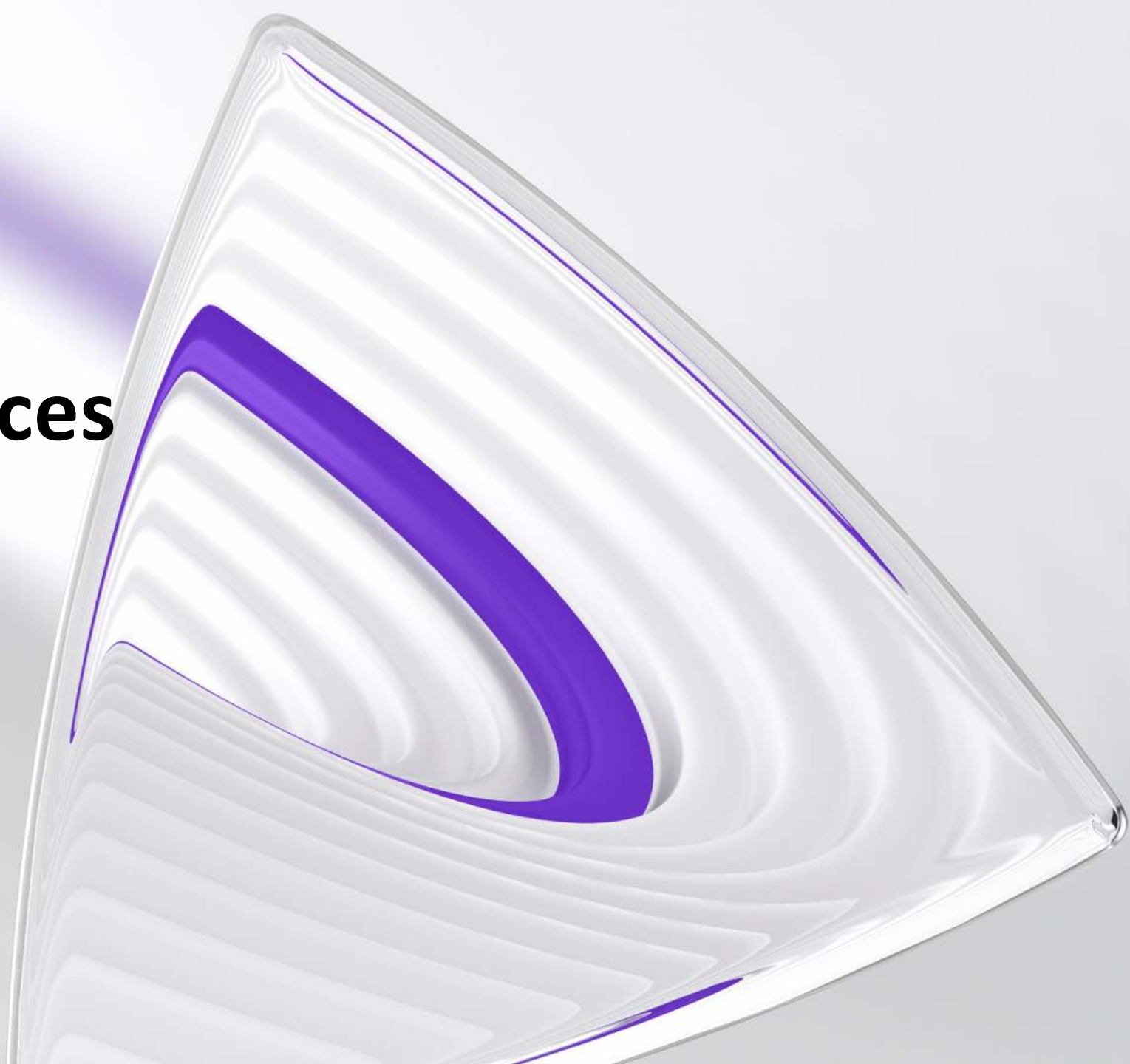




**Find reliable sources  
of API with  
Cortellis Generics  
Intelligence**



# Find reliable sources of API with Cortellis Generics Intelligence

## Questions you need to answer:

- Who has experience manufacturing my API?
- Are there sufficient suppliers available to manufacture my API?
- To which markets can this manufacturer supply?
- Who can serve as an alternate supplier in case there is a supply chain disruption?

## Common challenges:

- Evaluating competitors and potential business partners based on incomplete data.
- Using unreliable sources like conferences, industry contacts, and news portals to identify API manufacturers.
- Loss of revenue due to inaccurate data and poor selection of API sources.

