

**Temporary letter of reference**

7.2.2025

Dnro FIMEA/2025/000381-3

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Kirsi Luoto (151289) has worked at the Finnish Medicines Agency Fimea in following roles:

Regulatory Procedure Unit, Application Coordination Section 2

Title: Coordinator for Marketing Authorisations

Period: 1.10.2023- ongoing (full-time)

Clinico-pharmacological Unit, Clinico-pharmacological Section

Title: Research Coordinator

Period: 8.3.2022-30.9.2023 (full-time)

Regulatory Procedure Unit, Application Coordination Section 2

Title: Coordinator for Marketing Authorisations

Period: 1.1.2016-7.3.2022 (full-time)

Main work tasks of Coordinator for Marketing Authorisations include processing marketing authorisation applications and variation applications for medicinal products, both in national and EU procedures. For most of her time at Fimea, Kirsi Luoto has worked as a Coordinator for Marketing Authorisations in Centralised procedure. In this role, collaboration with the European Medicines Agency and other national agencies is continuous. This role involves daily cooperation in cross-functional and international teams.

Main work tasks of Research Coordinator included clinical assessment of marketing authorisation applications for generic medicinal products, assessment of user test of package leaflets of medicinal product, assessment of human factor studies, linguistic review of clinical sections of product information and classification of clinical variation applications.

The work tasks of Kirsi Luoto have also included mentoring new employees, being a tester and super user of a new national marketing authorisation database, coordinating paediatric investigation plan (PIP) procedures and being a product owner in a development project for marketing authorisation operations (since 09/2024).



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The employment is ongoing.

Signatures

This documents has been electronically signed.

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TYÖTODISTUKSET MYLA RPY (HAKO2) 2025

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Työtodistus Kirsi Luoto MYLA RPY HAKO2

Allekirjoitukset / Underskrifter / Signatures: