cytiva

Change control and regulatory documentation

Navigation and access

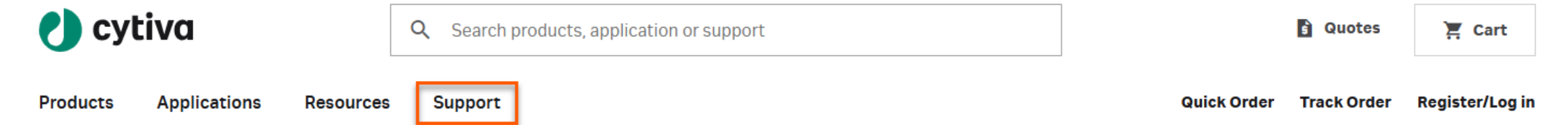
danaher

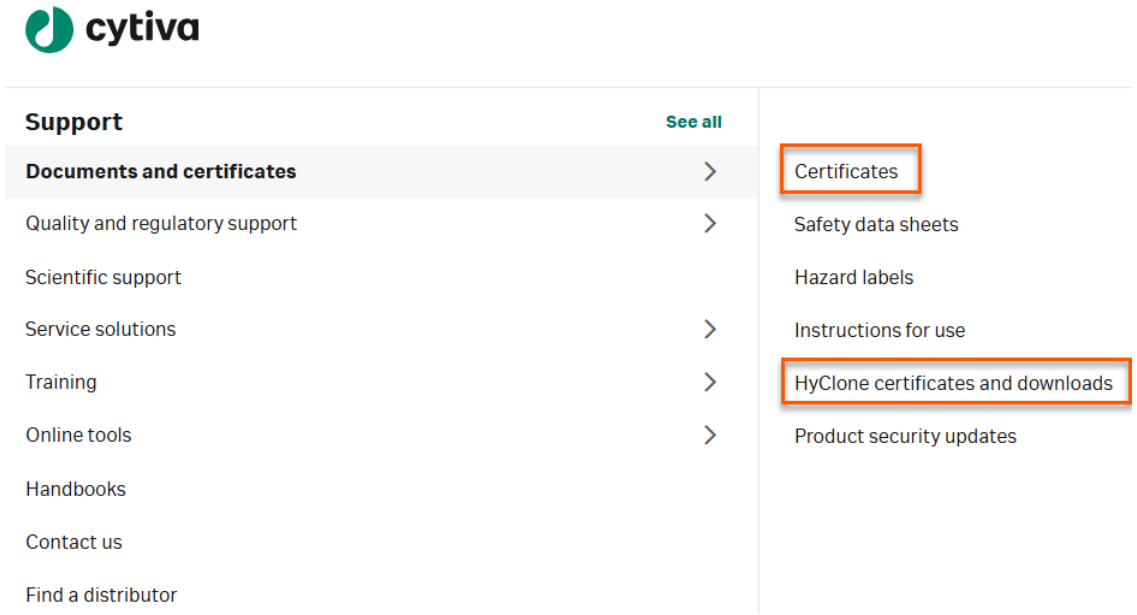
The regulatory support documentation is an invaluable starting point for process development and validation. It is also critical for preparing standard operating procedures (SOPs), quality control, and for supporting clinical and marketing applications to regulatory agencies.

Presentation overview and quick links

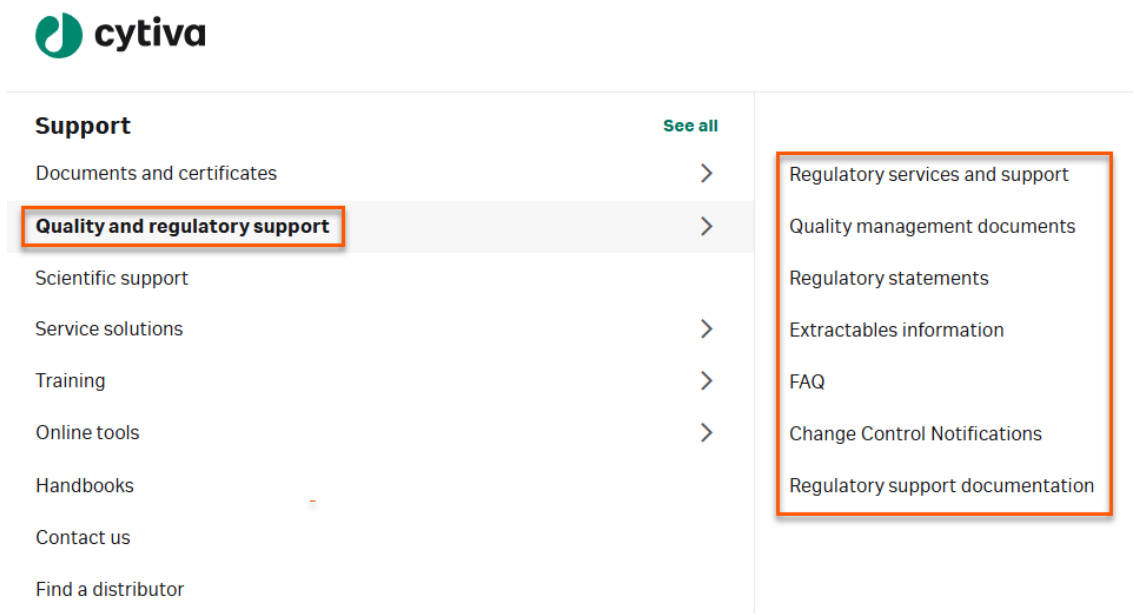
- Two separate online systems
  - Cytiva's regulatory support documentation – summary
- Accessing extractables information
- Locating your lot-specific product certificate
- Log in to the regulatory support website
  - Start your subscription
  - View your active subscriptions
- E-mail notifications
- 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





www.cytiva.com/certificates



www.cytiva.com/rsf

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.

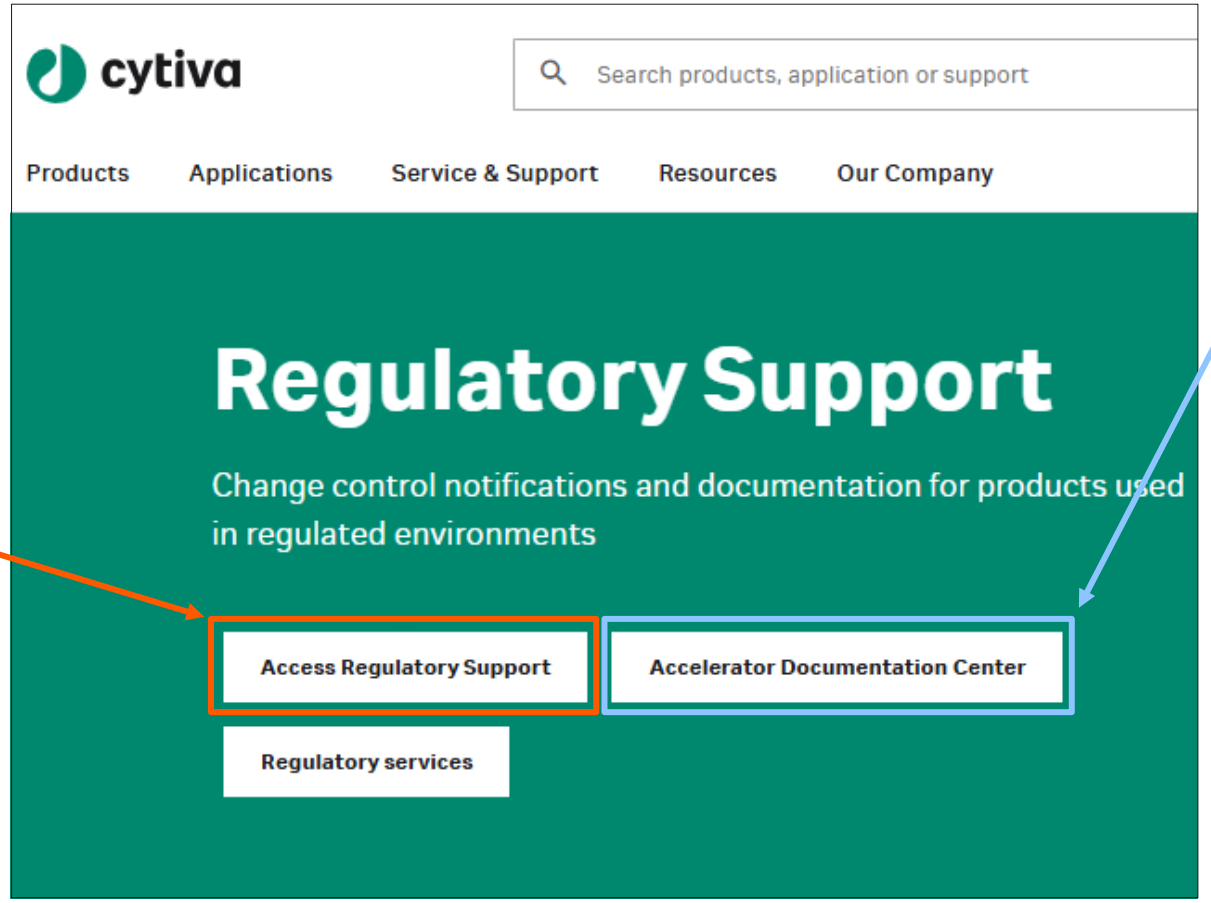
Two separate online systems

With different documents and different logins

Regulatory support 1

For all Change Control Notifications (CCN) and Regulatory documents such as RSF, VG, VSF and EI.

cytiva.com/rsf
Login: Cytiva web account required



2 **Accelerator documentation center**

For documents related to Allegro™ single-use systems and associated filters and aseptic connectors. Includes drawings, compliance reports, and technical details. Sometimes an NDA is required

cytiva.com/adc
Login: Separate account required

Cytiva's regulatory support documentation – summary

Access without login

- Quality management documents
- Regulatory statements
- Extractables testing/approach
- Global site certificates such as ISO certificates

