

Curriculum Vitae

Work experience

Personal information Berendina Maria van den Hoorn

- 1. Employer: Medicine Evaluation Board
 - Start date: 102013 End date:

Position: Assessor Preclinical Pharmacology, Kinetics & Toxicology Activities: At the Medicine Evaluation Board, I am involved in the assessment of non_clinical pharmacodynamics, pharmacokinetics and safety of new medicines, medicines in development and post_registration. My work is focused on, but not restricted to, Advanced Therapy Medicinal Products (ATMPs). As a regulator I am involved in (early) development (Innovation Task Force (ITF) meetings and Scientific Advises), market applications and applications for post_registry changes. Furthermore, I co-operate with colleagues on a national and international level to shape the regulatory landscape of (preclinical) development of ATMPs by playing a role in TPI (investigating possibilities for transition animal_free innovation for ATMPs in the Netherlands), by providing input on newly written guidelines and by participating in a global project on the development of cell_therapies within HESI (see below). As side projects, I investigate together with Master students the developmental practice of (genetically modified) cell products and in vivo gene therapies using the information present in scientific advises given by the EMA over the last 6_7 years. This position requires team_work, analytical thinking, creativity, good communicative skills and flexibility.Country: Netherlands

- 2. Employer: Health and Environmental Sciences Institute Not for profit
 - Start date: 052019

 Start date: 052019
 End date:
 Position: Vice_chair of CT_TRACS committee (not for profit)
 Activities: As vice_chair of the CT_TRACS (Cell Therapy _ TRAcking, Circulation, & Safety) committee at HESI I am involved in bringing together partners from industry, academia and regulators or governmental organizations to address issues in the field of cell and gene therapies. Activities include investigating the possibilities for in vitro identification of the tumorigenicity of cellular therapies, investigating the possibilities for studying in vivo biodistribution and dynamics of cellular therapies, and in the near future to study ways to better identify the safety and efficacy issues with immune therapies involving cells. • Country: United States

- 3. Employer: Dutch Applied Research Organisation (TNO) Start date: 012012

 - End date: 092013
 - Position: Scientist

Activities: As a Scientist at TNO, I was involved in different projects. Activities imply literature study, experimental design, supervising technicians and presentation. This function requires cooperative and communicative skills, creative thinking, delivery of results and effective . planning.

- Country: Netherlands 4. Employer: Genmab A/S
 - - Start date: 032011 End date: 082011
 - Position: Scientific writer

 Activities: My position as Scientific Writer with Genmab B.V. includes translating experimental results into patents, scientific reports and presentations. Besides that, it involves literature studies, which are important to determine the strategic direction of projects. This function requires active participation in project teams, writing skills, effective planning and communication.

- Country: Netherlands 5. Employer: Dutch Cancer Institute (NKI_AVL)
 - Start date: 112004
 - End date: 102010
 - Position: Researcher / PhD student

• Activities: Researcher (PhD student) in the laboratory of Prof. Dr. J.J. Neefjes in a international environment, where I Investigated the cellular process of MHC class II antigen presentation. Several approaches, a.o. live microscopy, biochemistry, genetics, proteomics and systems biology, were integrated and resulted in a better understanding and novel insights in the process of MHC class II antigen presentation.

Country: Netherlands

Education and training

- 1. Subject: diverse
 - Start date: 012015 End date:

 Unit date:
 Qualification: not applicable (Gaining more knowledge on ATMPs)
 Organisation: 2020: Virtual ISCT _ Preparing CT_TRACS session imagine of cells _ (at ho 2019: CAR_T HESI/FDA meeting, Silver Springs, (USA) 2019: F2F meeting (CT TRACS) _ presentation on preclinical development of cell therapies, Washington DC, (USA) 2019: HESI meeting, Virginia, (USA) 2016: ESGCT / ISSCR conference 'Changing the fate of modern (at home) medicine: Stem cells & Gene Therapy', Firenze (IT) 2015: National conferences on gene and cell therapy (NSGCT, DSSCR), Utrecht and Lunteren (NL) 2015: European conference onAdvanced Therapy Medicinal Products (PDA_EU) Brussels (BE)

Country: 2. Subject: Diverse

- Start date: 032014
 - End date:

Qualification: Toxicologist Organisation: Molecular Toxicology (NVT), Pathology in Drug Development (ScafeSciMET), PharmacoKinetics Course (Kinesis Pharma) the Qualification of Toxicologist will be awarded when a sufficient set of courses are succesfully followed.