## 3 steps

Find your answers with  
Cortellis Generic Intelligence

1. Identify manufacturers associated to your API.
2. Confirm their experience with more regulated markets like Europe and the USA.
3. Understand their level of production.

# 1. Identify manufacturers associated to your API

Once in the product record, go to the **API Manufacturers** tab to find names of companies, manufacturing status, regulatory filings, and other details.

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PRODUCT KEY INSIGHTS **API MANUFACTURERS** REGULATORY FILINGS APPROVALS CONSTRAINT DATE FORECAST & EXCLUSIVITIES PATENTS & SPCS US PATENT CHALLENGES DEALS COMPETITIVE INSIGHTS R&D SCIENTIFIC

LAUNCHES & PACK PRICES US MARKET SHARE LATAM MARKET SHARE

Filters Corporate API Rating Manufacturing Status Regulatory Filings Country/Territory

API Manufacturers Customize Columns Export Showing 1-25 of 35

API MANUFACTURER ↑	COUNTRY/ TERRITORY ↑	GDUFA FEE PAYMENT DATE	FDA INSPECTION DATE	MANUFACTURING STATUS ↑	CORPORATE GROUP ↑	CORPORATE API RATING ↑	REGULATORY FILINGS ↑
<a href="#">Xellia Pharmaceuticals Ltd</a>	Hungary	2021 Fiscal Year	01-Feb-2019	Commercially Available	<a href="#">Novo AS</a>	Big Pharma	US DMF JP DMF
<a href="#">ACS Dobfar SpA - ACSD6</a>	Italy	2013 Fiscal Year	13-Dec-2019	Innovator or Marketer	<a href="#">ACS Dobfar SpA</a>	Established	KR DMF
<a href="#">CKD Bio Corp</a>	South Korea	2021 Fiscal Year	26-Oct-2018	Unconfirmed API Activity	<a href="#">Chong Kun Dang Holdings</a>	Established	US DMF
<a href="#">Cadila Healthcare Ltd</a>	India	2021 Fiscal Year	26-Jul-2019	Not Manufacturing	<a href="#">Zydus-Cadila Healthcare Ltd</a>	Established	No data

## 2. Confirm their experience with more regulated markets like Europe and the USA

Select 'Established' and 'Less Established' in **Corporate API Rating\*** filters at the top to identify which manufacturers have worked with more regulated markets - USA, Japan, Australia or EU.

The screenshot shows a data table with the following columns: COUNTRY/TERRITORY, GDUFA FEE PAYMENT DATE, FDA INSPECTION DATE, MANUFACTURING STATUS, CORPORATE GROUP, CORPORATE API RATING, and REGULATORY FILINGS. The 'Corporate API Rating' filter is expanded, showing 'Established' and 'Less Established' selected. The table shows two rows of data:

COUNTRY/TERRITORY	GDUFA FEE PAYMENT DATE	FDA INSPECTION DATE	MANUFACTURING STATUS	CORPORATE GROUP	CORPORATE API RATING	REGULATORY FILINGS
Italy	2013 Fiscal Year	13-Dec-2019	Innovator or Marketer	ACS Dobfar SpA	Established	KR DMF
South Korea	2021 Fiscal Year	26-Oct-2018	Unconfirmed API Activity	Chong Kun Dang Holdings	Established	US DMF

\*Corporate API Rating is a proprietary analytic to indicate how capable the corporate group is of supplying bulk to more regulated markets, according to Cortellis Generics Intelligence.

### 3. Understand their manufacturing capabilities

Go to *Manufacturing Status*\* filter and select 'Commercially available' to identify which companies are already producing your API in commercial quantities.

The screenshot shows a web application interface with a filter menu open for 'Manufacturing Status'. The filter menu is highlighted with a blue box and contains the following options:

- Select all / Clear all
- Commercially Available
- Early API Activity
- Unconfirmed API Activity
- Innovator or Marketer
- Not Manufacturing

The table below shows the results of the filter:

API MANUFACTURER	PIA FEE PAYMENT DATE	FDA INSPECTION DATE	MANUFACTURING STATUS	CORPORATE GROUP	CORPORATE API RATING	REGULATORY FILINGS
Chongqing Daxin Pharmaceutical Co Ltd	9 Fiscal Year	04-Aug-2016	Commercially Available	Founder Group	Established	US DMF
Concord Biotech Limited	1 Fiscal Year	20-Sep-2019	Commercially Available	Concord Biotech Limited	Established	No data

\***Manufacturing Status** is a proprietary analytic to indicate the current manufacturing status, or relationship, between the API and the manufacturing site according to Cortellis Generics Intelligence.

# Your list of reliable API manufacturers

API manufacturers with experience in more regulated markets with commercial production of your API.