Access with login

- Change control notifications (CCN) by subscription

Access via subscription with login + online CDA

- Regulatory support documentation by subscription
- Regulatory support files, validation guides, and validation support files
- Extractables reports
- Visual inspection libraries

Accelerator documentation center with login

- Documentation* for Allegro single-use systems and associated filters and aseptic connectors
- Drawings and bill of materials (BOMs)
- Compliance documents and The claims and compliance report
- Validation documents and technical reports
- Extractables reports
- Visual inspection library

On request only

- 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/us/support/quality/regulatory-support/extractables-information

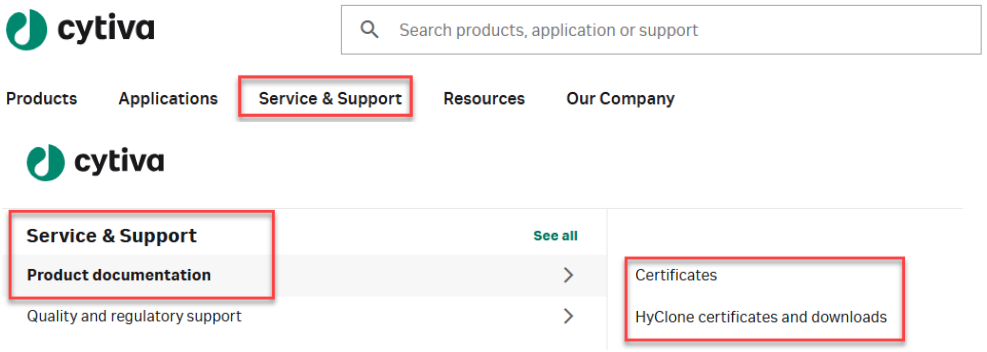
The actual information and reports are accessible on our two websites:

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

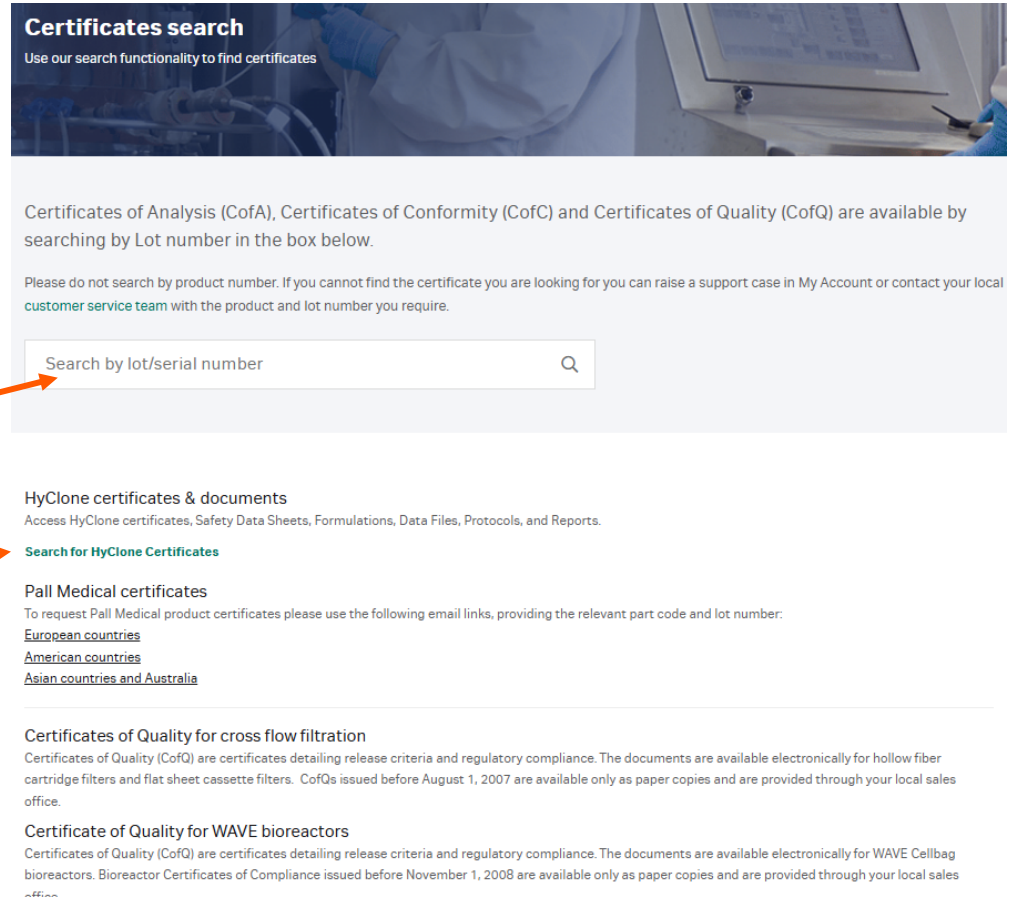
The webpage above guides you on where to locate extractables information and reports based on product type.

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

Locating your lot-specific product certificate



- www.cytiva.com/certs
- Search by lot or serial number
- Additional links for Hyclone™ and Pall Medical products



Regulatory support documentation: on request only

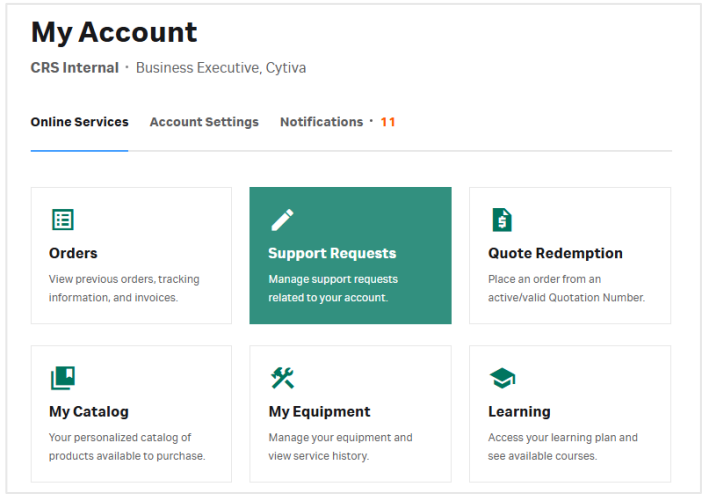
For inquiries or requests not addressed by the Cytiva information platforms

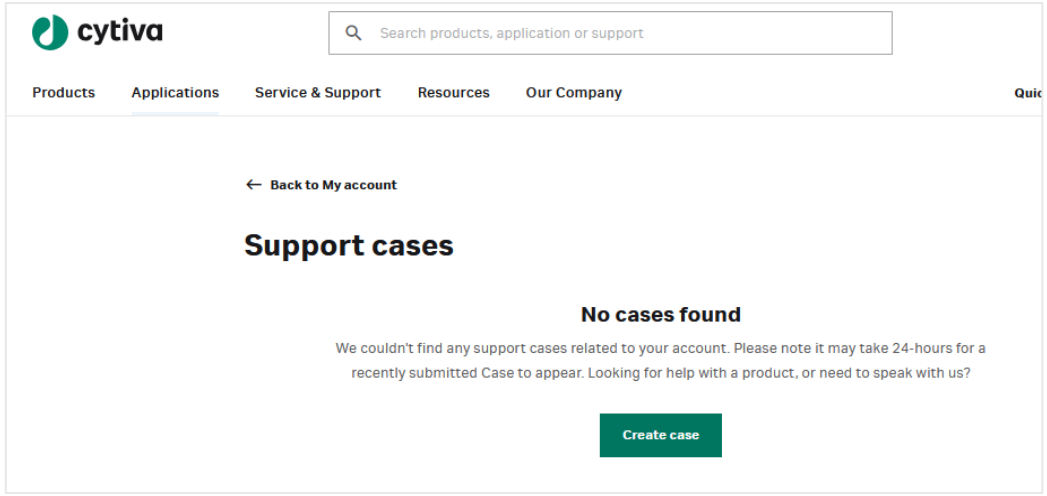
1. Go to www.cytiva.com/account

2. Select 'Support cases'

3. Create case

4. Follow the help and 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

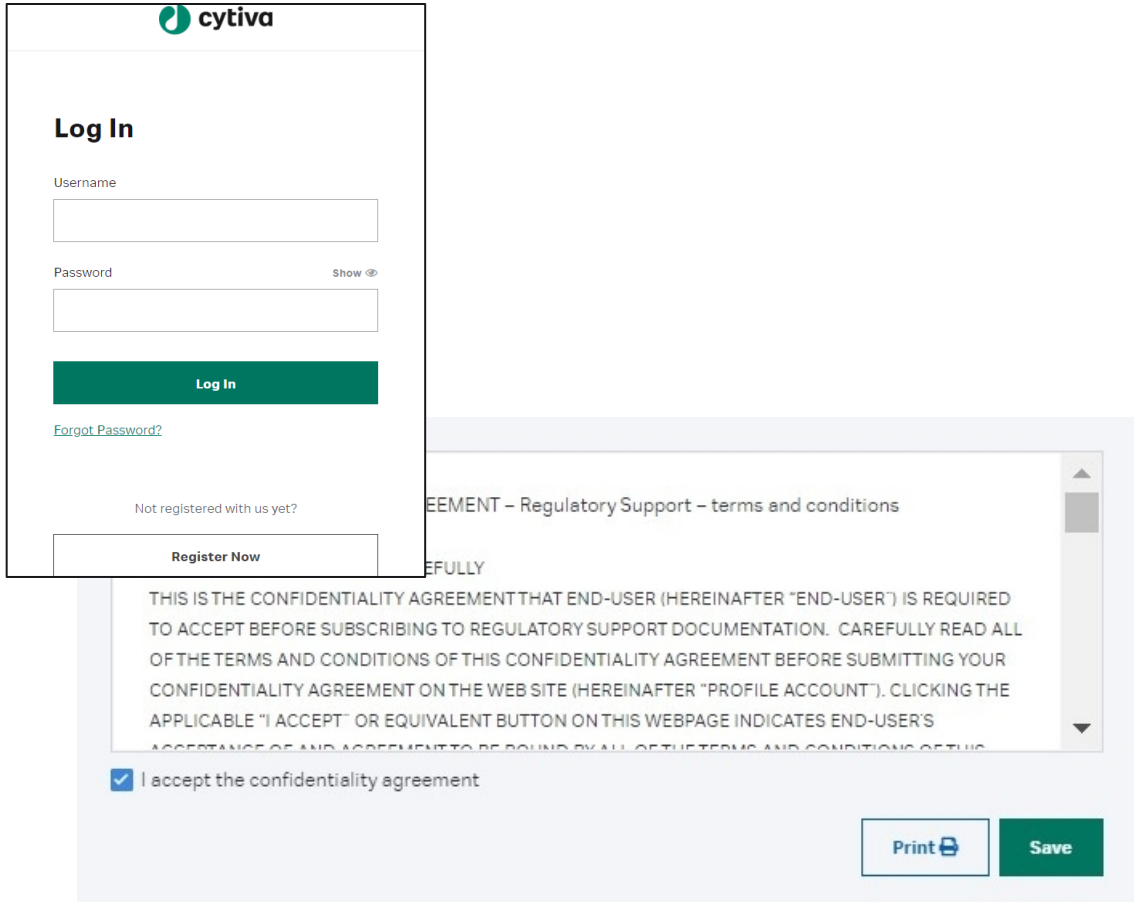
If you already have a cytiva.com account, log in to www.cytiva.com/rsf, with your e-mail address and password.

