Qualified Person's declaration concerning GMP compliance of the active substance manufacture "The QP declaration template"

PART A: Concerned active substance manufacturing sites

Name of Active Substance: Teriparatide

Name and Address of Active Substance Manufacturing Site[1,2]	**Manufacturing Operation / Activity[3]**
[redacted]	Full manufacture of active substance

1. List each site involved in the synthesis of the active substance beginning with the introduction of the designated active substance starting material, include intermediate manufacturing sites / part–processing sites.

2. State the site name and address in detail, including the building numbers (if applicable).

3. For example – Full or partial manufacture of the active substance, micronisation.

PART B: Manufacturing / Importer Authorisation Holder(s) (MIAHs) to which this QP declaration applies

This QP declaration is applicable to the following registered MIAH(s), that use the active substance as a starting material and/or is responsible for QP certification of the finished batch of a human or veterinary medicinal product, where the active substance is registered as a starting material and is manufactured at the sites listed in Part A:

MIAH Site	**MIAH Number**	**Manufacturing Activity**
	1084	Pen assembly Secondary packaging Responsible for batch release.
	M 16/333	Bulk Product Manufacture Primary packaging.

PART C: Basis of QP Declaration of GMP Compliance

Please tick section (i), complete the table in section (ii) and, if applicable, add the supplementary supporting information to section (iii).

(i) ☒ On-site audit of the active substance manufacturer(s)

(ii) Audit(s) of the active substance manufactured at the site(s) listed in PART A has/have been completed either by the MIAH(s) listed below or by a third party auditing body(ies) i.e. contract acceptor(s) on behalf of the MIAHs i.e. contract giver(s) as listed:

MIAH Site (or contract giver)	Auditing body (contract acceptor)	Site audited	Date of audit[4]
	---		6 September 2017

4 Justification should be provided if the date of last audit exceeds 3 years:

(iii) Supplementary supportive information (optional):

Results of inspections or GMP certificate(s) issued by EEA, MRA partners or other recognised authority together with other supporting information are attached.

Summary of supporting information provided
N.A.

PART D: QP declaration of GMP compliance

I declare that:

QP Responsibility

- I am a QP with specific responsibility for GMP compliance of the active substance manufactured at the sites listed in Part A and I am authorised to make this declaration.
- The audit report(s) and all the other documentation relating to this declaration of GMP compliance of the active substance manufacturer(s) will be made available for inspection by the competent authorities, if requested.

GMP Compliance

- The manufacture of the named active substance at sites given in Part A is in accordance with the detailed guideline on good manufacturing practice for active substances used as starting materials as required by Article 46(f) of Directive 2001/83/EC and Article 50(f) of Directive 2001/82/EC.
- This is based upon an audit of the active substance manufacturer(s).
- The outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.

Audit

- In the case of third party audit(s), I have evaluated each of the named contract acceptor(s) given in Part C and that technical contractual arrangements are in place and that any measures taken by the contract giver(s) are documented e.g. signed undertakings by the auditor(s).
- In all cases, the audit(s) was/were conducted by properly qualified and trained staff, in accordance with approved procedures.

Responsibilities in the case of multiple MIAH(s):

- This declaration is made on behalf of all the involved QPs named on the relevant MIAH(s) specified in Part B;
- A documented procedure defining GMP responsibilities is in place and that technical agreements exist between the named companies concerning management of GMP responsibilities.

Part E: Name and Signature of QP responsible for this Declaration

This declaration is submitted by:

Signatory _____ **Print name** **CRISTINA MAZÓ** **Date** 30th OCTOBER 2018 **Status (job title)** **QUALIFIED PERSON**	**MIAH Site** **MIAH number**