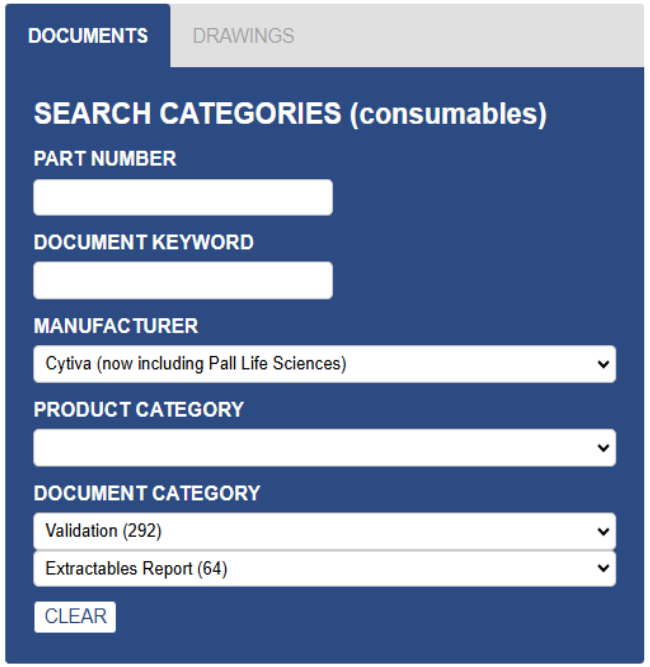
- Searching by component '**Part number**' displays the component's status, the description, and the manufacturer.
- Searching by '**Manufacturer**' displays the available supplier documents.
- Searching by '**Document keyword**' lets you search using exact matches from document names.
- Refine results by product category or document category (or sub-category) e.g., extractable reports.

After entering your search criteria, the availability column will show either '**View**' or '' for documents you can access. **Download**.

For confidential or third-party documents, '**Request**' will appear—this initiates the NDA process.

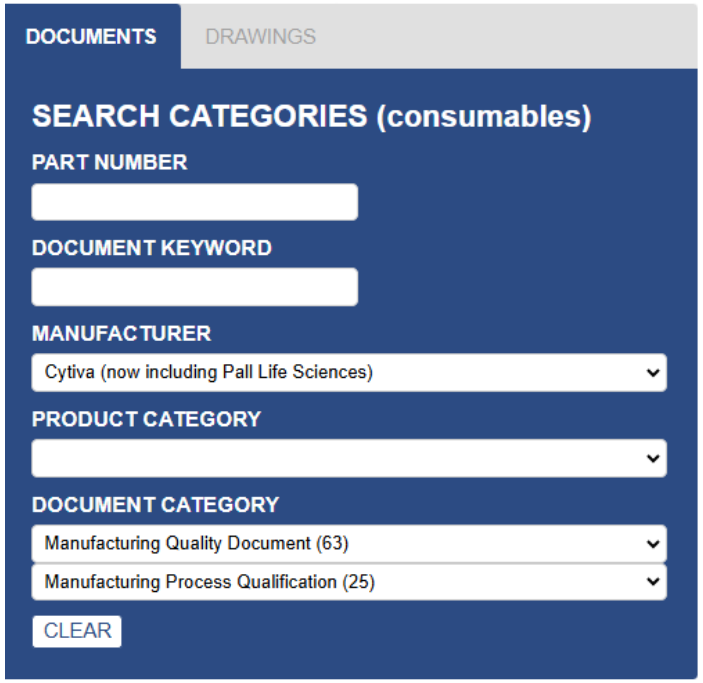
Common document searches

How to find extractable reports, if you do not have a specific ref.

