Cytiva

Change control and regulatory documentation

Navigation and access





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.

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Navigating cytiva.com

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Products Applications Resources	Support			Quick Order T	Frack Order	Register/Log in
🕑 cytiva			🕑 cytiva			
Support	See all		Support	See all		
Documents and certificates	>	Certificates	Documents and certificates	>	Regulatory	services and support
Quality and regulatory support	>	Safety data sheets	Quality and regulatory support	>	Quality man	agement documents
Scientific support		Hazard labels	Scientific support		Regulatory	statements
Service solutions	>	Instructions for use	Service solutions	>	Extractables	information
Training	>	HyClone certificates and downloads	Training	>	FAQ	
Online tools	>	Product security updates	Online tools	>	Change Cor	trol Notifications
Handbooks			Handbooks		Regulatory	support documentation
Contact us			Contact us			
Find a distributor			Find a distributor			

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



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

Regulatory support

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

cytiva.com/rsf

Login: Cytiva web 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.

Key available quality management documents

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

<u>Cytiva Rx-360 general quality systems</u> <u>- Questionnaire responses</u>

Quality policy

Quality management system

Standard for Cytiva change control and notification process for designated products

<u>Cytiva change control and notification process</u> <u>for Pall Medical products</u>

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)

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

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

Locating your lot-specific product certificate



Certificates of Quality (CofQ) are certificates detailing release criteria and regulatory compliance. The documents are available electronically for WAVE Cellbag bioreactors. Bioreactor Certificates of Compliance issued before November 1, 2008 are available only as paper copies and are provided through your local sales of fine.

Regulatory support documentation: on request only

For inquiries or requests not addressed by the Cytiva information platforms



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



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 <u>www.cytiva.com/rsf</u>, 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.

🕐 cytiva	
Log In	
Log III	
Username	
Pasaward Show @	
Log In	
Forgot Password?	
	A
Not registered with us yet?	EEMENT – Regulatory Support – terms and conditions
Register Now	
 THIS IS THE CONFIDENTIALITY.	_FFOLLY AGREEMENT THAT END-USER (HEREINAETER "END-USER") IS REQUIRED
TO ACCEPT BEFORE SUBSCRIBI	NG TO REGULATORY SUPPORT DOCUMENTATION. CAREFULLY READ ALL
OF THE TERMS AND CONDITION	NS OF THIS CONFIDENTIALITY AGREEMENT BEFORE SUBMITTING YOUR
CONFIDENTIALITY AGREEMENT	ON THE WEB SITE (HEREINAFTER "PROFILE ACCOUNT"). CLICKING THE
APPLICABLE "I ACCEPT" OR EQ	UIVALENT BUTTON ON THIS WEBPAGE INDICATES END-USER'S
	ENTTO BE BOUND BY ALL OF THE TEDMO AND CONDITIONS OF THE
I accept the confidentiality agr	eement
	Print 🖨 Save

Start your subscription

After logging in to <u>www.cytiva.com/rsf</u>,

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.

Regulatory support

Streamline your life sciences journey with access to Change Control Notifications and regulatory support documentation.



Subscribe to change control notifications (CCNs)



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.

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



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

🜒 cytiva

Q Search products, application or support

Products Applications Service & Support Resources Our Company

Regulatory Support

Change control notifications and documentation for products used in regulated environments



Accelerator Documentation Center

Sign in or register to an Accelerator Documentation Center account using the forn you will be able to browse and download available documentation.

Sign in	Register	Help
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Register and log in to the Accelerator documentation center

If you already have an account, log in to <u>cytiva.com/adc</u>, 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.

Create a Cytiva Accelerator Documentation Center Account Please enter the details below							
First Name Email Job Title	Last Name Company Site Location						
Country By clicking this box I acknowledge that I have Signup Cancel	Log into Cytiva Accelerator Documentation Center Please enter your email and password Email test@company.com						
	By entering this site you agree that: 1. You will only use the information for purposes of regulatory compliance 2. You will only share the information with those in your company that have a need to know 3. You will be bound by the terms of the confidentiality agreement executed by your company as a requirement to access the data in this site SIGN IN Don't have an account? Click here to create an account Forgot your password? Click here to reset your password						

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 <u>help guide</u>.

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

Accelerator Documentation Center

Sign in or register to an Accelerator Documentation Center account using the forn you will be able to browse and download available documentation.



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 <u>Help guide</u>.

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 subcategories to help you refine your search further.

A table of categories and sub-categories is available in the <u>help guide</u>.

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

DOCUMENTS	DRAWINGS
SEARCH C (consumal PART NUMBER	CATEGORIES ples)
DOCUMENT KI	EYWORD
MANUFACTUR	ER
Pall	~
PRODUCT CAT	EGORY
	~
DOCUMENT C	ATEGORY
Validation (1)	~
X-Ray Irradiation	Compatibility (1)

If an issue or concern is identified about a specific document please select the ALERT button to the le document title and enter the concern or query in the pop up box followed by submit. Cytiva will invest respond with a correction or explanation.

	DOCUMENT	OWNER	U/L DATE	A۱
ALERT	X-Ray Irradiation Compatibility (Technical Report - USTR 3631 - Materials Assessment - Part II: Silicone, EPDM, TPE, and SBC)	Pall	27 Sep 24	VIEW
results fr	om 1438 total documents	10 🗸		

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

DOCUMENTS DRAWINGS		DRAWING NUMBER	DRAWING TYPE	REVISION	APPROVAL DATE	AVAILABILITY		
SEARCH DRAWINGS	DETAILS	4600-2082U NS	Customer Standard Drawing	1.0	18 Oct 23	VIEW DOWNLOAD		
DRAWING NUMBER	DETAILS	6090-2082V	Customer Drawing	1.0	18 Oct 23	VIEW DOWNLOAD		
CUSTOMER REFERENCE	2 results fro	m 3 total documents		10	~			
OCUMENT TYPE	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.							
CLEAR		You can refine either o	your results by se customer drawing	electing a part	product famil mer standar	y or drawing type— d drawings.		

