

**3.2.P.3.1. MANUFACTURER(S)**

Table 3.2.P.3.1-1 lists the sites that have responsibilities in the production of BNT162b2 drug product and their specified functions.

**Table 3.2.P.3.1-1. Sites and Responsibilities for BNT162b2 Drug Product Manufacture**

Site	FEI / DUNS Numbers	Responsibility
Pharmacia & Upjohn Company LLC <sup>c</sup> 7000 Portage Road Kalamazoo, MI 49001 United States	FEI: 1810189 DUNS: 618054084	LNP production and bulk drug product formulation Fill and finish Primary packaging Secondary packaging Release and stability testing: (b) (4)
Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs, 2870 Belgium	FEI: 1000654629 DUNS: 370156507	LNP production and bulk drug product formulation Fill and finish Primary packaging Secondary packaging Release and stability testing: (b) (4)
(Pfizer Global Supply) Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC <sup>a</sup> 1 Burt Road Andover, MA 01810 United States	FEI: 1222181 DUNS: 174350868	Release and stability testing: (b) (4)

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**Table 3.2.P.3.1-1. Sites and Responsibilities for BNT162b2 Drug Product Manufacture**

Site	FEI / DUNS Numbers	Responsibility
(Analytical Research & Development) Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC <sup>a</sup> 1 Burt Road Andover, MA 01810 United States	FEI: 1222181 DUNS: 174350868	Drug Product release and stability testing: (b) (4) [Redacted] In-process testing
Pfizer Inc. 875 Chesterfield Parkway West Chesterfield, MO 63017 United States	FEI: 1940118 DUNS: 004954111	Release and stability testing: (b) (4) [Redacted]
Pfizer Ireland Pharmaceuticals Grange Castle Grange Castle Business Park Clondalkin, Dublin 22 Ireland	FEI: 3004145594 DUNS: 985586408	Release and stability testing: (b) (4) [Redacted]
Hospira Zagreb Ltd. <sup>b</sup> Prudnička cesta 60 10291 Prigorje Brdovečko Croatia	FEI: 3010630287 DUNS: 500625201	Release testing: Sterility
SGS Lab Simon SA Vieux Chemin du Poète 10 Wavre, 1301 Belgium	FEI: 3004186644 DUNS: 283063907	Release testing: Sterility

a. The legal entity name change from Wyeth BioPharma Division of Wyeth Pharmaceuticals was changed at the acquisition by Pfizer in 2009, since then the Wyeth Pharmaceuticals manufacturing site in Andover, Massachusetts belongs to Pfizer’s production sites and is embedded in Pfizer’s GMP system. Pfizer will be utilized throughout the CTD.

b. Hospira is a wholly owned subsidiary of Pfizer Inc.

c. Pharmacia & Upjohn Company LLC is a wholly owned subsidiary of Pfizer Inc.

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