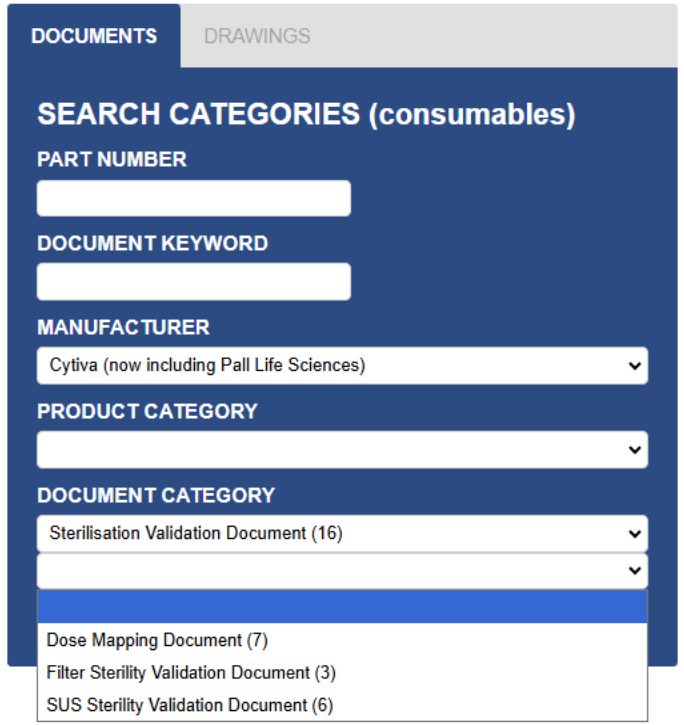


Another optional way to find CCN related extractable reports is available, please see the Help guide.

How to find qualification reports for CCN, if you do not have a specific ref.



How to find sterilization reports and sterilization sites, if you do not have a specific ref.



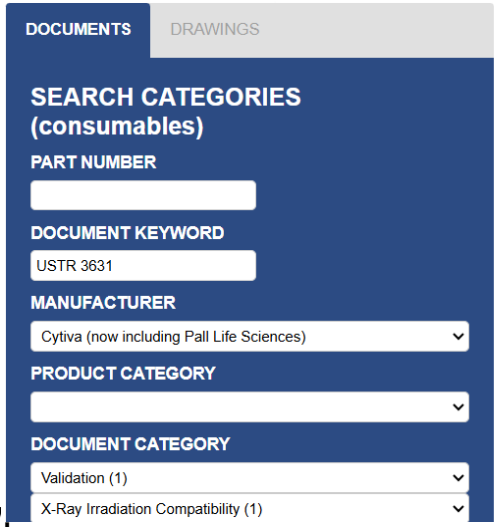
Document categories in the Accelerator documentation center

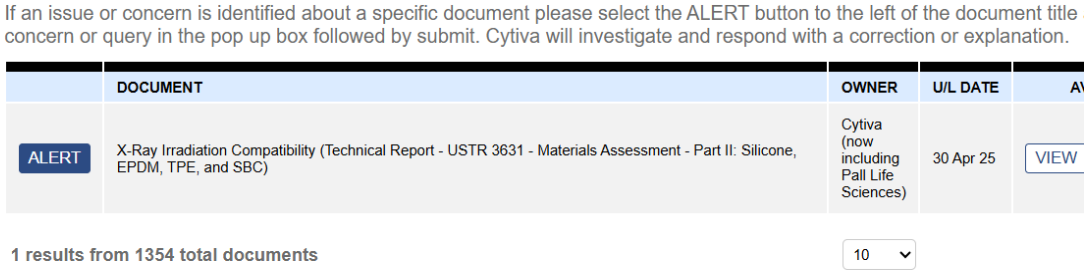
Use the document category dropdown to narrow your search.

Some document categories have sub-categories to help you refine your search further.

A table of categories and sub-categories is available in the help guide.

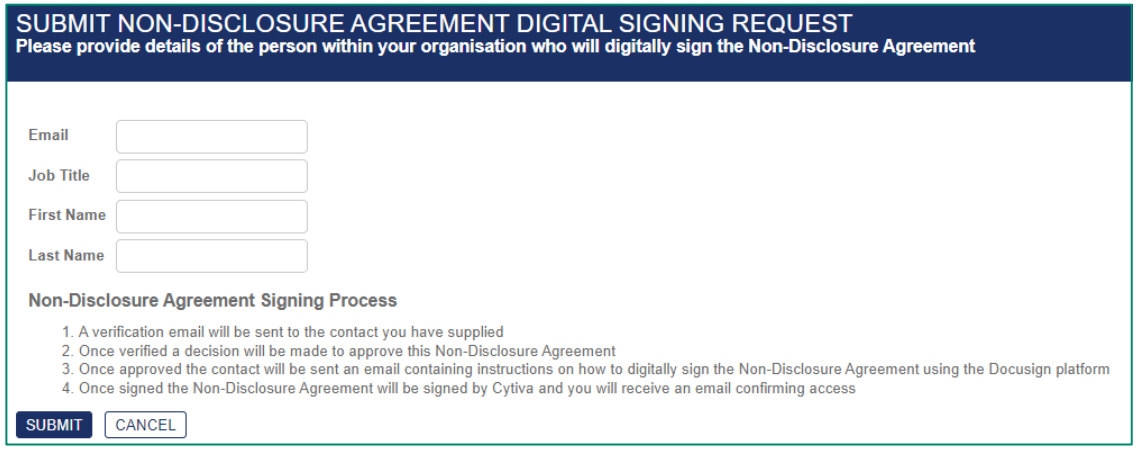
The number in brackets next to each category name indicates how many documents are available in each category.





