

# Cortellis Supply Chain Network

[Help File/Glossary](#)




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## Types of Access

There are three types of access:

**Explore Mode:** Users that have logged in, requested linking to a company and awaiting confirmation. Company linking requests are typically completed within 1-2 working days. Some features and functionality are not available while you're in Explore Mode, such as Chat and Update My Company Page.

**Instant Access:** Registered users with a free subscription. Some functionality and data is locked or limited, look out for the padlock icon (  ), which indicates something is unavailable.

**Premium:** Registered users will full access to all available data and functionality, including unlimited chat, RFQ (request for quotation) and quotation forms. Plus the ability to upload documents to your associated company and request verified status.

# Quick Search

The Quick Search bar allows fast and intuitive search of known Products or Companies. Autocomplete suggestions appear after the user has introduced three or more characters, for both Products (including US brand name, UNII and CAS number) and Companies. For Companies, Corporate Groups are displayed in brackets after the subsidiary name.

## Product Search Results

List of all suggested suppliers for the product selected in the Quick Search bar. Default view is API suppliers with a toggle in the top-right of the screen to switch to dose form suppliers. Selecting a manufacturer name in the first column will take you to the product page for the selected supplier.

Column headers with an arrow are sortable. Filters are available on the left-hand-side of the screen; the “Apply” button must be selected for filters to be actioned.



The blue icon alongside supplier names indicates that the supplier has users active on Cortellis Supply Chain Network.



Note that not all information is available to instant access “free” users. A Premium subscription is required for full access to all data points and to enable access to the the filters.

## Company Search Results

List of all suggested results for Company names typed in the Quick Search bar. Selecting a manufacturer name in the first column will take you to the supplier page for the selected supplier.

Column headers with an arrow are sortable. Filters are available on the left-hand-side of the screen; the “Apply” button must be selected for filters to be actioned.



The blue icon alongside supplier names indicates that the supplier has users active on Cortellis Supply Chain Network.



Note that not all information is available to instant access “free” users. A Premium subscription is required for full access to all data points and to enable access to the the filters.

# Supplier Page

The Supplier Page provides a brief overview of company details at the subsidiary level including full address, corporate group, subsidiary type and website. Further details are available by selecting the Cortellis Generics Intelligence link (subscription required).

## Subsidiary Types

Includes: API Manufacturer, Finished Dose Manufacturer, Excipients Manufacturer, Fine Chemicals Manufacturer, Intermediates Manufacturer, Marketer, CRO, CMO/CDMO, Other Subsidiary.



A “blue tick” icon is presented alongside fields that have been verified by the Cortellis research team.



Note that not all information is available to instant access “free” users. A Premium subscription is required for full access to all data points.

There is an option to start a chat with the supplier, if the supplier has active users on the platform. Note that only buyer accounts can start a chat. In case the supplier does not have any active users on the platform, an option to follow the company will be made available soon.

## Regulatory Inspections Summary

Information is split in US FDA and all other indexed Regulatory Inspections. US FDA information such as GDUFA Fee Payment Date (fiscal year), Facility Registration Date (fiscal year), and the most recent dates for FDA Warning Letter and FDA Inspection Date, is provided if reported.

### Facility inspection certificates

Includes: Australia (TGA), Austria (AGES), Austria (BASG), Belgium (FAMHP), Brazil (ANVISA), Bulgarian Drug Agency, Canada (Health Canada), China (NMPA), Croatia (HALMED), Czech Republic (SIDC), Danish Health and Medicines Authority, Estonia Ravimiamet, EU (EDQM), Finland (Fimea), France (ANSM), Germany (BFARM), Germany Bayern (ZAB), Germany District Gov. of Cologne, Germany Lower Saxony, Germany Regional Gov. Office, Germany Regional Gov. Office, Germany Schleswig-Holstein (LASD), Greece (EOF), Hungary (GYEMSZI), Hungary (NIPN), Hungary (OGYI), India (CDSCO), Ireland (HPRA), Italy (AIFA), Italy (DGSAFV), Japan (PMDA), Korea (MFDS), Latvia (SAM), Malta Medicine Authority, Mexico (COFEPRIS), Netherlands (IGZ), Norway (NoMA), Poland (Main Pharmaceutical Inspector), Portugal (INFARMED), Romania (NAMMD), Slovenia (JAZMP), Spain (AEMPS), Sweden (MPA, Medical Products Agency), Switzerland (Swissmedic), Taiwanese FDA, UK (MHRA), US FDA, WHO.