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.

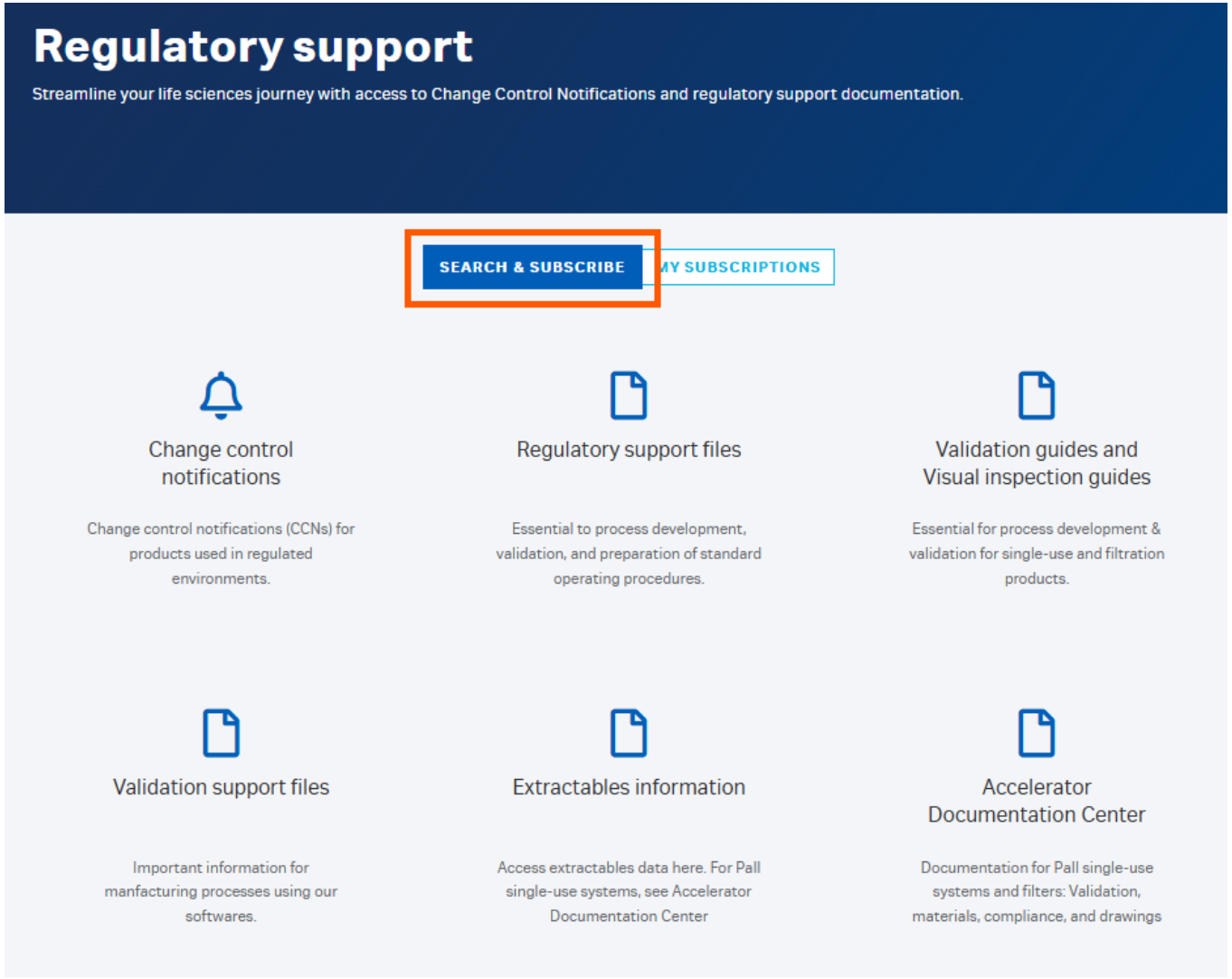
If you wish to access confidential files, i.e., validation guides, extractables studies, etc., you can accept the online CDA during registration. Otherwise, you will be prompted when you request access to these documents.



Start your subscription

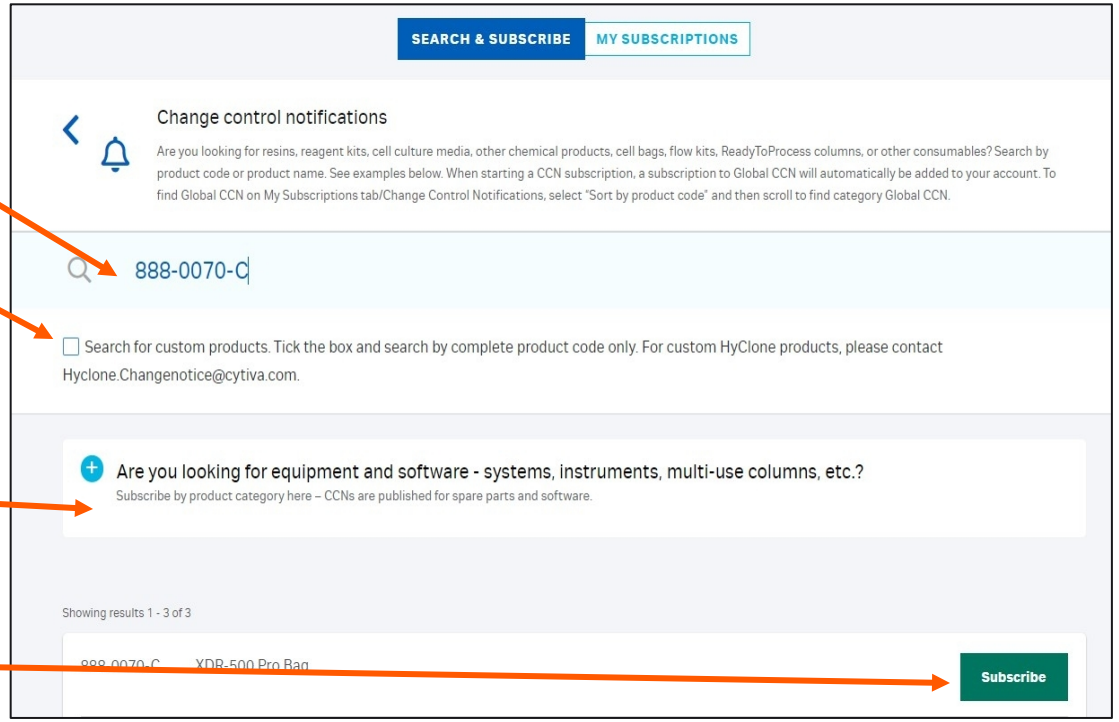
After logging in to www.cytiva.com/rsf, you will be redirected to 'Search & subscribe' on the regulatory support website.

Select the document types you want to subscribe to by clicking the boxes.



Subscribe to change control notifications (CCNs)

- Search for a product code (e.g., 888-0070-C) to generate a list of search results.
- For custom products, ensure this box is checked.
  For custom Hyclone products – please email: changenotice@cytiva.com
- For equipment and software, search by category here.
- Click ‘Subscribe’ to subscribe to a product in the search results.