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PRODUCT KEY INSIGHTS | **API MANUFACTURERS** | REGULATORY FILINGS | APPROVALS | CONSTRAINT DATE FORECAST & EXCLUSIVITIES | PATENTS & SPCS | US PATENT CHALLENGES | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC

LAUNCHES & PACK PRICES | US MARKET SHARE | LATAM MARKET SHARE

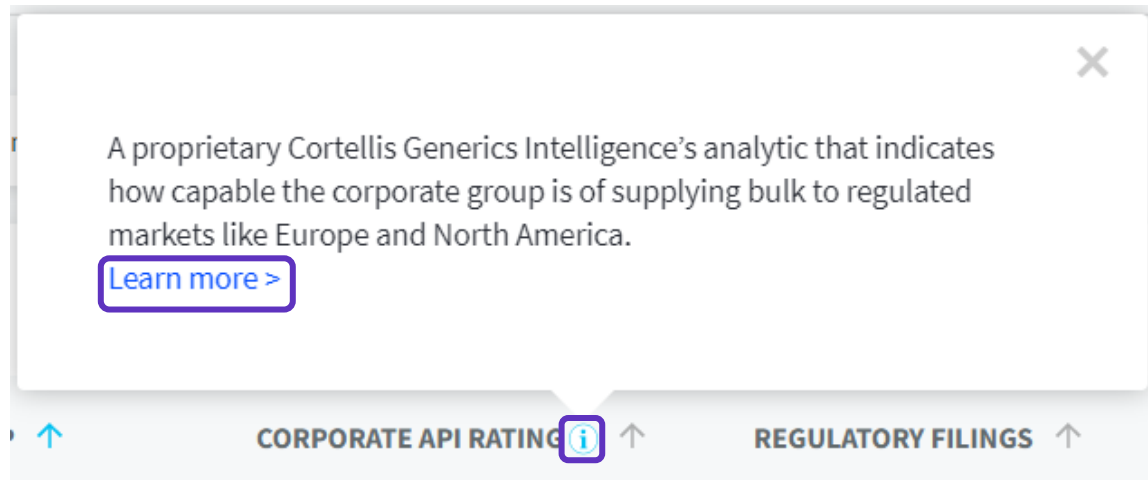
Filters: Corporate API Rating (2) | Manufacturing Status (1) | Regulatory Filings | Country/Territory

API Manufacturers Customize Columns Export Showing 1-7 of 7

API MANUFACTURER ↑	COUNTRY/ TERRITORY ↑	GDUFA FEE PAYMENT DATE	FDA INSPECTION DATE	MANUFACTURING STATUS ↑	CORPORATE GROUP ↑	CORPORATE API RATING ↑	REGULATORY FILINGS ↑
<a href="#">Chongqing Daxin Pharmaceutical Co Ltd</a>	China	2019 Fiscal Year	04-Aug-2016	Commercially Available	Founder Group	Established	US DMF
<a href="#">Concord Biotech Limited</a>	India	2021 Fiscal Year	20-Sep-2019	Commercially Available	Concord Biotech Limited	Established	No data
<a href="#">Hisun Pharmaceutical Hangzhou Co Ltd</a>	China	2021 Fiscal Year	10-Apr-2019	Commercially Available	Zhejiang Hisun Pharmaceutic...	Established	KR DMF
<a href="#">Livzon Group Fuzhou Fuxing Pharmaceutical Co Ltd</a>	China	2021 Fiscal Year	03-Aug-2018	Commercially Available	Joicare Pharmaceutical Grou...	Established	US DMF KR DMF
<a href="#">Olon SpA</a>	Italy	2021 Fiscal Year	14-Sep-2018	Commercially Available	P and R Holding	Established	US DMF KR DMF
<a href="#">Zhejiang Hisun Pharmaceutical Factory</a>	China	2021 Fiscal Year	07-Jun-2019	Commercially Available	Zhejiang Hisun Pharmaceutic...	Established	US DMF
<a href="#">Zhejiang Medicine Co Ltd Xinchang Pharmaceutical</a>	China	2021 Fiscal Year	30-Nov-2018	Commercially Available	Zhejiang Medicine Co Ltd	Less Established	US DMF

