

### 3.2.P.3.1. MANUFACTURER(S) – PRE-FILLED SYRINGE (REFRIGERATED, GLASS)

Table 3.2.P.3.1-1 lists the sites that have responsibilities for the production and testing of BNT162b2 drug product in pre-filled syringe (PFS) (Refrigerated, Glass) presentation and their specified functions.

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

| Site  | Responsibility   |
|---|--|
| Pfizer Manufacturing Belgium NV<br>Rijksweg 12<br>Puurs-Sint-Amands,<br>2870<br>Belgium           | <b>Manufacture (30 µg RNA dose)</b> 4.2 1st ind. [REDACTED]<br><br><b>DP Release and stability testing</b> 4.2 1st ind. [REDACTED]<br><br><b>Batch release by Qualified Person in EEA [European Economic Area]<sup>a</sup></b> |
| BioNTech Manufacturing GmbH<br>Kupferbergterrasse 17<br>– 19<br>55116 Mainz<br>Germany            | <b>Batch release by Qualified Person in EEA [European Economic Area]</b>   |
| Pfizer Ireland Pharmaceuticals<br>Grange Castle Business Park<br>Clondalkin, Dublin 22<br>Ireland | <b>DP Release and stability testing</b> 4.2 1st ind. [REDACTED]  |

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

| Site   | Responsibility                            |
|--|---|
| Wyeth BioPharma <sup>b</sup><br>Division of Wyeth<br>Pharmaceuticals LLC<br>1 Burt Road<br>Andover MA 01810<br>United States | Stability testing 4.2 1st ind. [REDACTED] |

- a. Batch release of commercial lots utilizing drug substance from Wyeth (Pfizer) site in Andover, MA, US or Pfizer, Grange Castle, Ireland.
- b. 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.

Abbreviations: DP = Drug Product