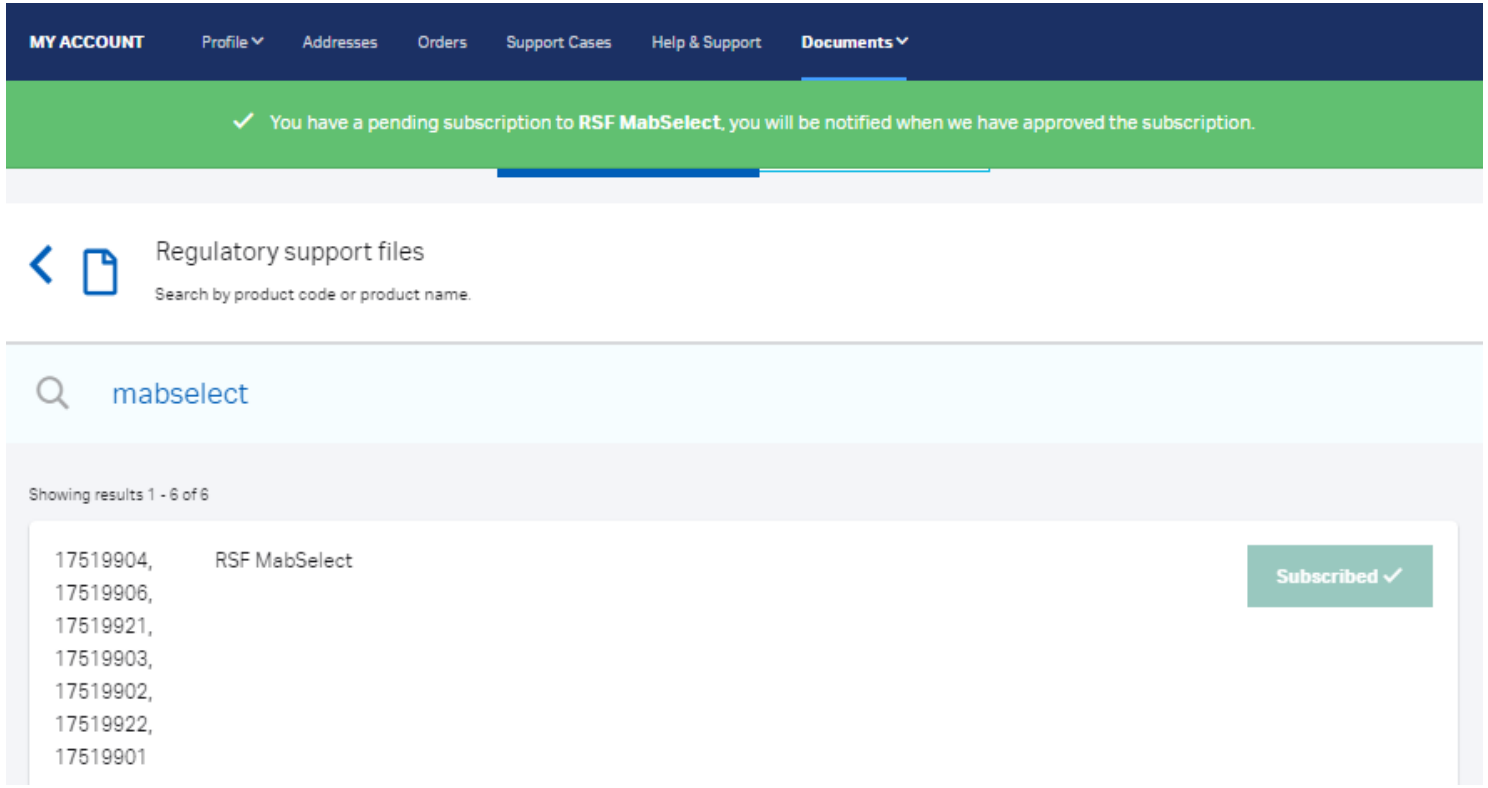
Note: Customers should subscribe to both equipment and consumables separately.
For ReadyToProcess™ columns packed with resins, both column and resin require subscriptions.

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 receive an email once it's approved.

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

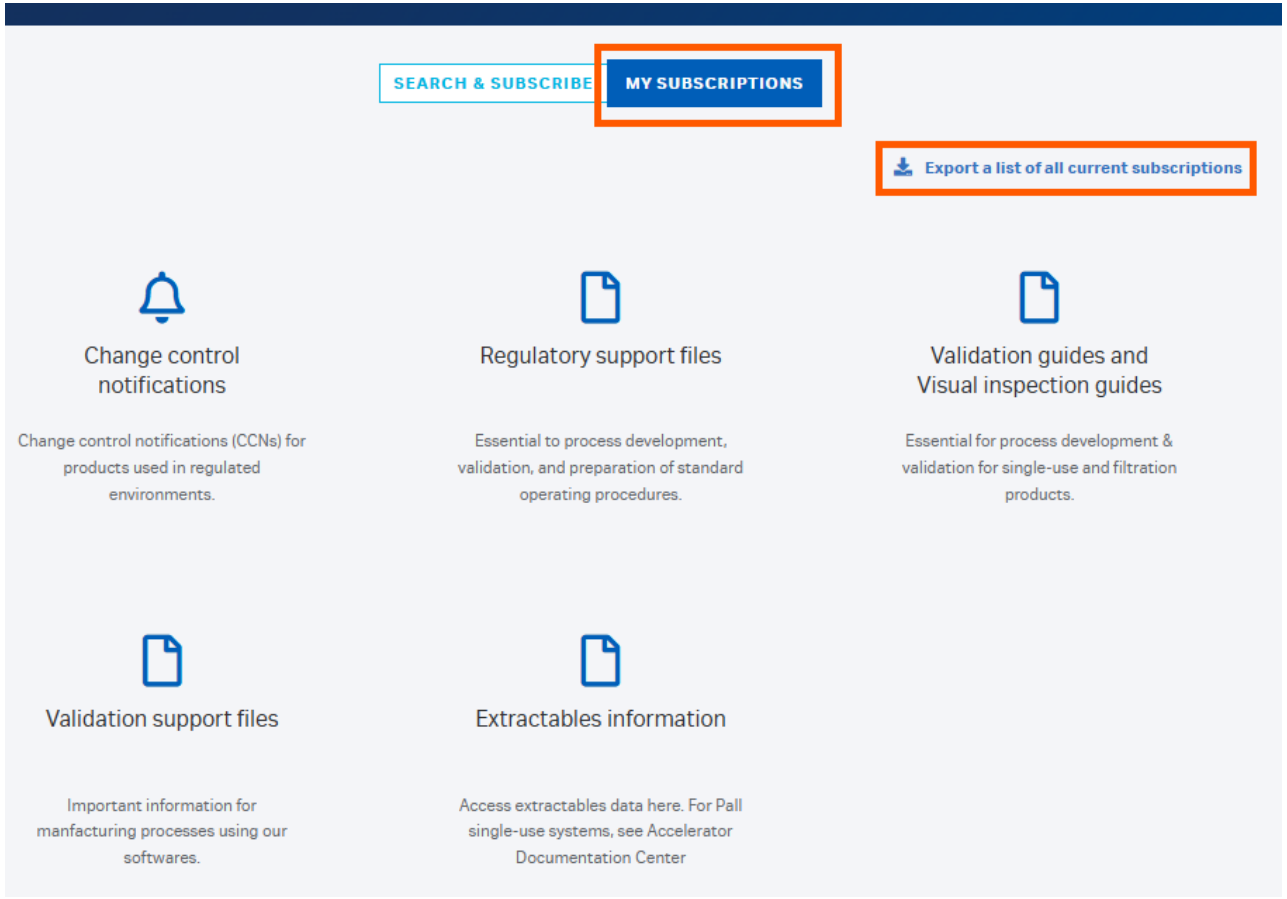
Note: Some subscriptions require an extra approval step due to the sensitivity of the information. If this applies to your request, you'll be notified online. Our support team will handle the additional review, and you'll receive a confirmation email once it's complete.



View your active subscriptions

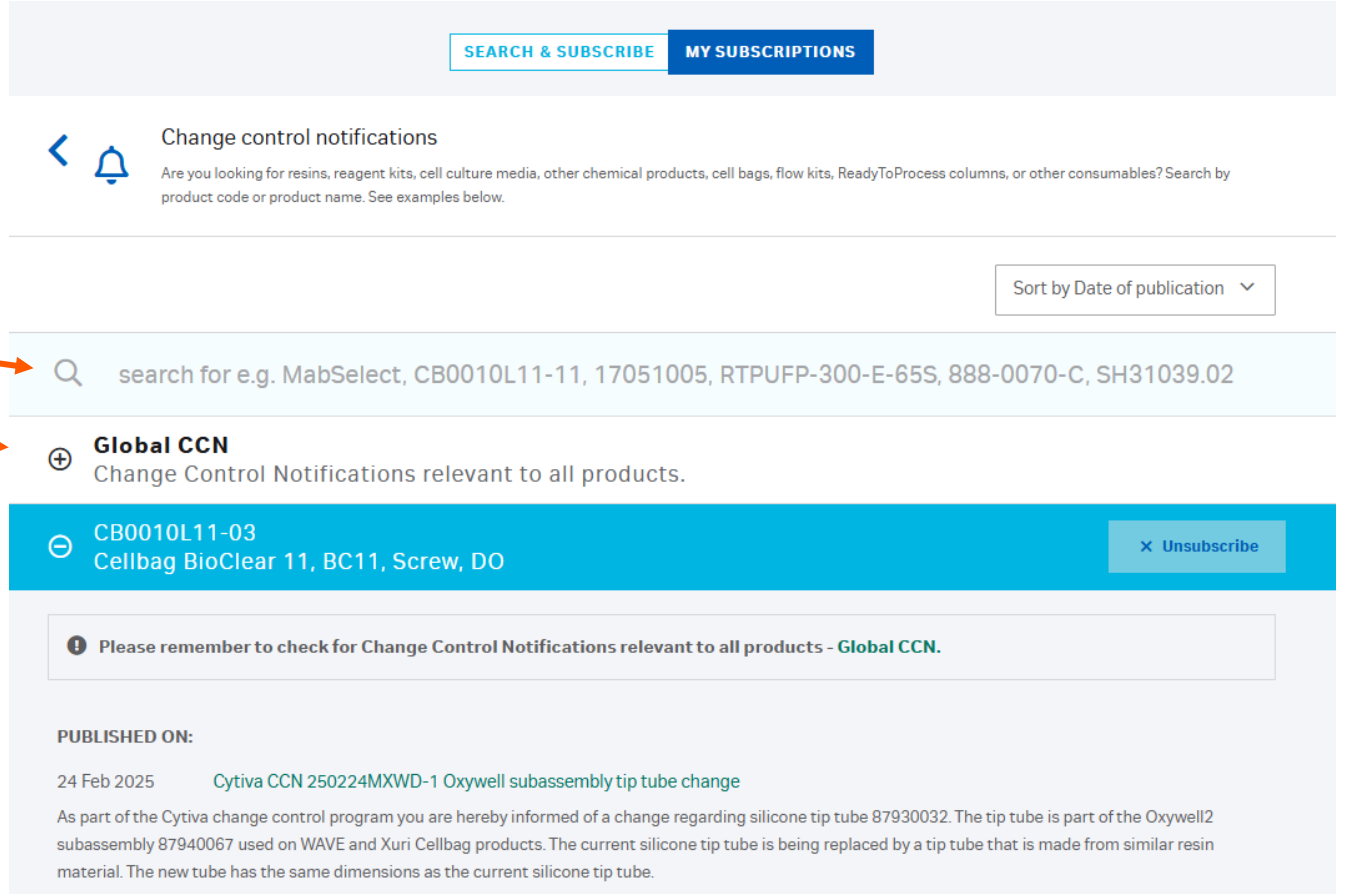
Go to 'My subscriptions' and select the type of document you want to view.

