3.2.S.2. Manufacture [{Drug Substance Name}, {Manufacturer}]

1. MANUFACTURER(S) [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing should be provided.

It is often easier for a reviewer to look at tables that list the company with their respective responsibility. A second table can also be added as in the example here to provide the reviewer a visual key for where the responsibilities change.

Table 1: Manufacturer Information

Facility	Responsibility
Chemical Company Inc Street Address City, State, Country Establishment Registration Number Contact person	Manufacture and control of Steps 1 to 3
API Chemical Company Inc Street Address City, State, Country Establishment Registration Number Contact person	Manufacture and control of Steps 3 to 5
Drug Substance Manufacture Inc Street Address City, State, Country Establishment Registration Number Contact person	Manufacture and Control of Step 6 Release Testing Stability Testing

Table 2: Manufacturer Responsibility Diagram

Responsibility	Chemical Company Inc	API Chemical Company Inc	Drug Substance Manufacture Inc
Step 1 to 2	X		
Step 3	X	X	
Step 4 to 5		X	
Step 6			X
Release and Stability			X

Testing			

Note: The steps in the tables above will be in reference to the Manufacturing Flow diagram contained in section 3.2.S.2.2. and in an electronic submission these will be hyperlinked.

Commercial drug substance lots will be manufactured, tested, released, packaged in bulk and tested for stability by the following proposed manufacturing site(s).

Table 3: Manufacturer Information

Facility	**Responsibility**