NDA request in the Accelerator documentation center

	DOCUMENT	OWNER	U/L DATE	AVAILABILITY
ALERT	Site Chain of Custody (Allegro™ SUS) - (Pall Hoegaarden, Belgium BV for Cytiva LLC)	Cytiva (now including Pall Life Sciences)	13 Aug 25	REQUEST
ALERT	Site Chain of Custody (Allegro™ SUS) - (Pall Medemblik, Holland for Cytiva LLC)	Cytiva (now including Pall Life Sciences)	13 Aug 25	REQUEST



- Begin the NDA signing process by selecting '**Request**' against a confidential/third-party document. You should receive a response within three business days.
- Assign someone with appropriate authorization to sign the NDA on behalf of your site.
- Cytiva will process your request. Once the NDA is signed, you'll be able to access confidential and third-party documentation within 48 hours.

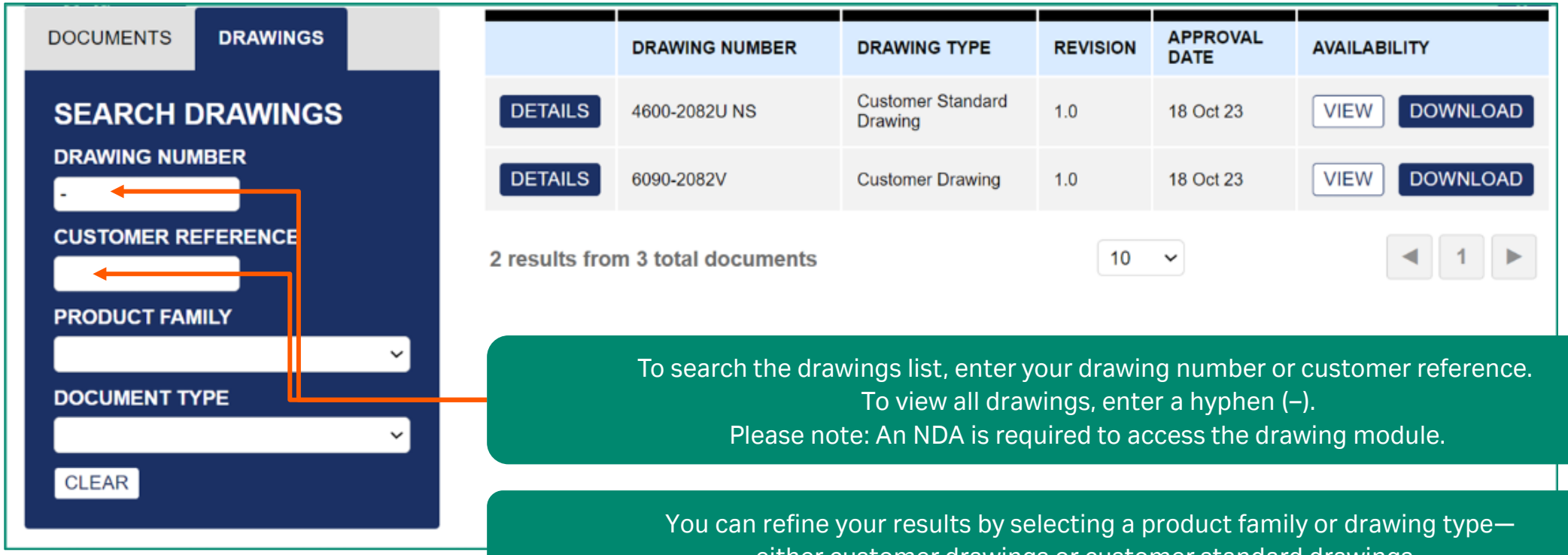
Document alert in the Accelerator documentation center