- Country: Netherlands
- 3. Subject: Leiden University & NKI_AVL Start date: 112004
 - End date: 102010
 - Oualification: PhD

Organisation: PhD study in the field of immunology, oncology and cell biology resulting in a thesis entitled; 'Novel insights in MHC class II antigen presentation'. Successfully defended at April 6th, 2011, Leiden University. I Followed a PhD program at the Amsterdam Oncology Graduate School Educational program to acquire PhD with following topics; Advanced microscopy, Drug development, Valorisation, Effective communication and cooperation, Scientific writing and presenting in English

- Country: Netherlands
 Subject: Utrecht University
 Start date: 091999
 End date: 082004

 - - Qualification: MSc
 - $\ensuremath{\mathsf{Organisation:}}$ BSc and MSc in Biology with a focus on cell biology, biochemistry, structural biology and microbiology
 - Country: Netherlands
- 5. Subject: Athenaeum
 - Start date: 091993 End date: 061999
 - Qualification: Diploma
 - Organisation: Focus on maths, biology, chemistry, economics
 - Country: Netherlands

Additional information

Publications

• B Duijndam, A Goudriaan, T van den Hoorn, JW van der Laan, B van de Water. Fluorescent reporters for pro_proliferative estrogen receptor alpha pathway activation (in preparation) • B M Helfer, V Ponomarev, S Patrick, P Blower, A Feitel, G Fruhwirth, S Jackman, L Pereira Mouriès, M Park, M Srinivas, D Stuckey, M Thu, T Van den P Blower, A Feitel, G Fruhwirth, S Jackman, L Pereira Mouriès, M Park, M Srinivas, D Stuckey, M Thu, T Van den Hoorn, CA Herberts, W Shingleton. Options for imaging cellular therapeutics in vivo; a multi stakeholder perspective. Cytotherapy August 2020 Submitted • P van Meer, P Theunissen, T van den Hoorn, CA Herberts, JW van der Laan. Animal free applications in the development of cell_based therapies British Journal of Clinical Pharmacology July 2020 Accepted for publication • T van den Hoorn, T Nackhedi, ACMT de Wolf, AMG Pasmooij, JW van der Laan, CA Herberts, Mining scientific advice reports on cell_based products; insight in the non_clinical development program. British Journal of Clinical Pharmacology July 2020 Accepted for publication • JW van der Laan, B Duijndam, van den Hoorn, T., R Woutersen, B van de Water. Changing the field of carcinogenicity testing of human pharmaceuticals by emphasizing mode of action. Current Opinion in Toxicology 2017 3, pp. 55_61 • T van den Hoorn, L Janssen, H Janssen & JI) Neefies. Dvnamics within tetraspanin pairs affect MHC class II expression. Journal of Cell Science 2012 125/Pt JJ Neefjes. Dynamics within tetraspanin pairs affect MHC class II expression. Journal of Cell Science 2012 125(Pt 2):328_339. • T van den Hoorn, P Paul, MLM Jongsma, MJ Bakker, RCC Hengeveld, P Cresswell, DA Egan, M van Ham, A ten Brinke, H Ovaa, RL Beijersbergen, C Kuijl and JJ Neefjes. A genome_wide multidimensional RNAi screen reveals pathways controlling MHC class II antigen presentation. Cell 2011 145(2): 268_83. • T van den Hoorn, P Paul, MLM Jongsma & JJ Neefjes. Routes to manipulate MHC class II antigen presentation Current Opinion in Current Opinion in Computer 20(1): 261(2) Immunology 2011 23(1): 88 _95. • C Lang, S Grava, T van den Hoorn, R Trimble, P Philippsen, SL Jaspersen. Mobility, microtubule nucleation and structure of microtubule_organizing centers in multinucleated hyphae of Ashbya gossypii Molecular Biology of the Cell 2010: 21(1) 18 _ 28. • T van den Hoorn & JJ Neefjes. Activated pDCs: Open to new antigen_presentation possibilities Nature Immunology 2008: 9: 1208 – 1210. • T van den Hoorn & JJ Neefjes. Nature Immunology 2008: 9: 1208 – 1210.

Projects

Memberships

Other Relevant Information