

Biosketch



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Nele Berthels is a clinical assessor at the Federal Agency for Medicines and Health Products in Belgium contributing to the marketing authorization of vaccines for human use in Europe and beyond. As Therapeutic Area Coordinator, she is responsible for the benefit-risk analysis of vaccines during their development and lifecycle.

She contributes to the agency's Innovation Office by advising industry and academic groups on their clinical development plans for new vaccines. She also contributes to scientific advice at the European level through the Scientific Advice Working Party of the European Medicines Agency (EMA).

She is a member of the Vaccines Working Party, the EMA body that provides recommendations to the Committee for Medicinal Products for Human Use (CHMP) on matters relating directly or indirectly to vaccines including the drafting of guidance documents.

Within the Belgian agency she is also involved in the activities of the Centre of Excellence of Vaccines. One project concerns the scientific and regulatory aspects of controlled human infection models and human challenge studies.

She obtained a MSc degree in bio-engineering and a PhD in biochemistry from KU Leuven (Belgium) in collaboration with Stellenbosch University (South Africa).