	DOCUMENT	OWNER	U/L DATE	AVAILABILITY
ALERT	Validation Reports - Performance Data - USTR 4041 Allegro Wand Mixers Performance Validation	Cytiva (now including Pall Life Sciences)	21 Oct 25	VIEW DOWNLOAD
ALERT	Validation Reports - Qualification Report - USTR 4091 - Cellulose material type 2 change in depth filter sheets, modules and capsules (CCN 240117PFOR-1)	Cytiva (now including Pall Life Sciences)	16 Oct 24	VIEW DOWNLOAD
ALERT	Validation Reports - USTR 3814 - Allegro Connect Depth Filtration System - Operating Limits	Cytiva (now including Pall Life Sciences)	29 Nov 24	VIEW DOWNLOAD

If an issue or concern is identified with a specific document, select '**Alert**' against the relevant document, enter the concern or query and submit or if, you prefer to, email acms-doccontrol@cytiva.com

Cytiva will investigate and respond with a correction or explanation within three business days.

Drawing module in the Accelerator documentation center



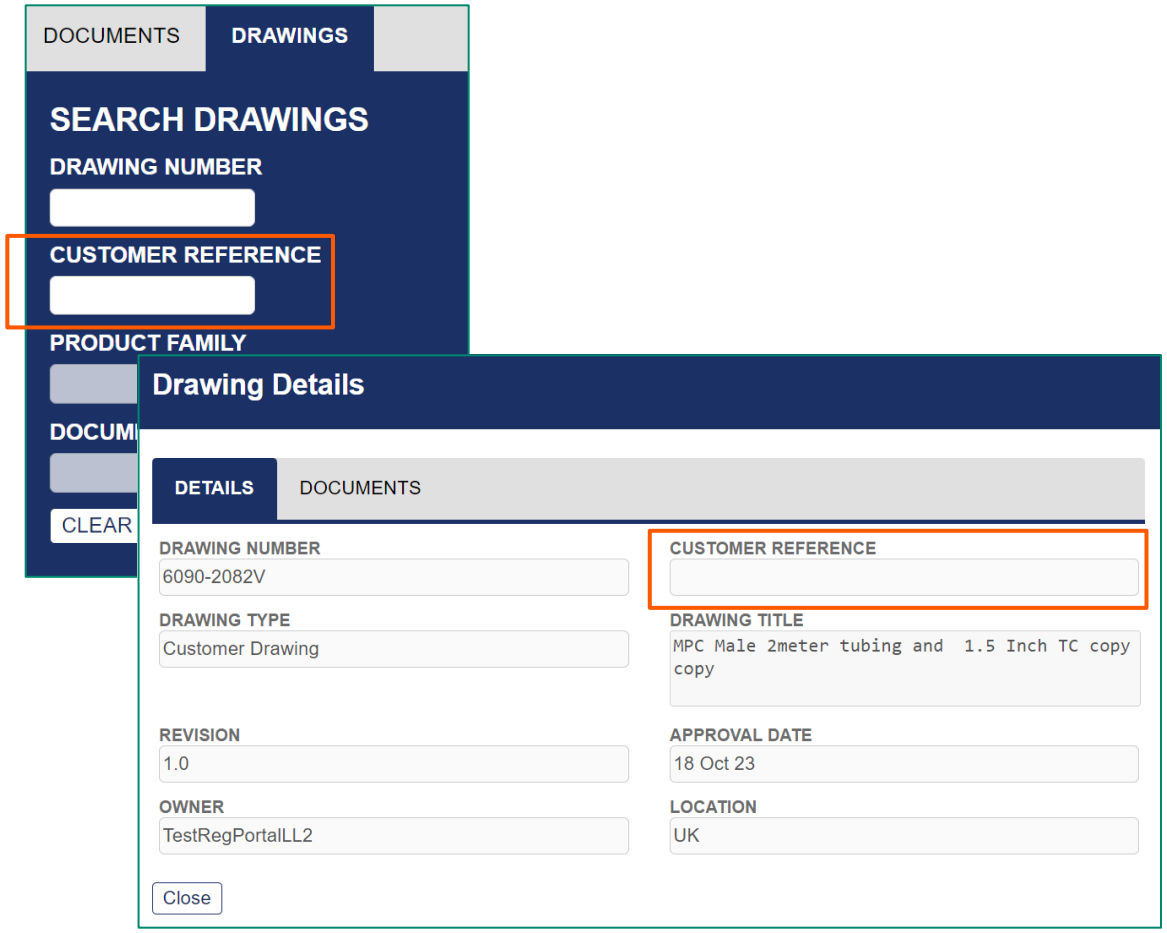
To search the drawings list, enter your drawing number or customer reference.
To view all drawings, enter a hyphen (–).
Please note: An NDA is required to access the drawing module.

