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Summary of Skills and Qualifications

I am a biomedical scientist by training and professional experience, holding a PhD in Biotechnology. My academic specialization in molecular immunology and flow cytometry has been a linchpin to build a diversified professional experience in biomedical research, laboratory diagnostics and IVD manufacturing.

Prior to my current function, I have been department head in an accredited Belgian medical laboratory, as well as department head in a global laboratory CRO for clinical trials. In these functions, I acquired profound experience with international standards for laboratory diagnostics (CLSI) and quality management systems (QMS) for medical laboratories. Trained as internal EN ISO 15189 auditor, I co-ensured continuous adherence of other departments to this aforementioned standard. As department head, I was end responsible for the verification, implementation and harmonization of various clinical assays in medical laboratories on multiple continents, in line with the analytical and quality requirements of laboratory tests for clinical trials. These clinical assays ranged from routine certified IVD assays (e.g., hematology, serology, clinical chemistry...) to laboratory-developed specialty tests (e.g. flow cytometry, electrophoresis, immuno-assays...).

My accumulated expertise in medical laboratory IVD devices (reagents and instruments) led me to my current function, wherein I work with IVD device manufacturers to ensure device compliance with Regulation (EU) 2017/46. This includes consultancy and gap assessment on regulatory compliance and performance evaluation strategy, as well as writing and reviewing of device technical documentation. I am currently managing a team of device compliance specialists, but I have previously authored and compiled technical documentation for over 50 devices, including the first Class C IVD device certified under Regulation (EU) 2017/46. As such, I am well-acquainted with various (EN) ISO / IEC standards relevant for IVD devices (QMS, risk management, labelling, performance evaluation...), interaction with different stakeholders (regulatory affairs, quality, R&D...) within IVD manufacturing companies, IVD technical documentation requirements, and document submissions to Notified Bodies.

Throughout my different professional functions, I have always worked in direct communication with my company's customers. My communication and collaboration skills were key elements in these roles, as well as my ability to follow up and steer projects at multiple locations to make sure timelines are met and, if needed, issues are escalated properly. I have experience in managing and motivating people, either as a direct people manager or as a technical specialist to support specific projects, via a positive attitude and clear communication. I am used to and enjoy working in culturally diversified teams using multiple languages.

Experience breakdown by IVDR codes

- Authoring or reviewing technical documentation, compliant with Regulation (EU) 2017/46
 - IVR 0301, 0503, 0602, 0701, 0702
 - IVS 1001, 1004, 1007, 1008
 - IVT 2005
 - IVP 3006, 3007
 - IVD 4005, 4008
- Other experience (medical laboratory or academic training)
 - IVR 0301, 0506, 0601, 0602, 0608

- IVS 1008
- IVT 2005
- IVP 3006, 3007, 3014
- IVD 4002, 4005, 4008

Self-evaluation

- Self-confident and enthusiastic person that likes to work with and for people
- Result-driven motivator that strives for improvement and welcomes organizational changes
- Good communicator and customer-oriented team player
- Works independently but benefits greatly from the team's input and advice
- Decision maker and long-term planner that sets objectives in the context of a bigger picture

Work Experience

Nov. 2019 – Now	<u>Medical Device Compliance Senior Consultant</u> , QARAD (part of QbD Group)
Jan. 2018 – Oct. 2019	<u>Head of Science Department</u> , Cerba Research (previously BARC Central Lab)
Mar. 2017 – Dec. 2017	<u>Scientific Liaison – Flow Cytometry</u> , Cerba Research (previously BARC Central Lab)
Sept. 2015 – Feb. 2017	<u>Customer Service Manager</u> , CRI Medical Lab (Cerba Research)
June 2014 – Aug. 2015	<u>Head of Flow Cytometry</u> , CRI Medical Lab & Cerba Research (previously BARC Central Lab)
Sept. 2012 – May 2014	<u>Operational lead – Flow cytometry technical support team</u> , BD Biosciences Europe
Jan. 2010 – Aug. 2012	<u>Flow cytometry specialist</u> – Departmental Core Facility, VIB Inflammation Research Centre & Ghent University
Apr. 2008 – Dec. 2009	<u>Post-doctoral researcher</u> – Unit Molecular Signaling and Cell Death, VIB Inflammation Research Centre & Ghent University