# Find further details on Manufacturing Status and Corporate API Rating

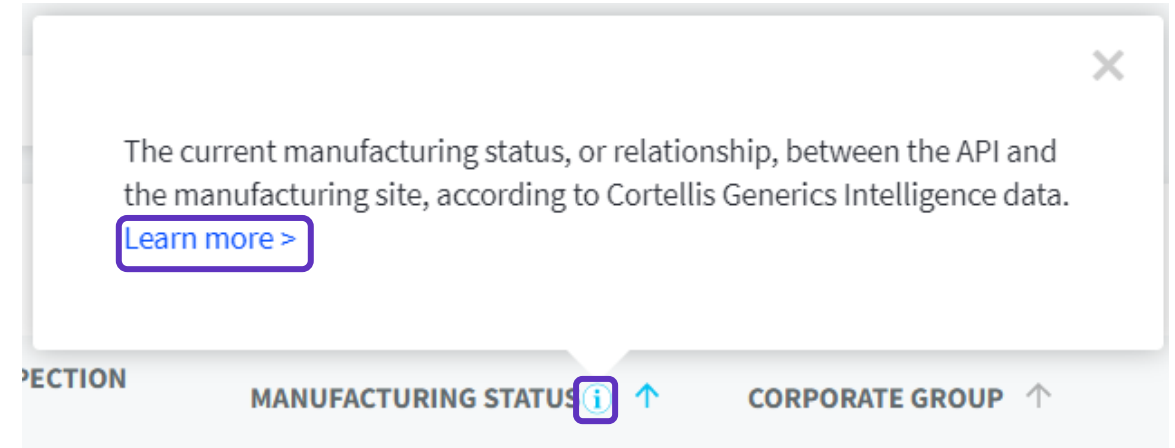
Click the 'i' icon next to the column heading to find definitions and levels of manufacturing and company rating



A proprietary Cortellis Generics Intelligence's analytic that indicates how capable the corporate group is of supplying bulk to regulated markets like Europe and North America.

[Learn more >](#)

↑ CORPORATE API RATING ⓘ ↑ REGULATORY FILINGS ↑



The current manufacturing status, or relationship, between the API and the manufacturing site, according to Cortellis Generics Intelligence data.

[Learn more >](#)

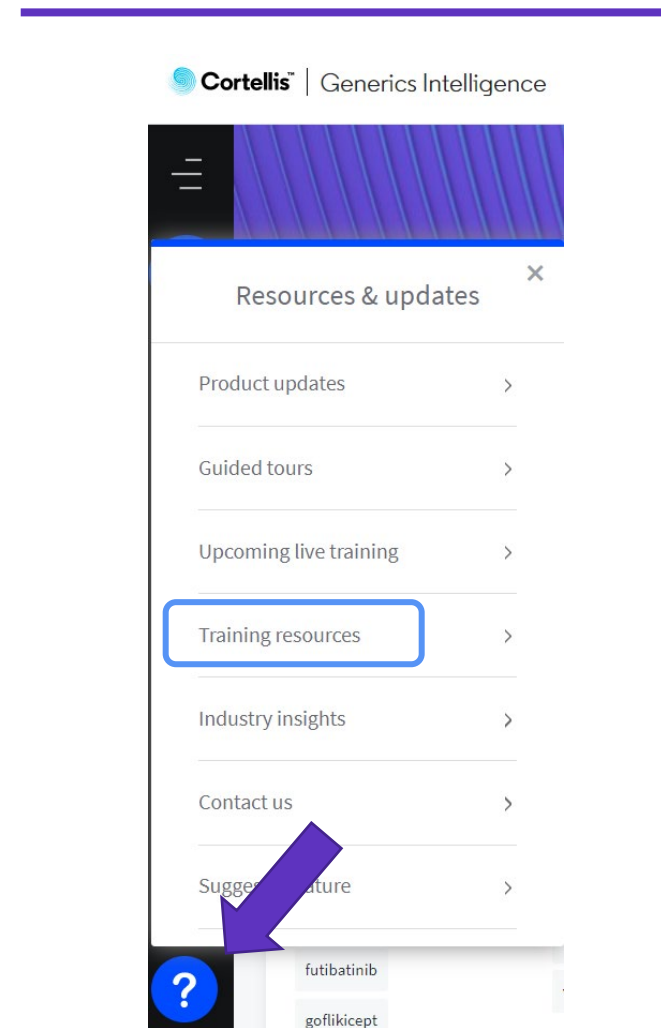
↑ PECTION ↑ MANUFACTURING STATUS ⓘ ↑ CORPORATE GROUP ↑

Hover and click the 'i' icon next these column heading to display definition and click 'Learn more' to go to a quick reference card explaining different levels of Corporate API Rating and Manufacturing Status.



## Need more guidance?

Go to Training resources via the question mark inside **Cortellis Generics Intelligence** to access quick reference cards, short videos and recorded sessions.





**To login to Cortellis  
Generics Intelligence  
[click here.](#)**

