Site Visit Report

The site visit process is a sample on a particular day of an installation's compliance with some of its licence conditions. Where non-compliance against a particular condition has not been reported, this should not be construed to mean that there is full compliance with that condition of the licence.

Instructions and actions arising from the visit shall be addressed, or where applicable noted, by the licensee in order to ensure compliance, to improve the environmental performance of the installation and to provide clarification on certain issues.

The licensee shall take the actions specified to close out the non-compliances and observations raised in this Site Visit Report.

The licensee may also be requested to provide a response to the Environmental Protection Agency (hereafter referred to as the Agency) in relation to the site visit report findings.

Licensee

Name of Installation	AbbVie Ireland NL B.V.
Licensee	AbbVie Ireland NL B.V.
Licence Register No.	P1087-1
CRO Number	906838
Site Address	Old Bundoran Road, Ballytivnan, Sligo, F91 K735
Site Visit Reference No.	SV21806

Report Detail

Issue Date	14/07/2021
Prepared By	Aisling Ryan

Site Visit Detail

Date Of Inspection	22/06/2021		
Time In	11:40	**Time Out**	13:35
EPA Inspector(s)	Aisling Ryan		
Additional Visitors			
Licensee Personnel and Role	Jim Leahy (Site Engineering Services and EHS Manager) Charlene Rooney (EHS Lead) James Guihen (Site Engineering Services Lead) Alan Quinn (Site Services Engineer) Marty Ryan (Technical Operations)		

Summary

The main purpose of this site inspection was to discuss the planned manufacturing activities at the installation in 2021. The Agency agrees with the proposed clinical trial scheduled in July 2021. The licensee is required to submit a report detailing the clinical trial for Product 1 within the timeframe outlined in this report. The licensee should note that the licence is in force from the date the licence is granted and that all conditions of the licence should be adhered to at all times. The licensee should be aware of what constitutes an incident and ensure the Agency is notified by phone and via the EDEN system as soon as practicable after the incident, regardless of whether the cause is known at that time or not. Two observations were noted in relation to the Emergency Response Procedure and surface water integrity test reports, which require addressing.

Site Areas Inspected

- Plant room and boilers

Documents Inspected

The following documents were reviewed:

- Safety data sheet for surrogate bulk drug substance used in Product 1 and Product 2 (name confidential)
- Planned manufacturing activities for 2021 licensee return LR59412 and LR059637 (reviewed remotely post site visit)

1. Chemical Sector: General

		Answer	Condition Number	Non Compliance	Observation
1.1	Is the licensee testing SW pipelines in accordance with the EPA Clarification Note on the Requirements for Underground Pipeline Testing at Industrial and Waste Licensed Sites?	Checked	6.9		Yes

Comment / Action Required

Comment:

The licensee stated that the surface water pipelines integrity test report requires reviewing to establish if the testing criteria previously used was in accordance with current Agency guidelines.

Action Required:

Ensure that the surface water pipelines are tested in accordance with the EPA guidance note published in 2019 which is available at

http://www.epa.ie/pubs/advice/licensee/epaclarificationnoteontherequirementsforundergroundpipelinestesting.html

		Answer	Condition Number	Non Compliance	Observation
1.2	Does the licensee have an emergency response procedure that covers foreseeable incidents that may happen on the site?	Checked	9.2		Yes

Comment / Action Required

Comment:

The ERP was reviewed by the licensee in September 2020 however it was unclear if the report was reviewed in accordance with the EPA's 2016 guidance note "Guidance to Licensees on the Preparation of Accident Prevention Procedures and Emergency Response Procedures". The licensee was unsure if the Agency had assessed the report since it has been finalised.

Action Required:

Ensure the ERP has been updated with reference to the EPA guidance note outlined above and submit to the Agency for review as a licensee return via EDEN.

		Answer	Condition Number	Non Compliance	Observation
1.3	Has a firewater risk assessment been carried out in accordance with the most recent EPA guidance document?	Checked	3.12		

Comment / Action Required

Comment:

The licensee indicated that the firewater risk assessment was being drafted by consultants and was reviewed with regard to the Agency guidance note published in 2019. The final draft is expected in mid-July. On completion, submit the report to the Agency for review as a licensee return via EDEN.

2. Site Specific Issues

		Answer	Condition Number	Non Compliance	Observation
2.1	Planned manufacturing activities	Checked			

Comment / Action Required

Comment:

The licensee gave an update in relation to the planned activities for the site. The Agency agrees to the clinical trial of Product 1 due to commence in July 2021 and notes the following:

- The licensee stated that they intend to receive a small quantity of pharmaceutical drug substance in July 2021 for filling and lyophilisation only and will be operating as a fill finish facility for the foreseeable future. The batches will be used for clinical trial only and are not commercial products.
- The licensee is currently engaging with IW to allow for the discharge of wastewater which may contain traces of drug substance produced during the clinical trials to discharge from the on-site wastewater treatment plant to Sligo UWWTP.

In view of the above, submit a report to the Agency on the clinical trial ***one month*** after completion.

FOLLOW-UP ACTIONS

The licensee is required to complete the actions outlined in this site visit report within the specified timeframes. Where required, the licensee shall also respond to actions specified in Compliance Investigations and/or submit a response to this site visit report via the EDEN system. The licensee shall maintain a documentary evidence, for review by the Agency, that the prescribed actions were completed within the required timeframe.

(i) Compliance Investigations

The Agency may generate a Compliance Investigation through the EDEN system and issue instructions and actions to the licensee. The licensee will receive notification when an instruction or action is issued and the licensee must respond to the actions within the Compliance Investigation within the specified timeframe.

(ii) Response to Site Visit Report

Where the licensee is requested to (or wishes to) respond to the Agency in relation to this site visit report, the licensee may select the 'Make a Response' link on the actions taken by the licensee to address the issues raised in this site visit report and the target completion dates. This Licensee Public Response provides the licensee with an opportunity to inform both the Agency and the public about the implementing of actions set out in the Agency site visit report. The response must be submitted **within 30 calendar days** of the issue date of this site visit report.

(iii) Publication of Reports

The site visit report will be made available for public viewing via the Agency's Licence Enforcement Access Portal (LEAP), within one day of the issue date. The Site Visit Report and the Licensee Public Response will also be published on the Agency's website, www.epa.ie, 60 calendar days after the site visit report issue date (on the Licence Details Page for the relevant licence).

Please note that licensees are required to comply with the conditions of the licence at all times, and where non-compliance occurs, compliance must be restored within the shortest possible time. These actions will be verified during subsequent Agency visits. Please quote the above Inspection Reference Number in any correspondence in relation this Report.