Education

2002 – 2008	<u>Doctor in Sciences: Biotechnology</u> . PhD thesis: ' <i>Molecular characterisation of macrophage activation and functions in mouse models of bronchial inflammation</i> '. Ghent University, Lab for Molecular Immunology. Promoter: Prof. Dr. Johan Grooten
2000 – 2002	<u>Master in Biotechnology</u> , Ghent University, finished with distinction. Master thesis: ' <i>Time- and level-controlled expression of anti-oxidant enzymes through a retroviral tetracycline system in tumor cell lines</i> '. Ghent University, VIB Inflammation Research Centre – Unit Molecular Immunology. Promoter: Prof. Dr. Johan Grooten
1998 – 2000	<u>Bachelor in Biology</u> , Ghent University, finished with distinction

Languages

- Dutch : native proficiency
- English : full professional proficiency
- French : professional working proficiency

Authorship on international, peer-reviewed scientific papers

De Koker S, Van Hoecke L, De Beuckelaer A, Roose K, Deswarte K, Willart MA, Bogaert P, Naessens T, De Geest BG, Saelens X, Lambrecht BN, and Grooten J. *Inflammatory monocytes regulate Th1 oriented immunity to CpG adjuvanted protein vaccines through production of IL-12*. *Sci Rep*. 2017 Jul 20;7(1):5986

Andries V, Vandepoele K, Staes K, Berx G, Bogaert P, Van Isterdael G, Ginneberge D, Parthoens E, Vandebussche J, Gevaert K, van Roy F. *NBPF1, a tumor suppressor candidate in neuroblastoma, exerts growth inhibitory effects by inducing a G1 cell cycle arrest*. *BMC Cancer*. 2015 May 10;15(1):391.

Goossens S, Blanchet O, Durinck K, Van der Meulen J, Radaelli E, Peirs S, Tremblay C, Tagon T, Costa M, Farhang Ghahremani M, De Medts J, Bartunkova S, Haigh K, Schwab S, Farla N, Pieters T, Matthijssens F, Van Roy N, Best A, Deswarte K, Bogaert P, Carmichael C, Rickard A, Suryani S, Bracken L, Alserihi R, Haenebalcke L, Clappier E, Rondou P, Slowicka K, Huylebroeck D, Goldrath A, Janzen V, McCormack M, Lock R, Curtis D, Harrison C, Berx G, Speleman F, Meijerink J, Soulier J, Van Vlierberghe P, Canté-Barrett K, Haigh J. *ZEB2 drives immature T-cell lymphoblastic leukemia development via enhanced tumor-initiating potential and IL-7 receptor signaling*. *Nat Commun*. 2015 Jan 7;6:5794.

Vanden Berghe T, Demon D, Bogaert P, Vandendriessche B, Goethals A, Depuydt B, Vuylsteke M, Roelandt R, Van Wonterghem E, Vandebroecke J, Choi S, Meyer E, Krautwald S, Declercq W, Takahashi N, Cauwels A, Vandenabeele P. *Simultaneous Targeting of Interleukin-1 and -18 is Required for Protection against Inflammatory and Septic Shock*. *Am J Respir Crit Care Med*. 2014 Feb 1;189(3):282-91.

Vanden Berghe T, Goethals A, Demon D, Bogaert P, Mak TW, Cauwels A, Vandenabeele P. *An inactivating caspase-11 passenger mutation muddles sepsis research*. *Am J Respir Crit Care Med*. 2013 Jul 1;188(1):120-1.

De Baets S, Schepens B, Sedeyn K, Schotsaert M, Roose K, Bogaert P, Fiers W, Saelens X. *Recombinant influenza virus carrying the respiratory syncytial virus (RSV) F85-93 CTL epitope reduces RSV replication in mice*. *J Virol*. 2013 Mar;87(6):3314-23.

Schotsaert M, Ysenbaert T, Neyt K, Ibañez LI, Bogaert P, Schepens B, Lambrecht BN, Fiers W, Saelens X. *Natural and long-lasting immune responses against influenza in the M2e-immune host*. *Mucosal Immunol*. 2013 Mar;6(2):276-87.

Pollard C, Rejman J, De Haes W, Verrier B, Van Gulck E, Naessens T, De Smedt S, Bogaert P, Grooten J, Vanham G, De Koker S. *Type I IFN Counteracts the Induction of Antigen-Specific Immune Responses by Lipid-Based Delivery of mRNA Vaccines*. *Mol Ther*. 2013 Jan;21(1):251-9.