You can also export a list of your current subscriptions.



View your active subscriptions for change control notifications

- On ‘My subscriptions’, on ‘Change control notifications’, you can view CCNs for your product subscriptions.
- You can search by part number.
- Global CCNs impact all products, and you are automatically subscribed to global CCNs upon subscription to any product.
- From this page you can also unsubscribe to any product/CCN category.



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.

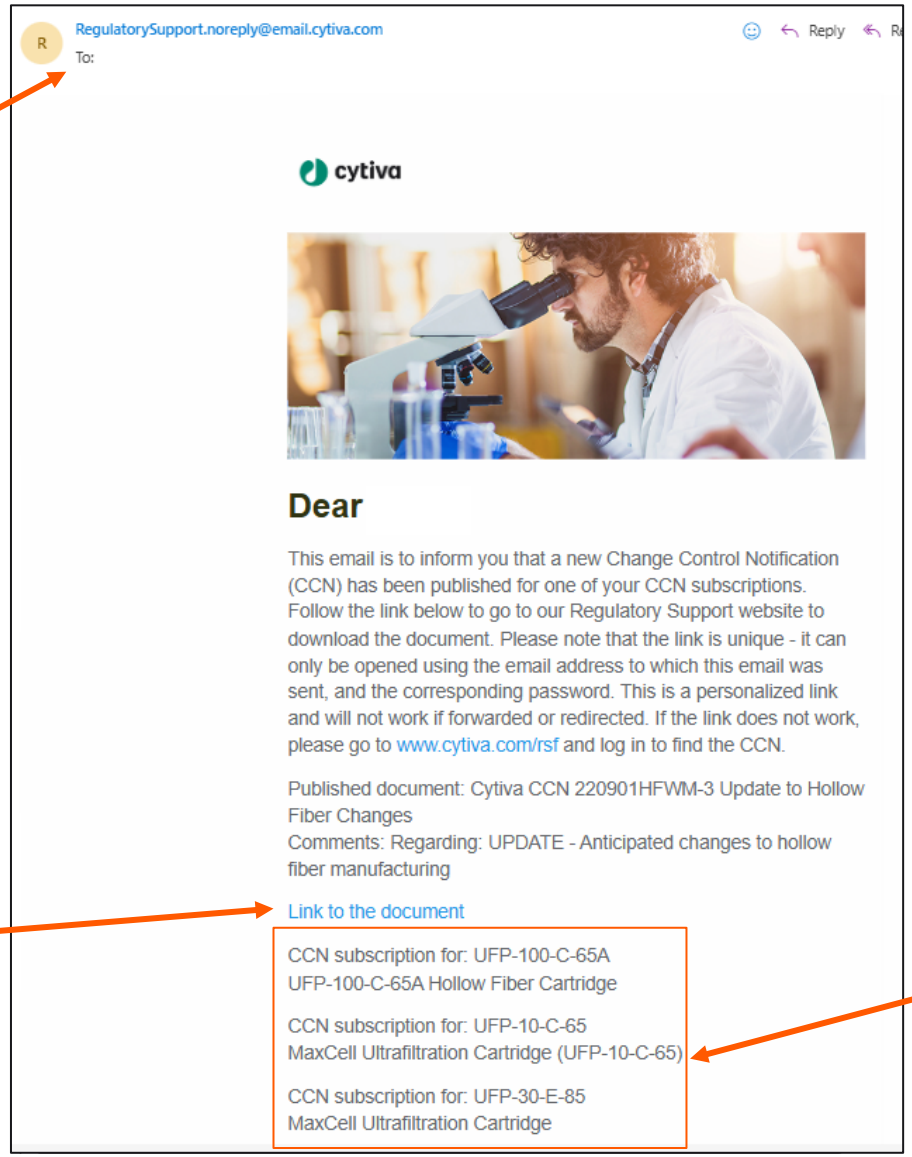
Regulatory support documentation

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.



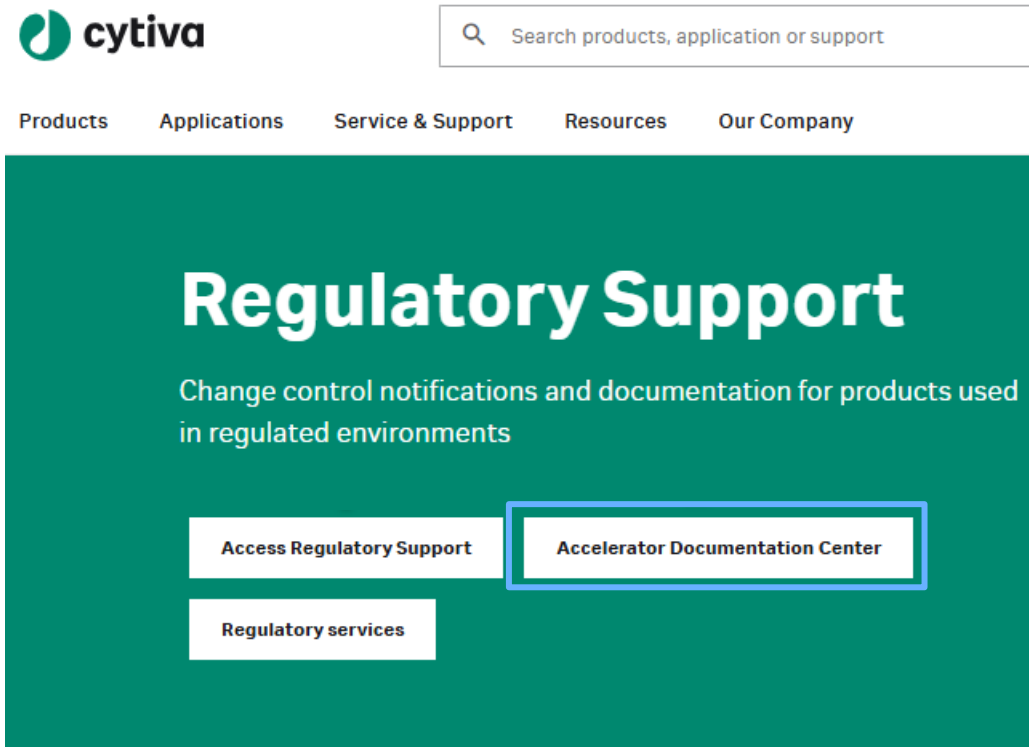
You must be logged in as the subscriber to access the document. Once downloaded, the CCN can be distributed internally.

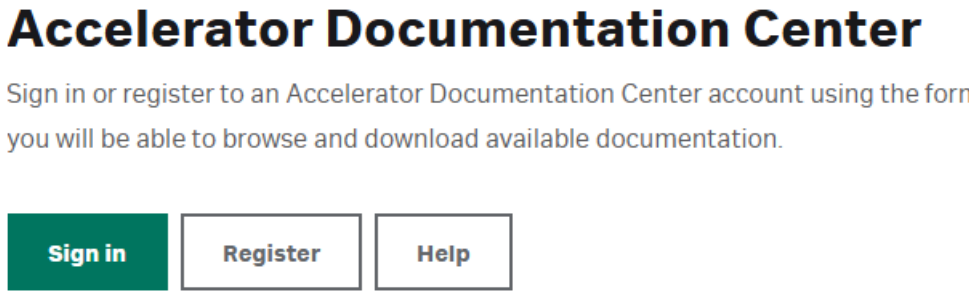
Click on this link to open the change control notification document.

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





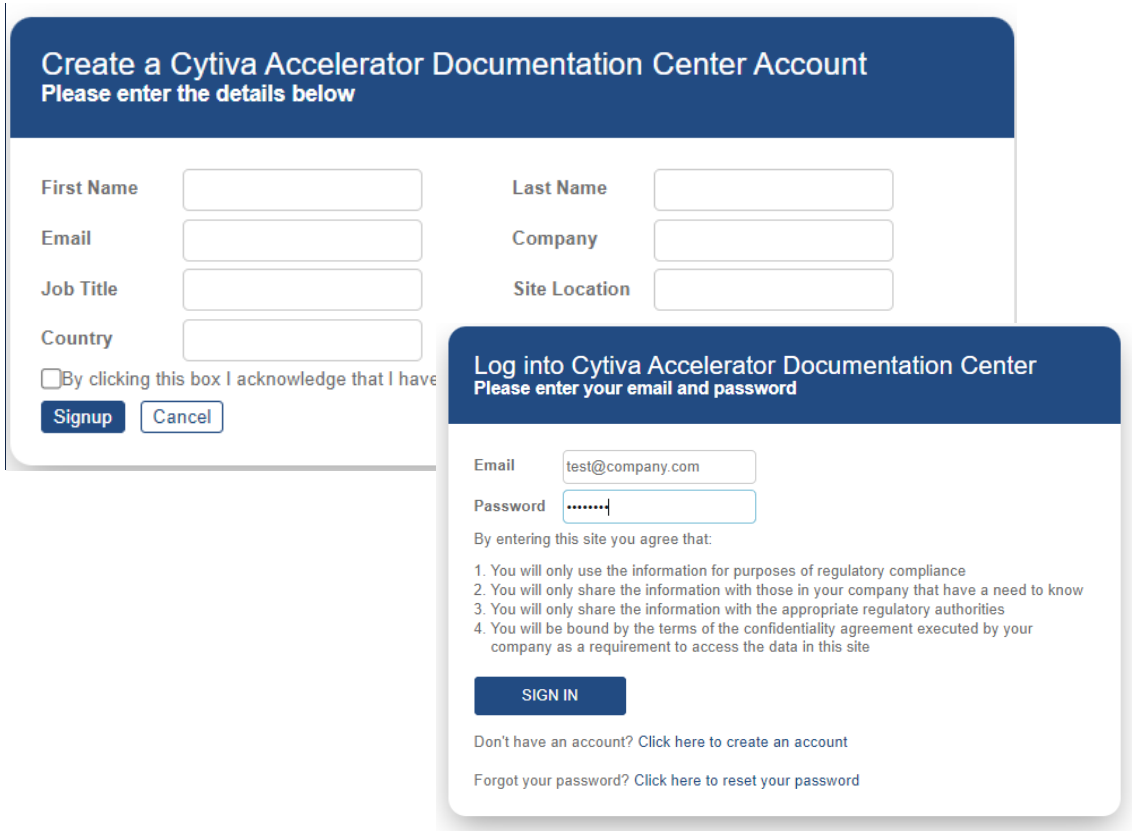
Register and log in to the Accelerator documentation center

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.

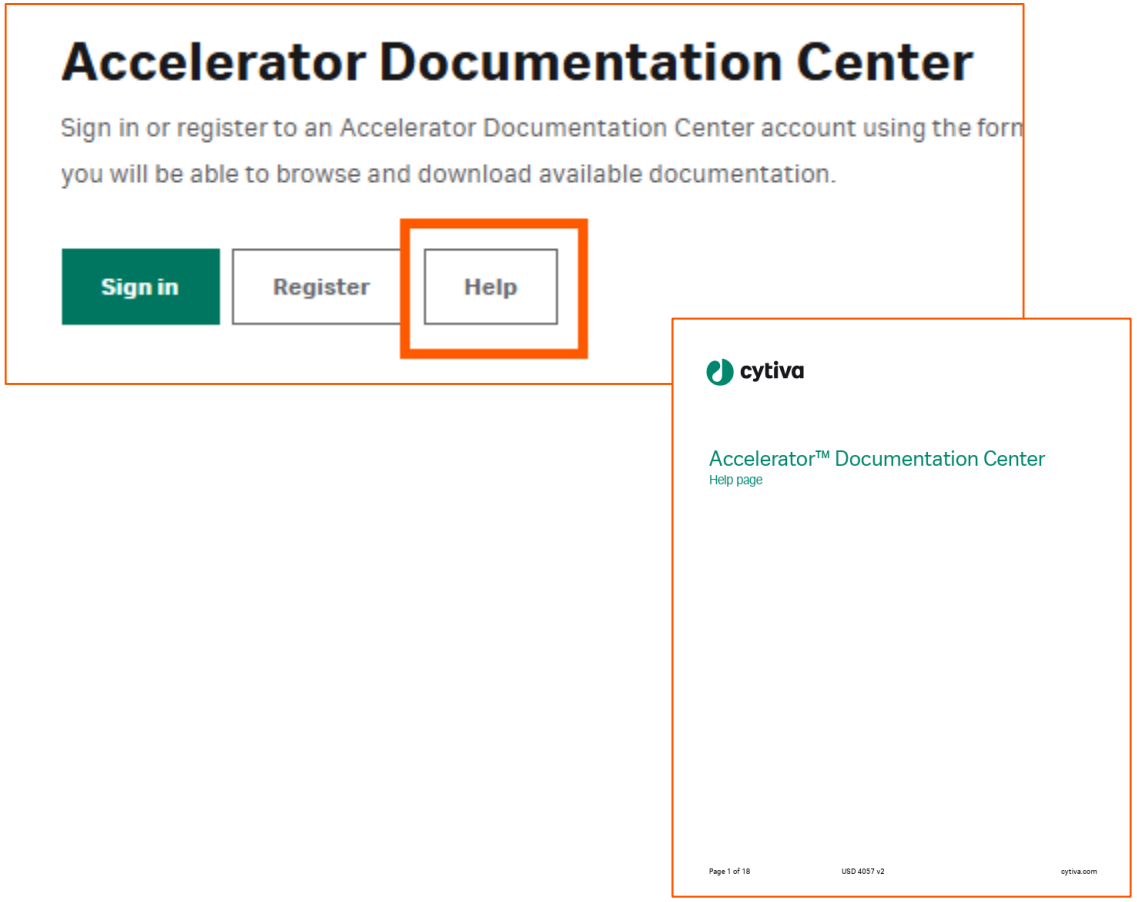


Note: Regulatory support and Accelerator documentation center require two separate login accounts.

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:

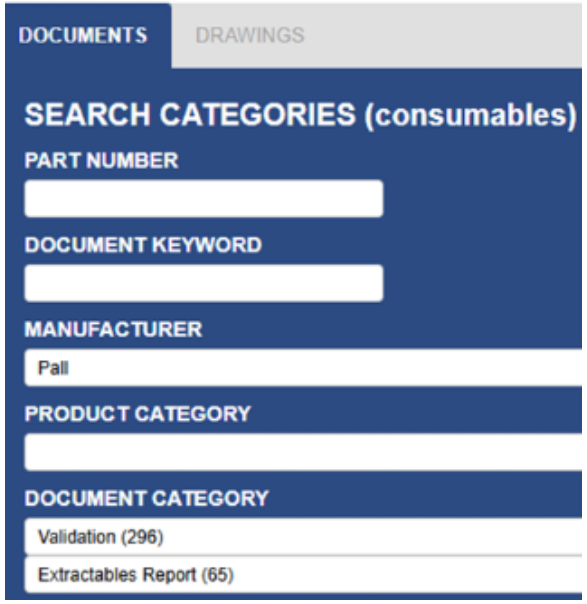
- Searching by component 'Part number' displays the component's status, the description and the manufacturer.
- Searching by 'Manufacturer' displays the available supplier documents.
- Searching by 'Document keyword' lets you search using exact matches from document names.
- Refine results by product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

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

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

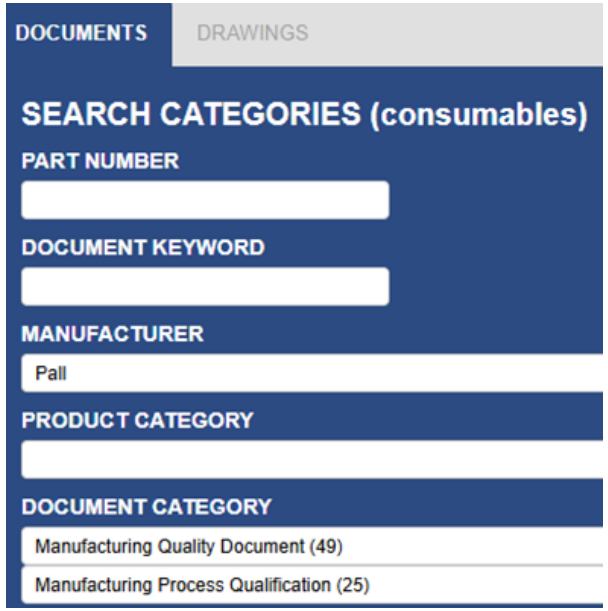
Common document searches

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

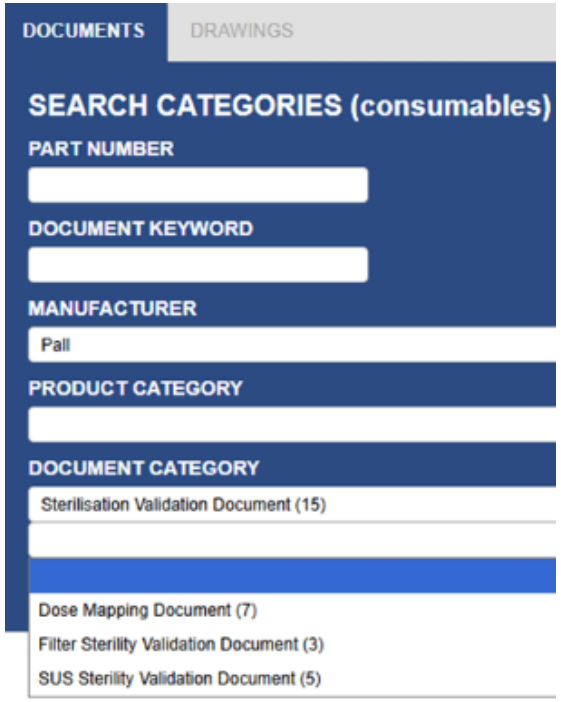


Another optional way to find CCN related extractable reports is available, please see the Help guide.

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.



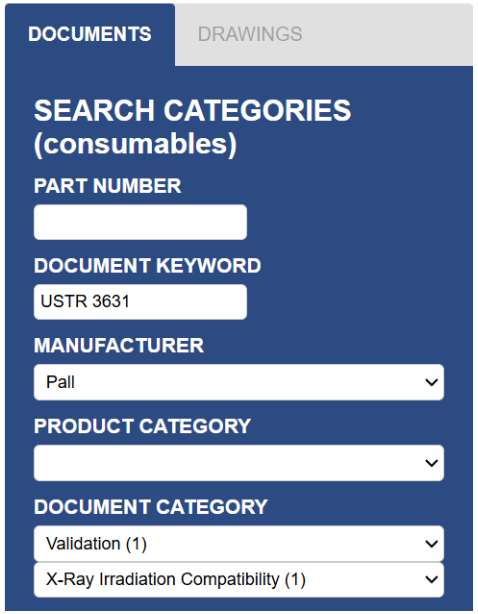
Document categories in the Accelerator documentation center

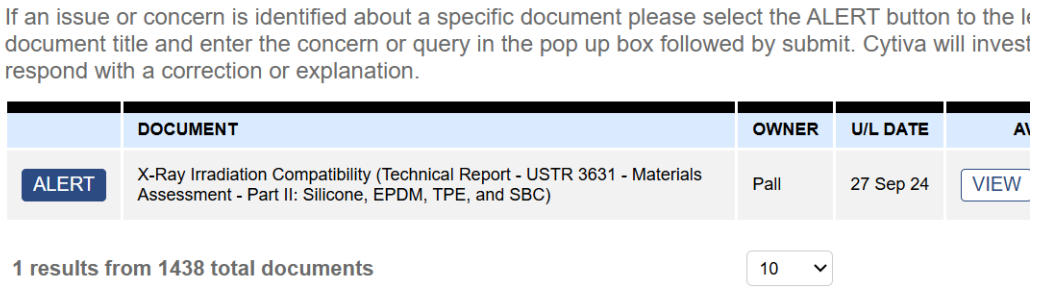
Use the document category dropdown to narrow your search.

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	Manufacturer Cleanroom Certificate - ISO 7 (Class 10,000) (At Rest) - (Cleanroom Summary Report) - (Pall Newquay, UK)	Pall	04 Oct 23	VIEW DOWNLOAD
ALERT	Site Chain of Custody (Allegro™ SUS / Newform) - (Pall Hoegaarden, Belgium BV for Cytiva LLC)	Pall	10 Oct 23	REQUEST
ALERT	Site Chain of Custody (Allegro™ SUS) - (Pall Medemblik, Holland for Cytiva LLC)	Pall	10 Oct 23	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.

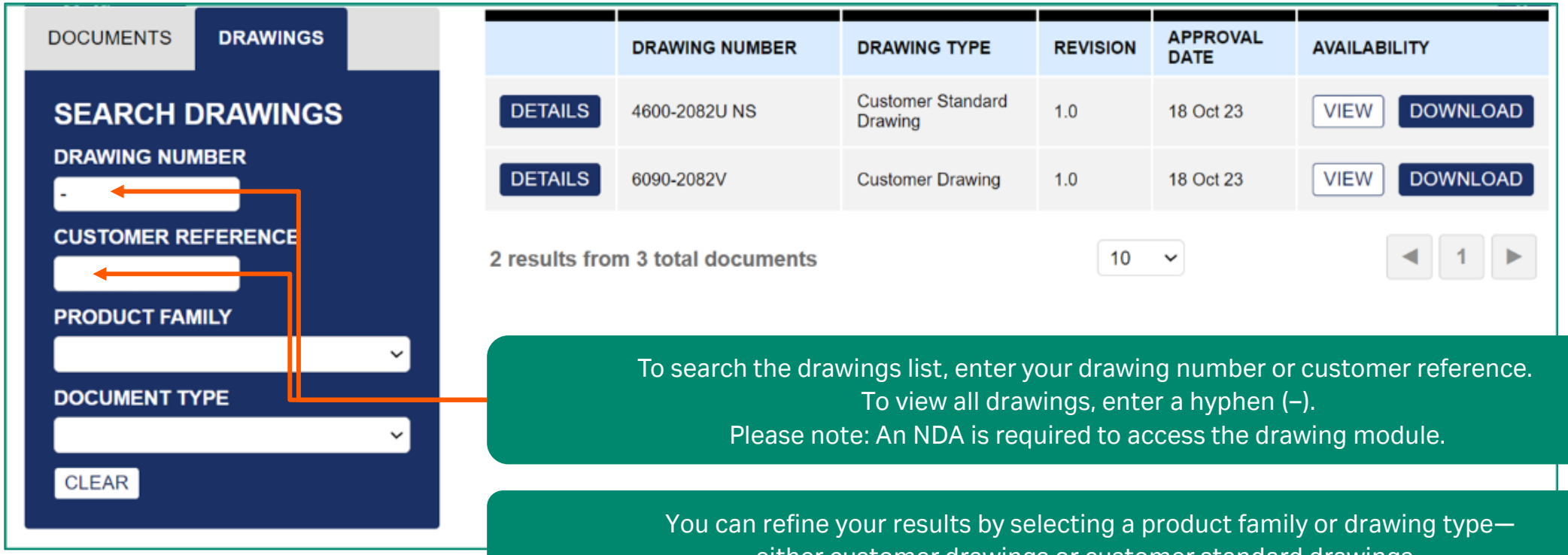
Document alert in the Accelerator documentation center

	DOCUMENT	OWNER	U/L DATE	AVAILABILITY
ALERT	Validation Reports - Regulatory Dossier - USTR 3705 - Allegro™ ¾ in. Blanking Caps With and Without Grip - Functional Testing	Pall	09 Aug 22	VIEW DOWNLOAD
ALERT	Deutsch) - (SUS – Visual Observation Library	Pall	09 Aug 22	VIEW DOWNLOAD
ALERT	Espanol) - (SUS – Visual Observation Library	Pall	09 Aug 22	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



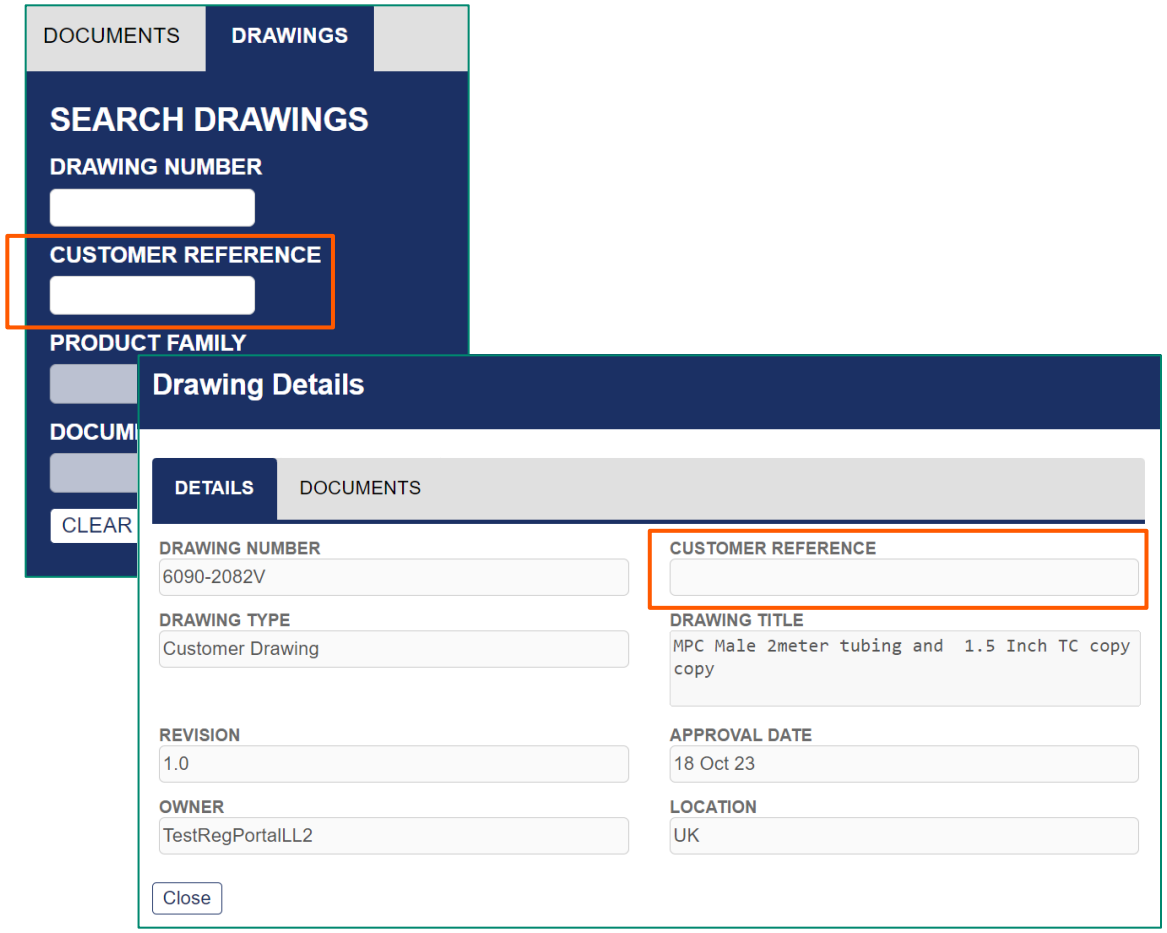
To search the drawings list, enter your drawing number or customer reference.
To view all drawings, enter a hyphen (–).
Please note: An NDA is required to access the drawing module.

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:

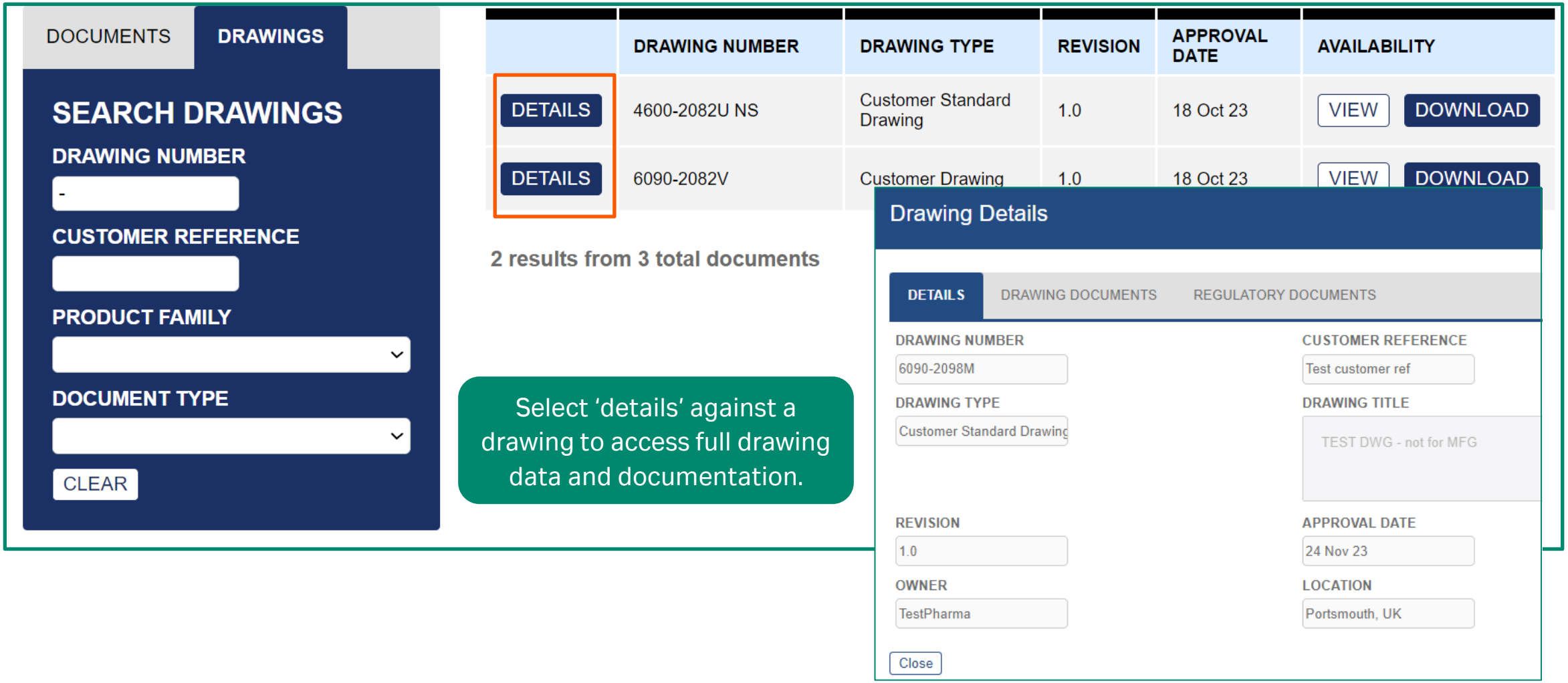
- Latest version of approved drawings only.
- English versions only.
- Your own designated sites' drawings.
- Drawings 'shared' with your designated site.

Drawing module in the Accelerator documentation center – customer references

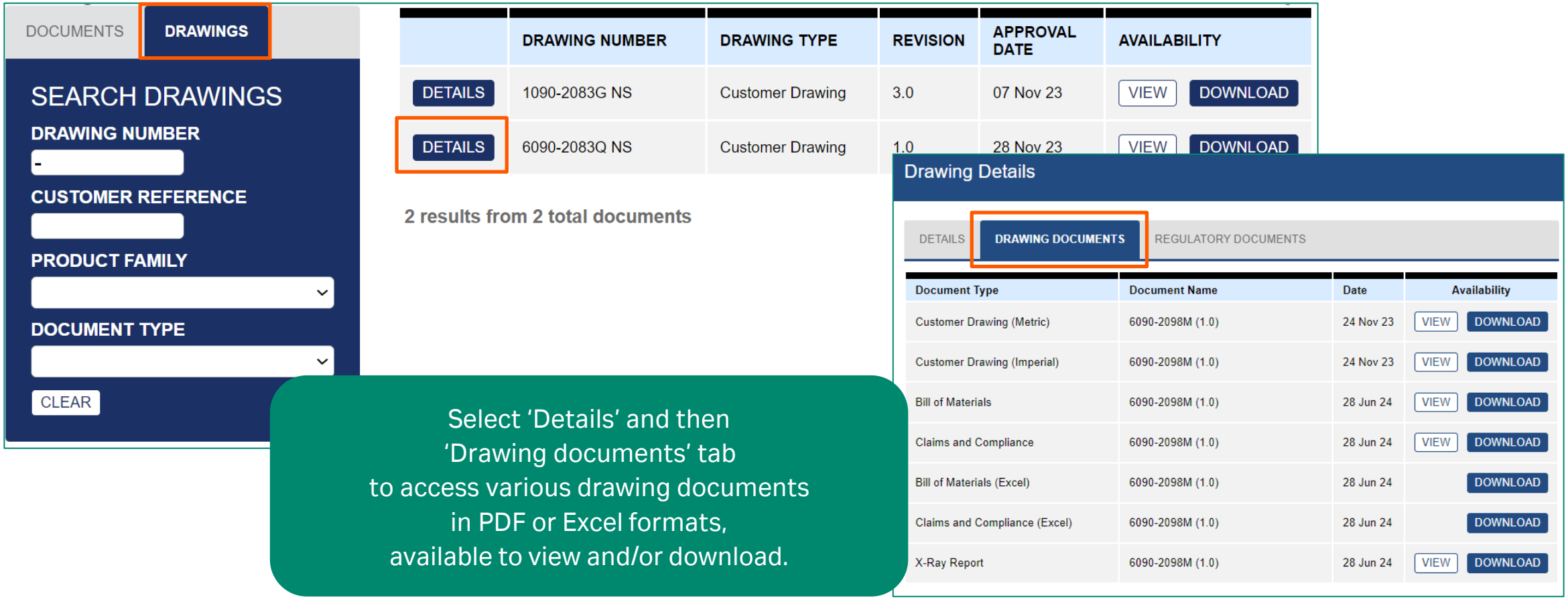


- You can request to add your own references to each design. Once added by your Cytiva sales/account manager, you can use these references to search for your drawings after 24 hours of the change.
- We can add customer drawing references without revision to the design.
- You can view your customer reference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

Drawing module in the Accelerator documentation center – drawing details

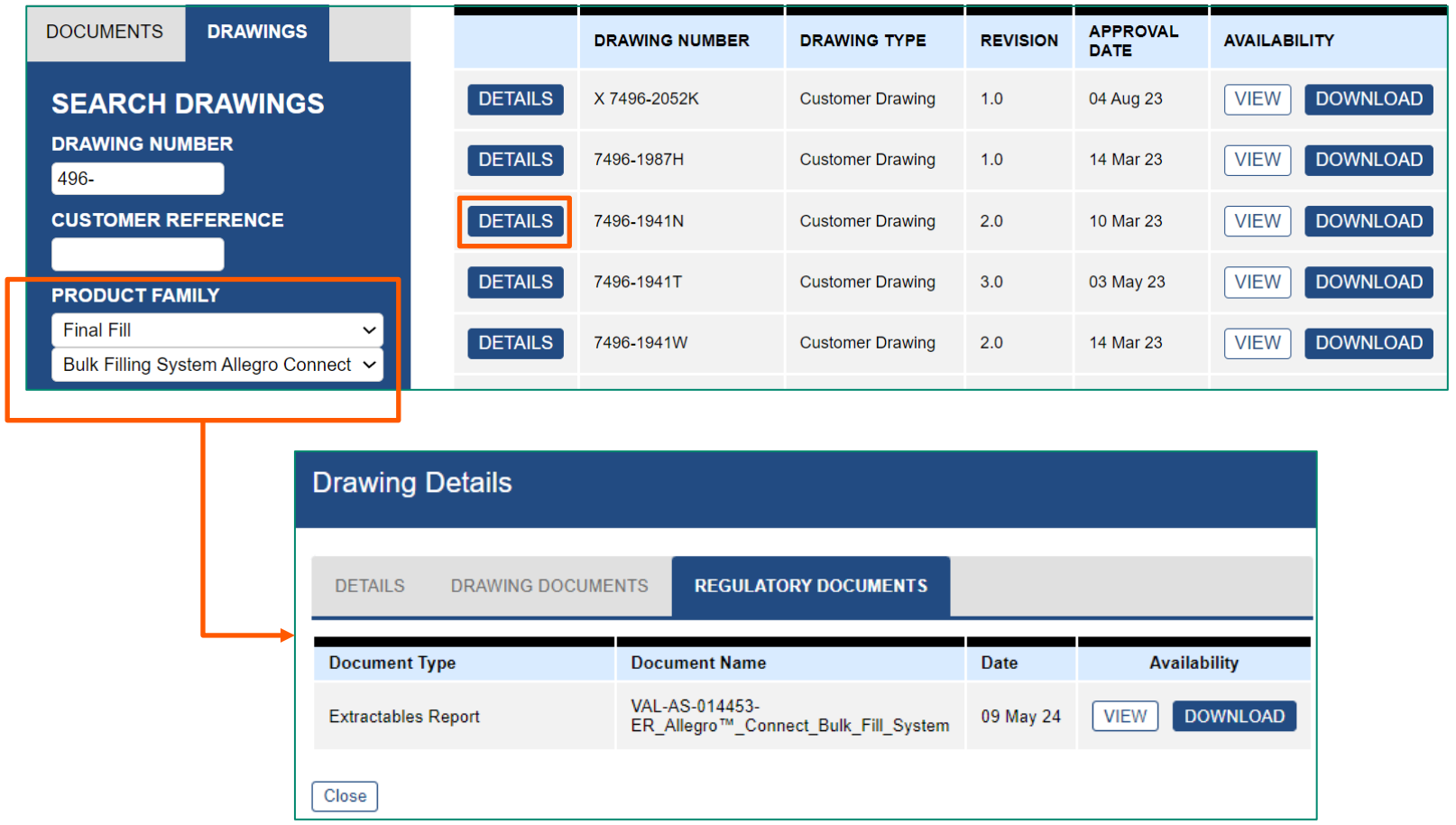


Drawing module in the Accelerator documentation center – drawing details



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	
Gamma	X-Ray Compatible	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.	Component Resin(s)	Wetted Surface Area(cm2)

Component Claims and Compliances							
Cytiva Component No.	Physiochemical	Animal-Derived Statement	Biocompatibility	Material Statements	Extractables	Fluid Path	Additional Specific Info

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.

Notification table of components containing substances of concern.

Definition table at end of report.

www.cytiva.com

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

CY54837-21Aug25-PP

cytiva.com