

## Faculty of Science and Engineering

**Profile report:** Advanced dosage forms (Geavanceerde toedieningsvormen)

- Discipline: Pharmaceutical technology, formulation, advanced dosage forms
- Level: Tenure-track Assistant professor
- Fte: Full time (1.0)

### 1. Scientific discipline

The ultimate efficacy of many of today's advanced drug molecules, vaccines, and drug or vaccine containing constructs, is predominantly determined by the way these drugs are administered. The development of targeted and controlled release drug delivery formulations and the targeting of drugs to the site of action form the basis of this field of research, in which nanotechnology and the development of nanomedicines play an increasingly important role. The broad applicability of these new medicines necessitates large scale production in an industrial setting in a controlled, high-quality manner. Because nanomedicines are currently still only administered by invasive routes, their use is highly inconvenient for patients. Further development of advanced formulation- and production-technologies for these new drug molecules or constructs, incorporating non-invasive administration strategies and simultaneously improving their stability, is therefore urgently needed.

### 2. Vacancy

This position is opened by the Board of the Faculty (PT/gl/22/00243) and will be embedded in the Groningen Research Institute of Pharmacy (GRIP), research group Pharmaceutical Technology and Biopharmacy (PTB). The position falls within the framework of the career development program, 'Career Paths in Science 4' ('Bèta's in Banen 4'). Please see the link for the [criteria and conditions](#).

### 3. Selection committee (BAC)

Prof dr. G.J. Poelarends, Scientific Director GRIP, Chair of the Selection Committee.

Prof dr. E. Hak, Director education cluster pharmacy

Prof. dr. P. Olinga, Professor of Translational Biopharmaceutics

Prof. dr. A. Salvati, Associate Professor of Nanomedicine

Prof. dr. K. Taxis, Professor of Pharmacotherapy and Clinical Pharmacy

(Pharmacotherapy, Epidemiology, and Economics); Program Director Master Pharmacy.

External member: Prof dr. T. Vermonden, Associate Professor of Biomaterials in Drug Delivery and Regenerative Medicine, UU.

Student-member: To be confirmed

Advisors: F. Salverda (HR advisor); dr. R.V. van Calck (scientific coordinator), Prof dr. J.G.W. Kosterink (head Department of Clinical Pharmacy, UMCG).

### 4. Research area

With the ultrafast development and introduction of mRNA-based vaccines against COVID, a next step has been taken in the advanced administration of complex drugs

and vaccines. The rapid and effective development of these vaccines was possible because it built on decades of gene therapy research. However, these developments were not accompanied by a similar development of novel formulation technologies and dosage forms. Although the current technology works, its process technology and utilization are underdeveloped. Aspects such as the chosen route of administration, the qualitative and quantitative composition and the structure of the formulation, and the functionality of the dosage form are essential in the application of many modern pharmaceuticals, for instance mRNA vaccines and monoclonal antibodies, in order to obtain the desired efficacy and to avoid serious side effects. Furthermore, the biopharmaceutical functionalities, and the implications of these new formulation technologies and dosage forms are barely known. Further development of these technologies into useful forms of administration and a deeper understanding of their biopharmaceutical performance are essential in order to be able to use the mRNAs as a therapeutic agent, in addition to being used as a vaccine.

The rapid introduction of mRNA vaccines has revealed an unprecedented new potential for new drugs: a potentially new class of therapeutics that goes beyond mRNA alone, but also includes other (antisense) oligonucleotides (including siRNA and miRNA). In addition to being used as a vaccine, these molecules also offer the possibility of being used as a gene therapeutic. However, the transition from genetically-based vaccines to gene-based therapeutics, still requires far-reaching developments regarding the formulation of the dosage form and deeper research into its biopharmaceutical aspects. This includes the development of formulations and delivery systems that, in contrast to current mRNA vaccines, are able to specifically exert their effect in targeted cells, as well as simpler forms of administration that can be used safely and on a regular basis. Another focus area is the impressive increase in the use of protein-based therapeutics. Over the past two decades the therapeutic application of protein-based drugs (mainly monoclonal antibodies) has become the mainstay in several therapeutic fields, including the treatment of oncological and inflammatory diseases. However, apart from injections, no other dosage forms have been developed that allow an effective, convenient and non-invasive administration of these products to the patient. A development which is urgently needed in light of the frequently long-term therapies with these drugs.

## **5. Embedding: institute**

The Groningen Research Institute of Pharmacy (GRIP) is positioned within the Faculty of Science and Engineering (FSE) and physically located within the University Medical Centre Groningen (UMCG) of the Faculty of Medical Sciences (FMS); hence, in an ideal position to benefit from collaborations between the two faculties. Together with Medical Sciences, GRIP participates in the Research Institute GUIDE (Groningen University Institute for Drug Exploration). Pharmaceutical and medical research within GRIP is highly multidisciplinary. It bridges clinical and biomedical sciences on the one hand and chemistry, mathematics (statistics) and physics on the other. The interaction between the pharmaceutical sciences with these fundamental and clinical sciences offers excellent opportunities for cutting-edge research.

