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1 Terms, definitions, abbreviations, glossary

Acceptance of...	Acknowledgement for a specific step
Hash algorithm, hash code	Checksum calculated for a submission or for individual files
CoA	Certificate of Analysis
Company reference	Reference, your reference
Dashboard	Work environment and input screen
Delivery	Delivery for new or ongoing applications
Delivery ID	Specific identification number of uploaded file
Doc ID	Identification number of transmitted file
Delivery status	Status of a delivery
eGov	eGovernment
eGov Service	Individual service within the eGov Portal
eSubmissions	Service for entering deliveries
GMP / GDP	Good manufacturing practice / Good distribution practice
Inbox	Mailbox in dashboard
mTan	Mobile transaction number via SMS
Notification	Notification by e-mail
Release	Version of the Portal software
Subject no., subject number	Identification number for applications, corresponds to delivery ID
Upload	Upload process

2 Objective and scope

This information sheet contains the basic information needed to use the Swissmedic eGov Portal, particularly the eGov **GMP-GDP** service.

User administrators should refer to the *Swissmedic Portal – Administrator functions* information sheet.

3 Conditions for the use of the Swissmedic eGov Portal

A User Agreement with Swissmedic must be signed in order to use the Portal.

Before a standard user can make use of the Swissmedic eGov Portal, a user administrator or account administrator at their company must set up a new standard user account for them. The new user will then receive an e-mail from Swissmedic (it@swissmedic.ch) with a link for setting up an initial password.

4 Access to the Swissmedic eGov Portal

The Swissmedic eGov Portal is accessed via the address www.portal.swissmedic.ch. Once the user has entered their user ID and previously established password, an SMS message containing a mobile transaction number (mTan) will be sent to the user's registered mobile phone number. This transaction number must be entered on the following screen in order to complete the login process. When a user logs in for the first time, and also following software updates, the user must agree to the latest terms of use.

The Portal includes an option for resetting the password. Once the user has entered their registered e-mail address, the system will send a new password to that address. This password should then be changed immediately by the user.

5 Using the eGov Portal

This section explains the basic functions and processes of the Swissmedic eGov Portal in greater detail. The Portal is the central access point for other eGov Services. The default language of the Swissmedic eGov Portal is English. The information sheets are available in German, French and English.

The home page displays the *Administration*, *CPP* and *eSubmissions* areas (depending on the user's authorisation).

The individual areas are explained in greater detail below.

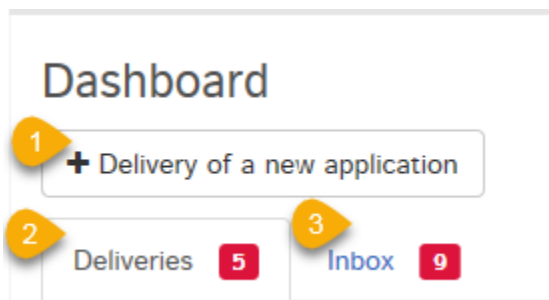
5.1 Administration area

Accessible to registered Portal administrators, this area is for configuring the necessary settings and, for example, creating users.

For further details please refer to the information sheet for administrators.

5.2 eGov GMP-GDP area

The order forms for GMP/GDP orders can be uploaded here in a screen-guided process (see 5.2.1). A dashboard (see diagram below) is provided for users:



The Swissmedic eGov GMP-GDP service offers the following options:

1	Delivery of a new application with file
2	List of most recent GMP-GDP deliveries
3	List of delivery confirmations from Swissmedic (identified by a doc ID)

5.2.1 Submission of a GMP/GDP certificate order

The complete process is illustrated below by means of an example.

In the *dashboard*, click on *Delivery of a new application* to initiate the process.

Subsequent steps: From the *Select service* dropdown menu choose "GMP-GDP" and under *Select subject* pick either