You can refine your results by selecting a product family or drawing type—
either customer drawings or customer standard drawings.

Drawings and drawing documents available are:

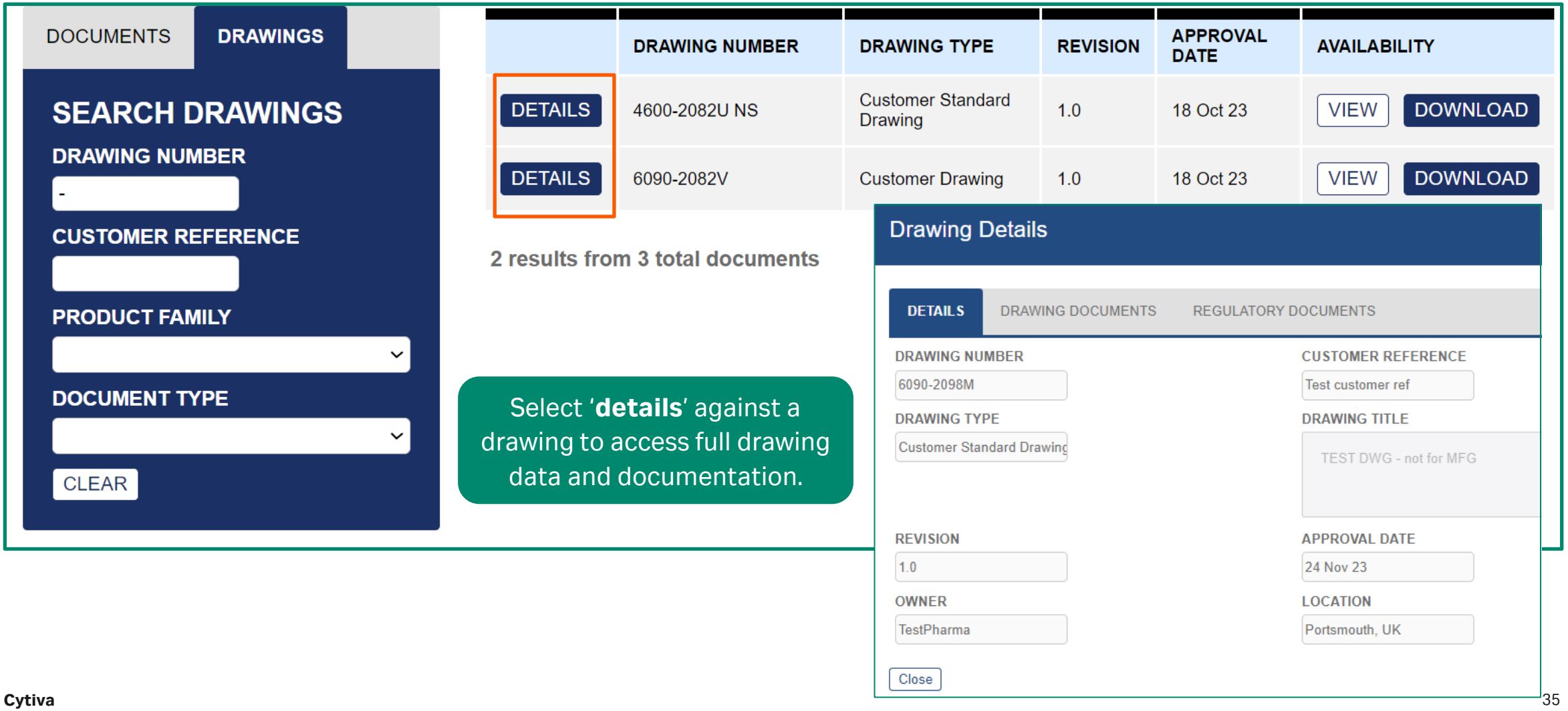
- Latest version of approved drawings only.
- English versions only.
- Your own designated sites' drawings.
- Drawings 'shared' with your designated site.

