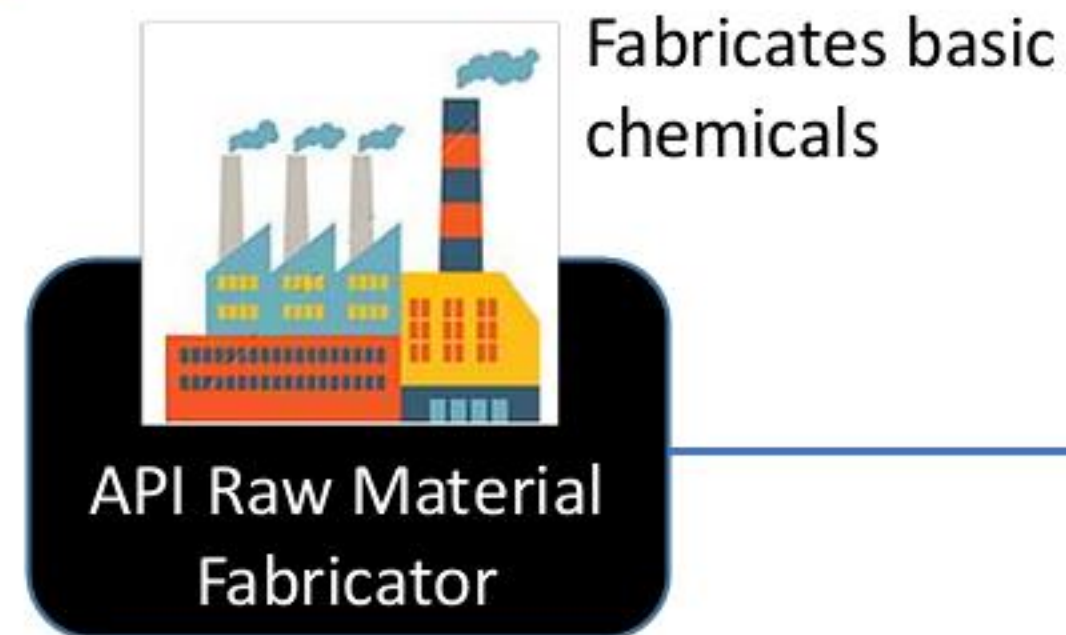




Scenario 1

Non-Sterile API Importation



-  Requires a DEL
-  Must be added to the API Annex of an Importer's DEL
-  No DEL, other standards



Distributing (DIN Holder) – maybe Importing



Distributor (DIN Holder) (API Importer)

DEL API Annex (Table A)
1. API Fabricator

Fabricating, Testing, Packaging/Labelling maybe Importing



FDF Fabricator (API Importer)



Pharmacy

Only 1 of the two buildings is the official importer. Who takes on the responsibilities of the importer may depend based on:

- Who purchases from FB (owns API)
- Who has quality / written agreement w/ FB
- Who can obtain GMP evidence for the FB



Fabricates basic chemicals



Fabricating API Intermediate and Packaging



Fabricating, Packaging and Labelling



Testing



Scenario 2 Outsourcing Activities

- Requires a DEL
- Must be added to the FDF Annex of an Importer's DEL
- Must be added to the API Annex of an Importer's DEL
- No DEL, GMPs apply
- No DEL, other standards

Fabricates non-sterile excipients



Fabricating FDF Partially Processed Intermediate



Fabricating FDF



Packaging / Labelling



Testing



DEL API Annex (Table A)

1. API Intermediate Fabricator
2. Finished API Fabricator
3. API Tester (or on FDF Annex)

DEL FDF Annex

1. FDF Intermediate Fabricator
2. FDF Fabricator
3. FDF Packager
4. FDF Tester



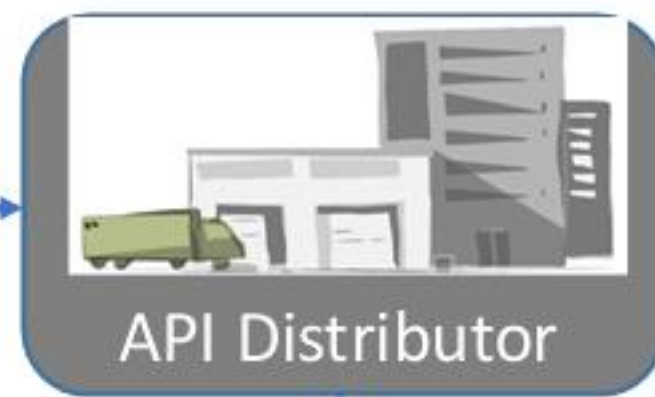


API Raw Material
Fabricator

Fabricating,
Testing, Packaging
and Labelling



API Fabricator



API Distributor

Scenario 3 The Supply Chain

- Requires a DEL
- Must be added to the FDF Annex of an Importer's DEL
- Must be added to the API Annex of an Importer's DEL
- No DEL, GMPs apply
- No DEL, other standards



API Importer



API Warehouse

Fabricating,
API Release Testing,
Packaging and
Labelling



FDF Fabricator



FDF Distributor
(DIN Holder)



DEL API Annex
(Table A)

1. API Fabricator

DEL FDF Annex

1. FDF Fabricator



FDF Importer



FDF Wholesaler



Pharmacy