- Authorisation post 01.01.2019 or
- Authorisation pre 31.12.2018

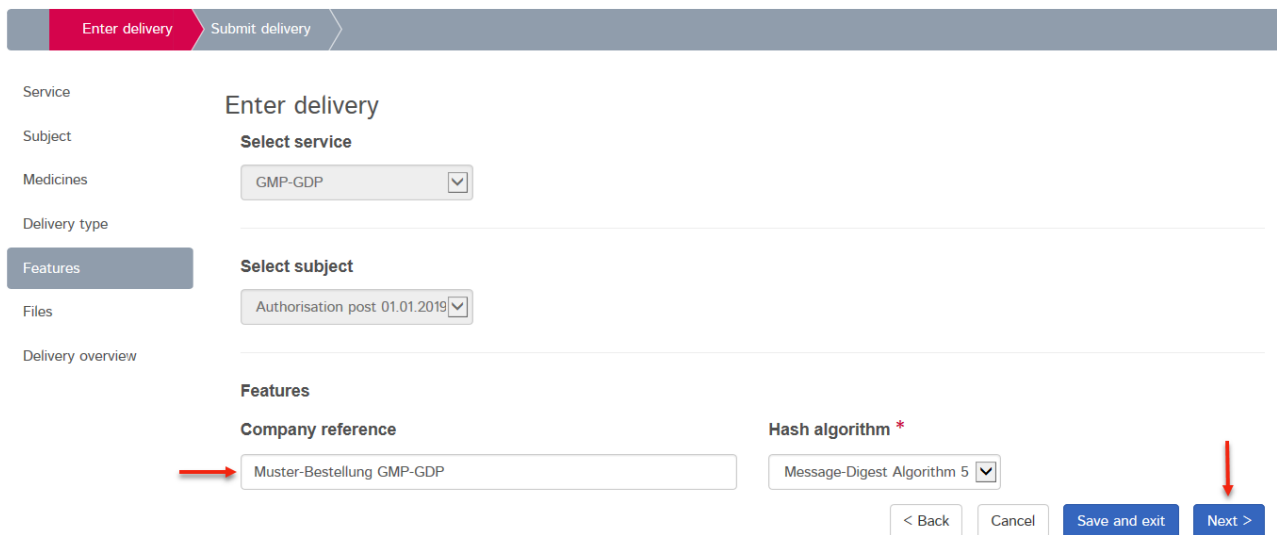
(for further options under *Select subject* see section 5.2.1.1) and click *Next* to confirm.

Deliveries



An internal *company reference* can optionally be provided under *Features*. This will appear in the dashboard, in the inbox and on the delivery confirmation and the acceptance of delivery acknowledgement as “Your reference”. The *company reference* is solely to help the user to keep track of applications delivered and is not considered in the certificate ordering process. Any references to be mentioned on the invoice can be stated on the request form for GMP/GDP certificates.

Deliveries



Next step: Under files click on **+Add file**. Under *Choose file* select the request form for GMP/GDP certificates (format: .pdf or .docx) and upload with *Upload*.



Special case: requests for GMP certificates for specific active substances

- If the basis for issuing the GMP certificate is a Swissmedic establishment licence based on Format 2 (see section 5.2.1.1 for details of the distinction between Format 1 / Format 2), then GMP certificates can be ordered for specific active substances.
To do so, click on *+Add another file* (Attachment), and select and upload (*Upload*) the following documents (permitted formats: .pdf, .docx and .xlsx):
 - A current Certificate of Analysis (CoA) for the last produced batch for each active substance to be mentioned on the GMP certificate
 - A letter, signed by the Responsible Person*, confirming that the corresponding active substances are manufactured at the operating site to be certified.

The Certificates of Analysis and the confirmation by the RP must be resubmitted with each request for an active substance-specific certificate.

* If the confirmation has been signed by the deputy Responsible Person, a separate letter from the RP submitted at the same time as this confirmation must confirm that the signatory is authorised to sign. This "signature declaration" must be enclosed with every RP confirmation that is not actually signed by the RP.



- If the basis for issuing the GMP certificate is a Swissmedic establishment licence based on Format 1 (see section 5.2.1.1 for details of the distinction between Format 1 / Format 2), then the issuing of GMP certificates for specific active substances as described above is no longer possible.
According to the new process, all GMP certificates are issued with the active substances as stated by the company on the application for the establishment licence. These must be requested in advance by submitting a corresponding variation application for the establishment licence.

During the upload an automatic technical check is performed (including a virus check and a correct file format check). NB: This is not the same as a technical validation or structural check of the documents.

The result of this automatic technical check will be displayed on screen. A green tick indicates that the Upload has been successful. Depending on the size of the delivery, this step may last several seconds.

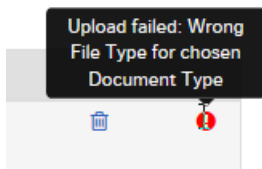
Files

Document type	File name		
Request form	Formular_Bestellung_für_GMP-GDP_Zertifikate.docx		

+ Add another file || Pause all



If the automatic check discovers an error, a red exclamation mark is displayed. Further information about the possible problem appears if you position the mouse cursor over the exclamation mark.



