DC02: Minor product changes waiver

Host institution: Eberhard Karls University of Tübingen (EKUT), Pharmaceutical Technology and Biopharmacy, Germany

Supervisor: Prof. Dominique Lunter

Co-supervisors: Prof. Ali Tfayli, University Paris-Saclay (Academic); Dr. Yvonne Sichhart, Dermapharm AG (Industrial)

Project description: Lifecycle management of cutaneous formulations frequently involves minor Q1/Q2 compositional changes that may not impact product performance. However, under the current EMA framework, even minor deviations often trigger full IVRT and IVPT reassessment, resulting in substantial experimental and regulatory burden.

This project aims to establish a scientific and regulatory framework for waiving IVRT and IVPT studies following minor formulation changes. The work will systematically investigate the impact of controlled Q1/Q2 deviations on formulation microstructure (Q3) and performance.

Formulations will be designed based on hypothesis-driven variations in excipient composition and characterised using microscopy and rheological profiling, followed by IVRT and IVPT. The project will intentionally include formulations exceeding current guideline limits to identify true performance-relevant thresholds.

The outcomes will include identification of excipient classes and compositional ranges that do not affect performance, development of validated analytical workflows to detect meaningful differences, and establishment of a decision tree for regulatory justification of minor changes. The results will directly support WP1 objectives and contribute to regulatory simplification and cost reduction in lifecycle management.

Host laboratory: The doctoral candidate will be hosted at the Institute of Pharmaceutical Sciences, Eberhard Karls University of Tübingen (EKUT), Germany. The institute is internationally recognised for its work in dermal drug delivery, IVRT and IVPT methodology and regulatory science. It provides advanced infrastructure for formulation development, rheological analysis and permeation testing. The research environment is interdisciplinary and closely connected to industrial partners, enabling translation of results into regulatory practice.

The University of Tübingen is committed to equity and diversity and actively promotes equal opportunities. The University seeks to raise the number of women in research and therefore encourages qualified female academics to apply for the position. Disabled candidates will be given preference over other equally qualified applicants.

The employment will be handled by the central administration of the University of Tübingen.

Secondments: This project is carried out in collaboration with the following company partners, and extended mobility to their laboratories is expected during the project:

- 12 months at Dermapharm AG, Germany (supervisor: Dr. Yvonne Sichhart)
- 6 months at Tiofarma BV, Netherlands (supervisor: Dr. Thijs Rooimans)

A willingness to travel and spend time abroad is therefore essential.

Tentative starting date: 1st Nov 2026

Eligibility conditions:

- Master's degree in pharmaceutics, pharmaceutical technology or related fields.
- Applicants must be doctoral candidates, i.e not already in possession of a doctoral degree.
- Mobility rule: researchers must not have resided or carried out their main activity in the country of the recruiting beneficiary for more than 12 months in the 36 months immediately before their recruitment date.

Required skills:

- Profound knowledge on pharmaceutical technology, ideally with prior knowledge on the design and physico-chemical and/or biopharmaceutical evaluation of semi-solid formulations for cutaneous use.
- Proficiency in the English language is required (minimum C1 level), as well as good communication skills, both oral and written. Successful candidates will need to provide an English test (e.g. IELTS, TOEFL, Cambridge English). You may be exempt if you are a national of a majority native-English speaking country, or have

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qualifications / degree that has been taught and assessed in English. The supervisor may also confirm that a candidate has the required level of English.

Remuneration:
The Doctoral Candidate will receive a gross yearly salary of ~48000 EUR in accordance with the MSCA Doctoral Networks programme, including a living allowance and a mobility allowance. This amount corresponds to the contractual gross salary and is indicated before deduction of employer costs, employee taxes and social security contributions. An additional family allowance (if applicable) is foreseen. The net salary will depend on local taxation, social security and employment regulations.

Enquiries:
For general information about the guideSkin Industrial Doctorate visit the project website (https://guideskin.eu/). Recruitment will be managed by the respective host or recruiting organisation. For additional information on this project, please contact Prof. Dr. Dominique Lunter (dominique.lunter@uni-tuebingen.de).

How to apply
Please send all the documents detailed below as one pdf file to dominique.lunter@uni-tuebingen.de.

Required documents:

- Statement of interest (limit of 2,500 characters) explaining why you wish to be considered for the fellowship and which qualities and experience you will bring to the role.
- Curriculum vitae et studiorum.
- A certificate of University examinations taken (with marks).
- A final degree certificate translated in English. If, at the time of application, candidates should not be yet in possession of a degree certificate, they can submit it at the time of the examination. However, if successful, the candidate will be required to provide a translated and legalised certificate as proof of eligibility for doctoral admission.

A limited number of applicants will be invited for an interview and will be required to provide contact information of up to two contact persons for reference letters.

Application deadline: The closing date for applications is **31st July 2026.**