With this vacancy, GRIP's ambition is to further build on the scientific knowledge generated by its preclinical and clinical research groups (e.g. Chemical and Pharmaceutical Biology, Drug Design, Pharmaceutical Analysis, Nanomedicine and Drug Targeting) and complement the research portfolio of these groups with knowledge, research and development capacity for advanced therapeutic molecules and constructs, thereby facilitating their further development in a clinical setting. Furthermore, this position strengthens the collaboration with different UMCG research programs such as GRIAC, MHD and 3GI. Finally, collaboration with the research group of Prof. H. Santos of the Kolff institute at the UMCG is foreseen.

The candidate will be embedded in GRIP's research group Pharmaceutical Technology and Biopharmacy (PTB), which has a mission to perform research on dosage forms and their interaction with the living organism and explores human tissue-based translational models used in drug development.

The new position fits exceptionally well in GRIP's research portfolio. Advanced drug and vaccine entities may come from research groups such as Chemical and Pharmaceutical Biology, or Drug Design, whereas advanced constructs and nanomedicines are the provenance of the group Nanomedicines and Drug Targeting. Investigations into the biopharmaceutical functionality of the new dosage forms can be performed in collaboration with the research group of Prof. P. Olinga, also embedded in PTB. His technologies, including the advanced human precision cut tissue slices, offer excellent opportunities to evaluate innovative dosage forms already in an early stage in human materials. These collaborations, as well as those with UMCG researchers and beyond, cover a broad spectrum of activities, ensuring the true translational potential of this research can be achieved.

## **6. Local and (inter)national position**

In the Netherlands, research and education in the area of pharmaceutical technology and biopharmacy is carried out at Utrecht University (UU), Leiden University (LU), and the University of Groningen (UG). Various subjects within this discipline are divided over the three universities. In Utrecht research focuses on the synthesis of biodegradable polymers and their application in implants (Prof. W. Hennink), furthermore research is performed on bio- and nanotechnology approaches to drug delivery (Prof. E. Mastrobattista) and biomaterials for drug delivery and regenerative medicine (Prof. T. Vermonden). In Leiden research focuses on polymer-based nanomedicines (Prof. T. Barz), the physicochemical characterization of advanced drug substances and products (the late Prof. W. Jiskoot), and transdermal delivery of biopharmaceuticals (Prof. J. Bouwstra).

The Groningen group has established a strong national and international reputation as a pioneer in inhalation technology, advanced forms for oral drug delivery and in the stabilization and administration of biopharmaceuticals and vaccines. As the only academic group in the world, they have been able to bring new inhalers to the market (in collaboration with industry). This strong international position is apparent from participation in international consortia such as the UniSec consortium; an EU FP7 program in which 11 partners are conducting research into new influenza vaccines, with a budget of 6 million Euros of which the UG was the principal partner (Principal Coordinating Investigator). The group is also (by invitation) a participant in the EU IMI

2 project “Inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis” (iABC) and the Synergia project “Novel Virucidal Drugs”. Furthermore, extensive collaborations with the international pharmaceutical industry exist.

### **7. Expected contributions to research**

The candidate is expected to (further) develop an excellent **research line on the technological and biopharmaceutical aspects of advanced dosage forms**, with the aim to open up new application fields (especially with regard to mRNA-based therapeutics and therapeutic proteins) and to establish collaborations with relevant industrial and academic stakeholders. Integral to this is the acquisition of external funding to maintain a level of funding which allows the assistant professor to perform world-class research in this field. The candidate is expected to contribute to the further development of mRNA-based drug products, through research on innovative dosage forms and routes of administration for these products. Starting from the newly developed lipid nano-spheres for mRNA administration, improvements considering aspects such as stability, ease and route of administration, and transfection efficacy are expected to be realized. These should be linked to the current research of the group in pulmonary and oral drug administration, and stabilization of biopharmaceuticals. Furthermore, research on the industrial production of the current and newly developed formulations is expected, with a focus on quality by design of the product and larger scale production. The formulation of therapeutic proteins to open new routes of administration is another topic on which the candidate is expected to work. An important aspect of the position will involve the supervision of PhD students.

### **8. Expected contributions to teaching**

The candidate is expected to teach the first-year pharmacy bachelor course Pharmaceutical Technology and Biopharmacy 1 (WLFP1012) and to contribute to teaching the courses Pharmaceutical Technology and Biopharmacy 2 (WBFA16002) and Drug Development (WMMP006-05). Coaching and supervision of bachelor and master students is an essential part of the teaching tasks. The candidate is also expected to teach several elective courses in the field. The candidate will also be actively involved in the development of new courses and/or revision of existing courses. For instance, in order to offer comprehensive education in vaccination and its associated technologies for future pharmacists, the candidate is expected to contribute to the development of a new course on this subject in conjunction with other staff members.

### **9. Expected contributions to the organization**

The candidate is expected to have an active interest in and provide a positive contribution to the management and organizational tasks of the institute. At the level of the FSE, the candidate will contribute to the organization of the faculty, for example by participating in working groups and committees, in the fields of teaching, research and management. The candidate will participate in relevant national and international organizations.