You cannot continue the process until the error has been corrected. First delete the upload containing the error by clicking the *trash can* symbol. You can then re-upload the corrected file.

If everything is correct, the delivery can be completed (*Next*) and handed over to the system. To this end, a delivery overview with a summary of the details is displayed.

Service

Subject

Medicines


Delivery type

Features

Files

Delivery overview

Delivery overview

 Please check the entries below for correctness before submission.

Service
GMP-GDP

Subject
Authorisation post 01.01.2019

Features

Company reference
Muster-Bestellung GMP-GDP

Files


Document type	File name	Hash
Request form	Formular_Bestellung_für_GMP-GDP_Zertifikate.docx	b5f97181505fe8f3b450304d4be82440

At this point, the *checksum* generated for each upload is also displayed. This *hash code* can be used to verify that the upload was complete. For reasons of improved traceability, the checksum calculated is also shown on the acknowledgements sent by the Portal.

Should you need to make changes, you can correct errors by clicking the *Back* button. If everything is correct, press the *Submit* button to complete the process.

A message confirming the successful submission is then displayed.

Submitted delivery

 The application was successfully submitted. You can find the corresponding delivery confirmation in your inbox.

Delivery ID
100010007608

Service
GMP-GDP

Subject
Authorisation post 01.01.2019

Features

Company reference
Muster-Bestellung GMP-GDP

Files

Document type	File name	Hash
Request form	Formular_Bestellung_für_GMP-GDP_Zertifikate.docx	b5f97181505fe8f3b450304d4be82440

[Dashboard](#)

The delivery will remain in the *Deliveries* area while it is being processed. The delivery confirmation has been created, and the delivery status is set to “Transmitted”. It may take several minutes to transmit the data. Once this process is complete and the documents have been transmitted, the acceptance of delivery acknowledgement will be created and the delivery status changed to “Accepted”.

Delivery status provides information on the processing status.

The following statuses are possible:



Status	Meaning
Paused	Delivery has been temporarily saved
Processing	Delivery is continuing
Transmitted	Delivery has been sent
Accepted	Delivery accepted

The magnifier icon that can be found under *Functions* can be used to obtain a detailed view of the delivery.

Dashboard

+ Delivery of a new application

Deliveries 4 | Inbox 22

Delivery ID	Your Reference	Service / Subject	Delivery type	Last updated at	Last updated from	Delivery status	Functions
100010007690	Muster-Bestellun...	GMP-GDP/Authorisation post 01.01.2019		13.08.2018 11:47		Accepted	 

All submission information is summarised in the delivery details.
 The application and the two acknowledgements (delivery confirmation and acceptance of delivery) can be downloaded as PDFs. The acknowledgements are also placed in the inbox.

Delivery details x

Delivery details

Delivery ID	100010007690	Application No.	Company/User No.
Dok ID	0010135882	Application Type	Company/User Name
Service	GMP-GDP	Application category	
Subject	Authorisation post 01.01.2019	Delivery Type	

Medicines

Features

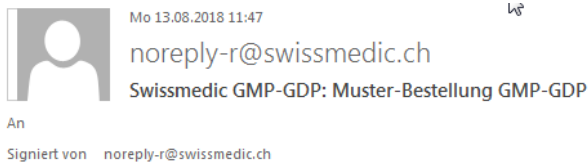
Company reference	Muster-Bestellung GMP-GDP	Hash algorithm	MD5
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Submitted files

File name	Document type	Structure format	eCTD dossier	File Status	Functions
Formular_Bestellung_für_GMP-GDP_Zertifikate.docx	Request form			Valid	

OutDok ID	Subject	Subject no.	Your reference	Document type	File name	Received on	Retrieved on	Func.
	Delivery	100010007690	Muster-Bestellu...	Acceptance of delivery	100010007690_ACCEPTE...	13.08.2018		
	Delivery	100010007690	Muster-Bestellu...	Delivery Confirmation	100010007690_SENT_20...	13.08.2018		

In addition, an e-mail will be sent to the user's registered correspondence e-mail address.



Dear Sir or Madam,

Swissmedic has uploaded a document to your account:

User-ID:

You can download this document to your computer by logging in to the Swissmedic portal.

Service: GMP-GDP
 Subject: Authorisation post 01.01.2019
 Your reference: Muster-Bestellung GMP-GDP

This email has been automatically generated. Never reply to this sender address.