## Manufacturing Capabilities Summary

List of Manufacturing Capabilities associated to the Subsidiary. There are 4 main Capabilities categories: Small Molecule, Biologic, Finished Dose and Other.

Also included is a status for “contract manufacturing” capabilities.

## Products

Available APIs or finished dose forms are presented in the Products section. Select the product to navigate to the associated product record for more information.

## Company Alerts

Cortellis Supply Chain Network users will have the ability to add company alerts for their listed company. Examples inc: Supply Issues, Drug Shortage, Export Ban and Change in Research Focus

# Product Page (API)

The Product Page for APIs (single-ingredients only) provides key data available for a given API associated to a specific supplier. The supplier is the first listed field and can be selected to navigate to the Supplier Page. Other available information includes CAS number.



A “blue tick” icon is presented alongside fields that have been verified by the Cortellis research team.



Note that not all information is available to instant access “free” users. A Premium subscription is required for full access to all data points.

There is an option to submit a “Request for Quotation” to the supplier, if the supplier has active users on the platform. This link is only visible to buyer accounts.

## Manufacturing Status

The current manufacturing status, or relationship, between the API and the manufacturing site, as follows:

- Commercially Available: the site is producing or is able to produce commercial quantities of the API.
- Under Development: the site is developing a process, has the capacity to manufacture clinical trial quantities, or is scaling up production of the API.
- Early API Activity: there may be a connection between the API and the manufacturing site
- Innovator or Marketer: API is manufactured by the marketer and/or innovator of the branded product or by a third party for exclusive use by the innovator/marketer.
- Unconfirmed: not been able to confirm or has conflicting information from multiple sources concerning the status of development at this site.

## Regulatory Filings Summary

Counts of the Regulatory Filings including: US DMFs, EU COS/CEPs, KR DMFs and JP DMFs. The counts only reflect the Regulatory Filings in force for the API and its Equivalents per each Regulatory Agency, this is Active US DMFs, Valid EU COS/CEP, Registered KR DMF and Registered JP DMF. In the caption of the analysis there is the total count of in force Regulatory Filings for the Product and its Equivalents.

### US DMF

A DMF (Drug Master File) is a confidential document covering a specific manufacturing facility, process or article used in the manufacture, processing, packaging or storing of a bulk API which is covered in an ANDA or NDA. DMFs are never approved or disapproved by the FDA. Instead, they are kept on file and only reviewed when a manufacturer files an ANDA or an NDA referencing a certain raw material supplier's DMF.

### EU COS/CEP

A Certificates of Suitability (EU COS/CEP) allows the manufacturer of a substance to provide proof that the purity of the substance is suitably controlled by the monograph of the European Pharmacopoeia. It is similar to a US DMF, but it is reviewed, and a paper approval is granted.

### JP DMF

A Japanese Drug Master File (JP DMF) is a file registered with the Pharmaceutical and Medical Devices Agency PMDA (Japanese regulatory agency) which provides detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and marketing of medicinal

products and devices. A JP DMF also indicates that the registrant's manufacturing facilities and the management methods comply with GMP. There are the following 4 types:

- Type 1 – Active Pharmaceutical Ingredients
- Type 2 – Additives
- Type 3 – Medical Device Materials
- Type 4 – Others

#### **KR DMF**

A Korean Drug Master File (KR DMF) is a file registered with the Korea Food & Drug Administration which provides detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and marketing of medicinal products and devices. A KR DMF also indicates that the registrant's manufacturing facilities and the management methods comply with Good Manufacturing Practices (GMP).

#### **GMP Certificates**

Good Manufacturing Practices (GMP) certification is given to API manufacturing sites upon the successful inspection of the site and manufacturing process for a specified API. Dates for certification are listed and the Certification Authorities are displayed in the tooltip. When a GMP certificate is Non-Compliant, it is specified together with the date. Certifications are provided by country/territory regulatory agencies and updated weekly.

#### **API Price**

Cortellis Supply Chain Network users can input a specific price or price range for products associated with their listed company.

#### **Upstream Supply**

Cortellis Supply Chain Network users will have the ability to add upstream manufacturing insights such as intermediates/reagents and/or suppliers for products associated with their listed company.

This feature will be available soon.

