

Confidentiality agreement  
nr PER-20/255

21.04.2025

1. Parties to the Contract

The Estonian State Agency of Medicines (Agency), registration code 70003477, represented by the Director General Katrin Kiisk, on the basis of the Statutes of the Medicines Agency, and Lekha Pezhumkattil, GMDP Inspector for Austrian Medicines and Medical Devices Agency performing work duties for the Estonian State Agency of Medicines on a temporary basis for a joint inspection of a medicinal product manufacturer GMP licence as an observer (hereinafter jointly referred to as the Parties), have concluded this Agreement as follows.

2. Subject of the Agreement

Pursuant to the Agreement, Lekha Pezhumkattil undertakes to ensure the confidentiality, without time limitation, of the information and personal data intended for internal use which are processed by the Agency or which come to his/her knowledge by chance within the Agency.

3. Obligations of the Parties

3.1. Lekha Pezhumkattil undertakes to keep confidential and not to disclose to third parties any information that has come to its knowledge while performing work duties for the Estonian State Agency of Medicines on a temporary basis for a joint inspection of a medicinal product manufacturer GMP licence as an observer, or accidentally.

3.2. Lekha Pezhumkattil undertakes to comply with the organisational, physical and IT security measures implemented by the Agency to protect the personal data processed against accidental or intentional unauthorised alteration, accidental destruction, intentional destruction, unauthorised access by unauthorised persons and unauthorised processing.

3.3 The obligation of confidentiality applies without time limitation.

4. Responsibility

4.1 A party who violates the requirements for the anonymisation of information intended for internal use, the processing of personal data and confidentiality requirements arising from the law or the contract shall be liable for such violation in accordance with the procedure laid down by law.

4.2. The Party shall be liable for any breach of the law relating to data protection under the Contract.

5. Confirmation by the Parties

The Parties confirm that they have read the terms and conditions of the Contract and understand the nature of the obligations they undertake by entering into the Contract.

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Katrin Kiisk

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Lekha Pezhumkattil