Best Regards,

Swissmedic - Swiss Agency for Therapeutic Products

Swissmedic will then begin processing the application.

5.2.1.1 Further options under *Select subject*

The latest valid Swissmedic establishment licence serves as the basis for issuing GMP and GDP certificates. Before selecting an option under *Select subject*, the specific format on which the establishment licence is based first has to be checked. The following table illustrates the distinction:

Format	Licence number as shown in the establishment licence	Option under <i>Select subject</i>
1	Licence no. xxxxxx-xxxxxxxx ¹⁾	Authorisation post 01.01.2019
2	Licence no. xxxxxx / Application no. (x)xxxxxxxx ¹⁾	Authorisation pre 31.12.2018

¹⁾ x = any digit

5.2.1.2 Further options when completing an application for a GMP/GDP certificate

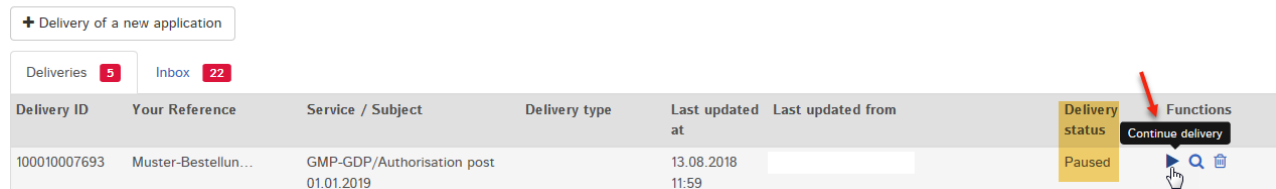
Change hash algorithm: The *hash algorithm* option can be used to select the method for calculating the checksum (technical control mechanism to identify transmission errors).

Pause application: If necessary, the delivery can be temporarily saved by clicking



without having to complete the process. The delivery can be completed later. The dashboard will show the status as *Paused*.

Dashboard



The dashboard shows a delivery with ID 100010007693, reference 'Muster-Bestellun...', and service 'GMP-GDP/Authorisation post 01.01.2019'. The status is 'Paused'. A red arrow points to the 'Continue delivery' button in the 'Functions' column.

To resume the delivery at a later time, click the arrow under *Functions* and *Continue delivery*. You can also completely delete incomplete deliveries by clicking the *Trash can* icon.

A paused delivery will be deleted automatically after 30 days and can then no longer be edited.

5.3 Inbox area

The inbox shows delivery documents for downloading. By entering various search terms, the filter function can be used to find and then download a document. The *Retrieve status* function shows whether documents have already been downloaded or not yet retrieved. GMP-GDP users will see their own applications only.

5.4 Acknowledgements and notifications

During the delivery process, the Portal automatically issues acknowledgements or so-called notifications containing e.g. important information on status, errors or confirmations.

5.4.1 GMP-GDP application acknowledgements

Acknowledgements are automatically created by the Portal for the individual steps connected with a submission. These acknowledgements can be downloaded in the dashboard for specific deliveries and in the inbox.

The following acknowledgement types exist:

- Delivery confirmation → Portal has received documents
- Acceptance of delivery → Portal has accepted delivery and forwarded it to the specialist department for checking and processing
- Denial of acceptance → Portal cannot process documents

These acknowledgements are generated immediately, as soon as the delivery has reached a certain status. Depending on the size and general input volume, this usually occurs within 10 hours.

Acceptance of delivery is considered to be an acknowledgement of receipt.

5.5 Technical details

The following section addresses certain technical details.

5.5.1 File formats

Document type	Authorised file formats
Request form	PDF / DOCX
Attachment	PDF / DOCX / XLSX

5.5.2 Doc ID

A Doc ID is created for every submission. In cases of doubt or if an unexpected problem is encountered with the Portal, Swissmedic can verify on the basis of the Doc ID number if an application has been received. The Doc ID is displayed as soon as the acceptance of delivery acknowledgement has been created.

The number can be seen in the delivery details and in the acceptance of delivery acknowledgement.

6 Cancellation of applications

As soon as the application has been transmitted by clicking *Submit*, it can no longer be cancelled. The GMP/GDP certificates are issued – as ordered – and charged for.

7 Support

E-mail: it@swissmedic.ch

Phone: +41 (0)58 462 06 00

www.swissmedic.ch/gate-support

Support is available on weekdays between 7:30 a.m. and 5:30 p.m.