#### **Product Alerts**

Cortellis Supply Chain Network users will have the ability to add product alerts for products associated with their listed company.

This feature will be available soon.

# Product Page (Dose Forms)

The Product Page for dose forms provides key data available for dose forms associated with a given API and specific to a dose form supplier (manufacturer or marketer). The manufacturer or marketer is the first listed fielded and can be selected to navigate to the Supplier Page, where available.



A “blue tick” icon is presented alongside fields that have been verified by the Cortellis research team. This feature is coming soon for dose form product pages.



Note that not all information is available to instant access “free” users. A Premium subscription is required for full access to all data points.

An option to submit a “Licensing Inquiry” to the supplier for dose forms is coming soon.

## Dose Form Summary

Available information includes:

- Available dose forms and strengths
- Brand names
- Countries in which the supplier has launched dose forms of the given API [includes a link to full details on pack pricing in Cortellis Generics Intelligence (subscription required)]
- Associated dose form manufacturers or marketers, as reported

## Upstream Supply

Cortellis Supply Chain Network users will have the ability to add upstream manufacturing insights such as API/excipients and/or suppliers.

This feature will be available soon.

## Product Alerts

Cortellis Supply Chain Network users will have the ability to add product alerts for products associated with their listed company.

This feature will be available soon.



# Chat and Inbox

Users on Cortellis Supply Chain Network can utilise real-time chat to communicate directly. Chat messages are encrypted to provide security and confidentiality.



The blue icon alongside supplier names on search results pages indicates that the supplier has users active on Cortellis Supply Chain Network.

Contact Supplier

Open Chat

The “open chat” status on supplier pages indicates the supplier has users active on Cortellis Supply Chain Network.

Two types of chat messages are available:

- General inquires: Sent from the supplier page
- Product inquires: Requests made via product pages



Note that instant access “free” users are limited in the number of chat messages they can send each month. The limit is three per month, and is reset at the start of each month. Instant access “free” users can see how many messages they have left for the month on the chat message counter – available from the Inbox and chat threads. Users can upgrade to Premium for immediate access to unlimited messages.

## Notifications

Inbox

New chat message notifications are visible in the header alongside the Inbox tab.

Email notifications are also sent to users whenever a new chat message is received (this feature is coming soon).

# Editing your Profile

Cortellis Supply Chain Network users that have been successfully linked to a company can edit its company profile and associated product pages, including adding new products.

To edit your company and/or product pages, select the company dropdown in the header and then select "Update My Company Page"

Updates are made to your profile in real-time and are available via search results within 24hrs.


## Company Profile


Almost all fields are editable except subsidiary name and corporate group name, which are managed by the Cortellis research team.

Editable fields: includes Subsidiary Type, Website URL, Location/Address, Company Alerts, Manufacturing Capabilities, Other Services.

Additional Supplier Information can be uploaded by Premium users only. Up to three documents can be shared to your company profile. Please note that the file name will be displayed on your company pr

## Regulatory Information

 FDA fields and other inspections already captured can be edited/updated by selecting the pencil icon. Please note, if you edit a verified item it will lose its verified status. Premium users can request verification by clicking the grey 'unverified status' icon, which opens a new email message to send to the Cortellis team.

 New inspections can be added by selecting the "Add row" button.

Changes are not final until you click Save Changes. You can click "Discard Changes" to revert to the previous state.

## Product List

The "Add new product" button is available to add a new API (single ingredients only) to your associated company profile. Start typing the first letters of a given API in the search box, select the API and then select "Add Product". Further information can be provided using the Edit Product function.

Products can be edited by selecting the edit button. This opens a separate window where all editable fields on the product page can be amended. Verified status can also be requested from here.

Note that the edit product function is currently available for API products only. This feature is coming soon for dose forms and other products.

# System requirements

The following systems are supported, latest versions are recommended.

<b>Devices</b>	Desktop
	Laptop
<b>Operating Systems</b>	Windows
	MacOS
<b>Browsers</b>	Chrome
	Firefox
	Edge
	Safari*
<b>Export</b>	Filename.xlsx; requires spreadsheet reader such as Microsoft Excel or similar
	Filename.pdf; requires PDF reader such as Adobe Reader or similar
<b>Additional</b>	Pop-up blockers need to be disabled
	No plug-ins are needed

\* Cortellis Supply Chain Network is tested on, but not optimized for these browsers.