Drawings and drawing documents available are:

- Latest version of approved drawings only.
- English versions only.

Your own designated sites' drawings.

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Drawings 'shared' with your designated site.

Drawing module in the Accelerator documentation center – customer references

DOCUMENTS	DRAWINGS		
SEARCH DRAWING NU			
	REFERENCE		
PRODUCT FA	MILY		
Dra	wing Details		
CLEAR DRA	ETAILS DOCUM	ENTS	CUSTOMER REFERENCE
609	0-2082V		
DRA	WING TYPE		DRAWING TITLE
Cus	stomer Drawing		MPC Male 2meter tubing and 1.5 Inch TC copy copy
REV	ISION		APPROVAL DATE
1.0			18 Oct 23
ow	NER		LOCATION
Tes	tRegPortalLL2		UK
Clo	se		

- 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

DOCUMENTS DRAWINGS		DRAWING NUMBER	DRAWING TYPE	REVISION	APPROVAL DATE	AVAILABILITY
SEARCH DRAWINGS	DETAILS	4600-2082U NS	Customer Standard Drawing	1.0	18 Oct 23	VIEW DOWNLOAD
DRAWING NUMBER	DETAILS	6090-2082V	Customer Drawing	1.0	18 Oct 23	VIEW DOWNLOAD
CUSTOMER REFERENCE	2 results fro	m 3 total documents	Drawing Details	S	REGULATORY D	OCUMENTS
PRODUCT FAMILY			DRAWING NUMBER			CUSTOMER REFERENCE Test customer ref
DOCUMENT TYPE	Select 'd drawing to a	etails' against a access full drawing	DRAWING TYPE Customer Standard Dra	wing		DRAWING TITLE TEST DWG - not for MFG
CLEAR	data and	documentation.	REVISION			APPROVAL DATE
			1.0 OWNER			24 Nov 23
			TestPharma			Portsmouth, UK
			Close			

Drawing module in the Accelerator documentation center – drawing details

DOCUMENTS DRAWINGS		DRAWING NUMBER	DRAWING TYPE	REVISION	APPROVAL DATE	AVAILABILITY		
SEARCH DRAWINGS	DETAILS	1090-2083G NS	Customer Drawing	3.0	07 Nov 23	VIEW DOWNLOAD		
DRAWING NUMBER	DETAILS	6090-2083Q NS	Customer Drawing	1.0	28 Nov 23	VIEW DOWNLOAD		
CUSTOMER REFERENCE	2 results fre	m 2 total decumenta		Drawing	Detalis			
	2 Tesuits Inc	on 2 total documents		DETAILS	DRAWING DOCUME	NTS REGULATORY DOCUMENTS		
				Document 1	Гуре	Document Name	Date	Availability
DOCUMENT TYPE				Customer Dr	rawing (Metric)	6090-2098M (1.0)	24 Nov 23	VIEW DOWNLOAD
~				Customer Dr	rawing (Imperial)	6090-2098M (1.0)	24 Nov 23	VIEW DOWNLOAD
CLEAR	Selec	ct 'Details' and th	en	Bill of Materi	als	6090-2098M (1.0)	28 Jun 24	VIEW DOWNLOAD
'Drawing documents' tab to access various drawing documents in PDF or Excel formats,			Claims and (Compliance	6090-2098M (1.0)	28 Jun 24	VIEW DOWNLOAD	
			Bill of Materi	als (Excel)	6090-2098M (1.0)	28 Jun 24	DOWNLOAD	
			Claims and (Compliance (Excel)	6090-2098M (1.0)	28 Jun 24	DOWNLOAD	
	available t	o view and/or dov	wnload.	X-Ray Repo	rt	6090-2098M (1.0)	28 Jun 24	VIEW DOWNLOAD

Drawing module in the Accelerator documentation center – regulatory documentation

DOCUMENTS DRAWI	NGS	DRAWING NUMBER	DRAWING TYPE	REVISION	APPROVAL DATE	AVAILABILITY
SEARCH DRAWI	NGS	X 7496-2052K	Customer Drawing	1.0	04 Aug 23	VIEW DOWNLOAD
DRAWING NUMBER	DETAILS	7496-1987H	Customer Drawing	1.0	14 Mar 23	VIEW DOWNLOAD
CUSTOMER REFERENC	E	7496-1941N	Customer Drawing	2.0	10 Mar 23	VIEW DOWNLOAD
PRODUCT FAMILY	DETAILS	7496-1941T	Customer Drawing	3.0	03 May 23	VIEW DOWNLOAD
Final Fill Bulk Filling System Allegr	o Connect 🗸	7496-1941W	Customer Drawing	2.0	14 Mar 23	VIEW DOWNLOAD

Drawing	Details			
DETAILS	DRAWING DOCUME	NTS REGULATORY DOCUMENTS		
Document T	уре	Document Name	Date	Availability
Document T Extractables	ype Report	Document Name VAL-AS-014453- ER_Allegro™_Connect_Bulk_Fill_System	Date 09 May 24	Availability VIEW DOWNLOAD

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	YYYYYY	-
Primary Cytiva manufacturing plant			Additional manufacturing plants			

System Design Information								
Sterilisation					Operating Lin	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.



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