Drawing module in the Accelerator documentation center – customer references

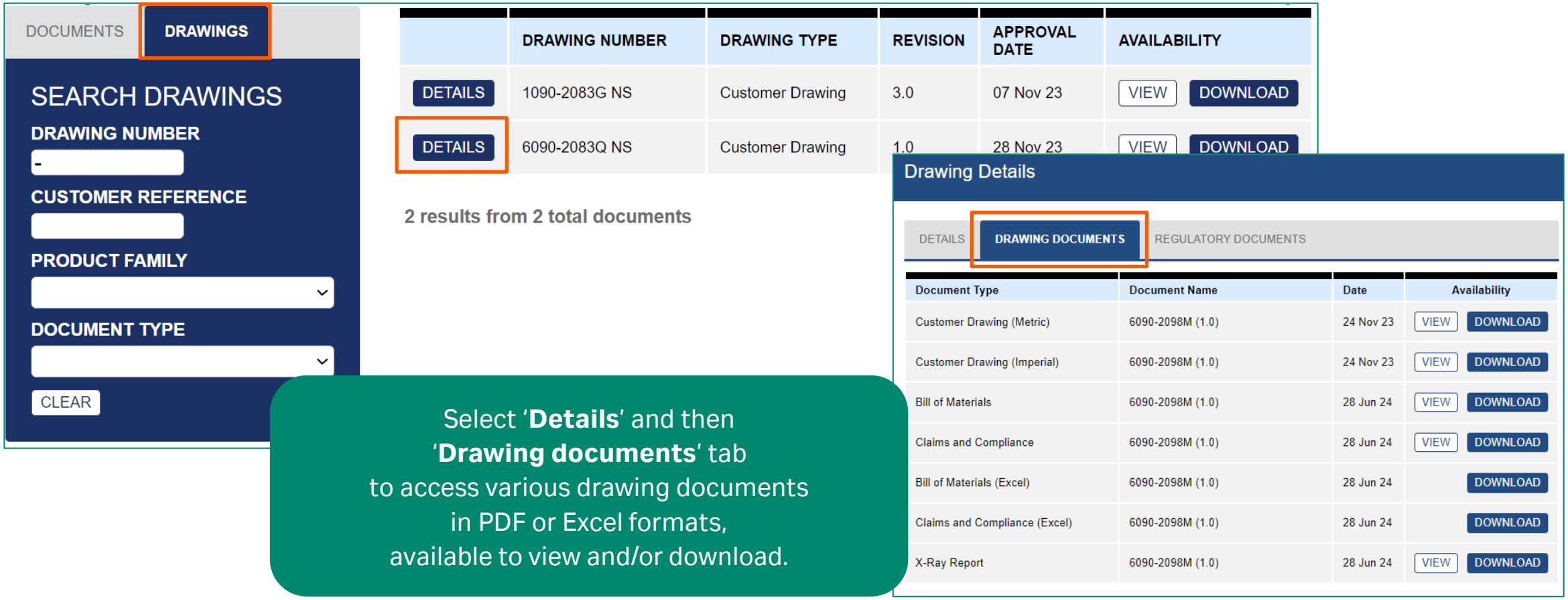


- You can request to add your own references to each design. Once added by your Cytiva sales/account manager, you can use these references to search for your drawings after 24 hours of the change.
- We can add customer drawing references without revision to the design.
- You can view your customer reference on the drawing details page.

Drawing module in the Accelerator documentation center – drawing details

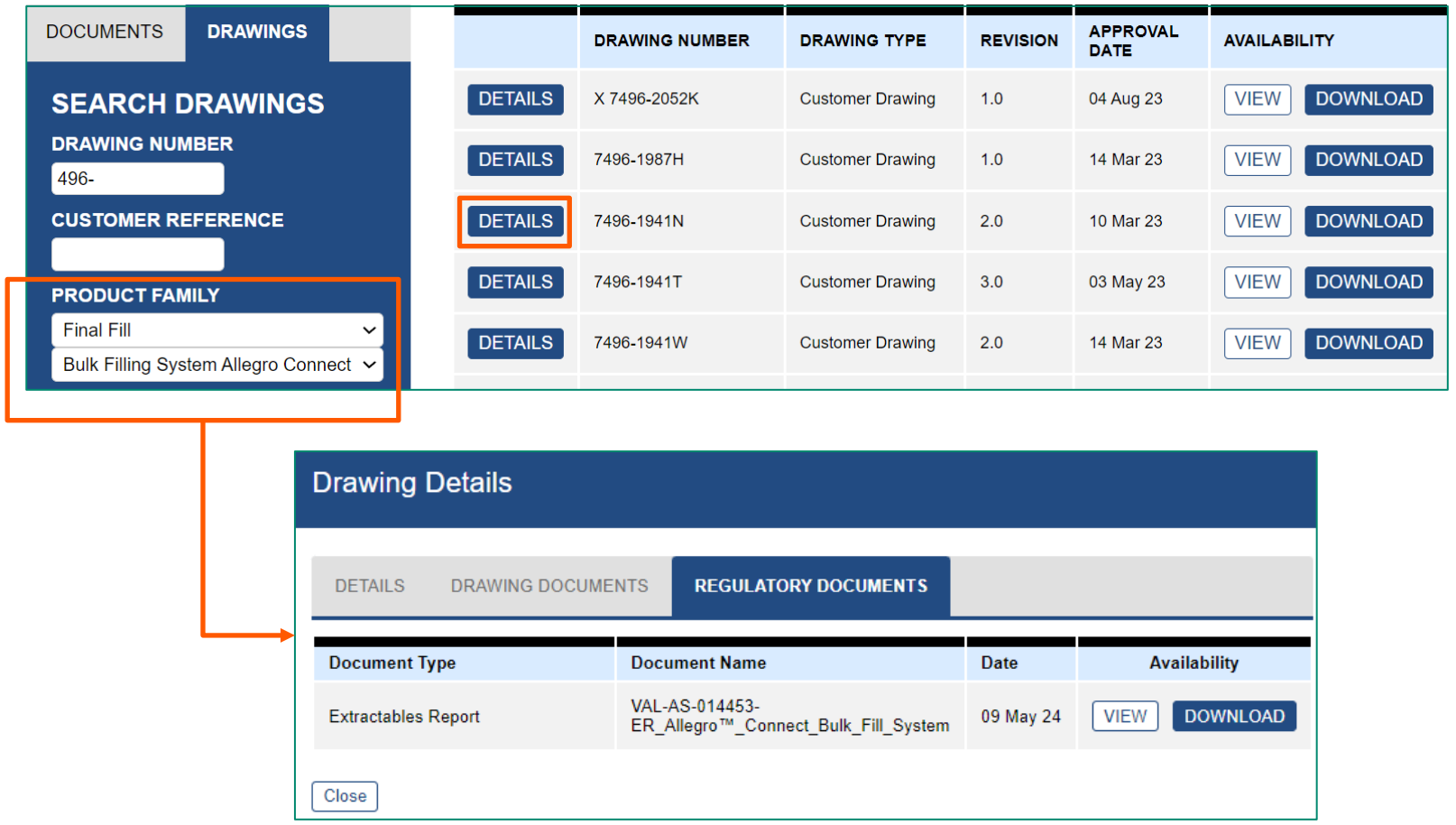


Drawing module in the Accelerator documentation center – drawing details



Select '**Details**' and then '**Drawing documents**' tab to access various drawing documents in PDF or Excel formats, available to view and/or download.

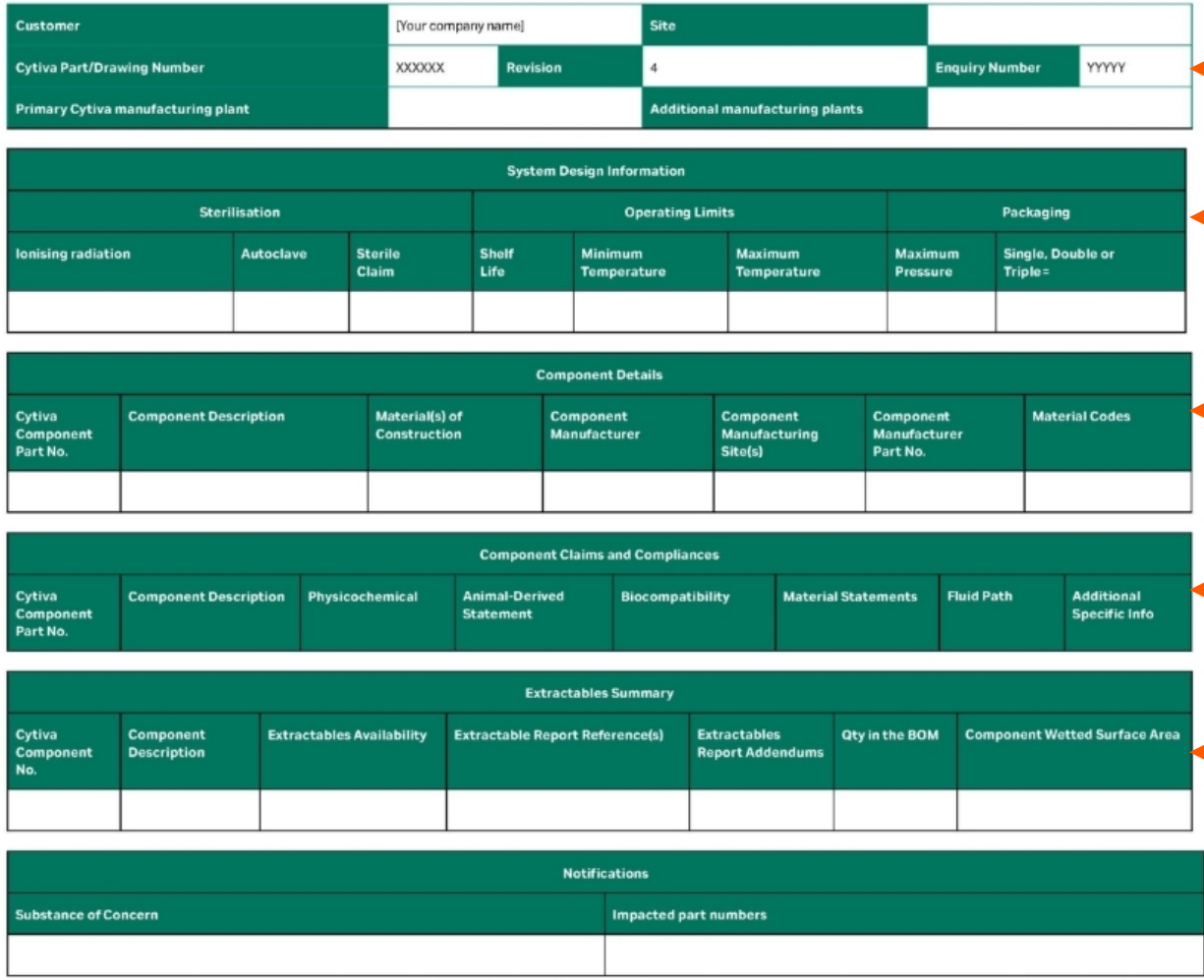
Drawing module in the Accelerator documentation center – regulatory documentation



Product-specific documentation is available under the '**Regulatory documentation**' tab for a drawing.

This shows documentation linked to a specific drawing product line.

Claims and compliance reports in the Accelerator documentation center



Customer	[Your company name]		Site		
Cytiva Part/Drawing Number	XXXXXX	Revision	4	Enquiry Number	YYYYY
Primary Cytiva manufacturing plant			Additional manufacturing plants		

System Design Information							
Sterilisation			Operating Limits			Packaging	
Ionising radiation	Autoclave	Sterile Claim	Shelf Life	Minimum Temperature	Maximum Temperature	Maximum Pressure	Single, Double or Triple=

Component Details						
Cytiva Component Part No.	Component Description	Material(s) of Construction	Component Manufacturer	Component Manufacturing Site(s)	Component Manufacturer Part No.	Material Codes

Component Claims and Compliances							
Cytiva Component Part No.	Component Description	Physicochemical	Animal-Derived Statement	Biocompatibility	Material Statements	Fluid Path	Additional Specific Info

Extractables Summary						
Cytiva Component No.	Component Description	Extractables Availability	Extractable Report Reference(s)	Extractables Report Addendums	Qty in the BOM	Component Wetted Surface Area

Notifications	
Substance of Concern	Impacted part numbers

Introduction page of claims and compliance report.

General drawing details, including the Cytiva primary/additional manufacturing sites.

System design information, such as pressure, shelf life.

Component details such as material of construction, Cytiva resin code, wetted surface area etc.

Where designs contain Cytiva-manufactured chambers, sub/ancillary component data is listed.

Component and sub-component claims and compliances.

Extractables summary.

Notification table of components containing substances of concern.

Definition table at end of report.

www.cytiva.com

Cytiva , and the Drop logo are trademarks of Life Sciences IP Holdings Corporation or an affiliate doing business as Cytiva.
Accelerator, Allegro, Biacore, Hyclone and ReadyToProcess are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.
Any other trademarks are the property of their respective owners.

The Danaher trademark is a proprietary mark of Danaher Corporation.

© 2026 Cytiva

For local office contact information, visit cytiva.com/contact

CY54837-16FEB26-PP

cytiva.com