Galle M, Jin S, Bogaert P, Haegman M, Vandenabeele P, Beyaert R. *The Pseudomonas aeruginosa Type III Secretion System has an Exotoxin S/T/Y independent pathogenic role during acute lung infection*. *PLoS One*. 2012 Jul 23;7(7): e41547.

Naessens T, Vander Beken S, Bogaert P, Van Rooijen N, Lienenklaus S, Weiss S, De Koker S, Grooten J. *Innate Imprinting of Murine Resident Alveolar Macrophages by Allergic Bronchial Inflammation Causes a Switch from Hypo- to Hyperinflammatory Reactivity*. *Am J Pathol*. 2012 Jul; 181(1):174-184.

De Geest BG, Willart MA, Hammad H, Lambrecht BN, Pollard C, Bogaert P, De Filette M, Saelens X, Vervaet C, Remon JP, Grooten J, and De Koker S. *Polymeric multilayer capsules mediated vaccination induces protective immunity against cancer and viral infection*. *ACS Nano*. 2012 Mar 27;6(3):2136-49.

Maelfait J, Roose K, Bogaert P, Sze M, Saelens X, Pasparakis M, Carpentier I, van Loo G, Beyaert R. *A20 (Tnfrsf25) Deficiency in Myeloid Cells Protects against Influenza A Virus Infection*. *PLoS Pathog*. 2012 Mar;8(3):e1002570.

Schepens B, Ibañez II, De Baets S, Hultberg A, Bogaert P, De Bleser P, Vervalle F, Verrips T, Melero J, Vandevelde W, Vanlandschoot P, Saelens X. *Nanobodies® specific for Respiratory Syncytial Virus Fusion protein protect against infection by inhibition of fusion*. *J Infect Dis*. 2011 Dec;204(11):1692-701.

- Vanlangenakker N, Bertrand MJM, Bogaert P, Vandenabeele P, Vanden Berghe T. *TNF-induced necroptosis in L929 cells is tightly regulated by multiple TNFR1 complex I and II members*. Cell Death Dis. 2011 Nov 17;2:e230.
- Dierendonck M, De Koker S, De Rycke R, Bogaert P, Grooten J, Vervaeke C, Remon JP, De Geest BG. *Single-step formation of degradable intracellular biomolecule microreactors*. ACS Nano. 2011 Sep 27;5(9):6886-93.
- Krysko DV, Kaczmarek A, Krysko O, Heyndrickx L, Woznicki J, Bogaert P, Cauwels A, Takahashi N, Magez S, Bachert C, Vandenabeele P. *TLR-2 and TLR-9 are sensors of apoptosis in a mouse model of doxorubicin-induced acute inflammation*. Cell Death Differ. 2011 Aug;18(8):1316-25.
- Goossens S, Bartunkova S, Yokomizo T, Drogat B, Crisan M, Haigh K, Seuntjens E, Umans L, Riedt T, Bogaert P, Haenebalcke L, Berx G, Dzierzak E, Janzen V, Huylebroeck D, and Haigh JJ. *The EMT regulator Zeb2/Sip1 is essential for murine embryonic hematopoietic stem/progenitor cell differentiation and mobilization*. Blood. 2011 May 26;117(21):5620-30.
- Bogaert P, Naessens T, De Koker S, Hennuy B, Hacha J, Smet M, Cataldo D, Di Valentin E, Piette J, Tournoy KG, Grooten J. *Inflammatory signatures for eosinophilic versus neutrophilic allergic pulmonary inflammation reveal critical regulatory checkpoints*. Am J Physiol Lung Cell Mol Physiol. 2011 May;300(5):L679-90.
- Festjens N, Bogaert P, Batni A, Houthuys E, Plets E, Vanderschaeghe D, Laukens B, Asselbergh B, De Rycke R, Willart MA, Jacques P, Elewaut D, Brouckaert P, Lambrecht BN, Huygen K, Callewaert N. *Disruption of the SapM locus in Mycobacterium bovis BCG improves its protective efficacy as a vaccine against M. tuberculosis*. EMBO Mol Med. 2011 Apr;3(4):222-34.
- Vanlangenakker N, Vanden Berghe T, Bogaert P, Laukens B, Zobel K, Deshayes K, Vucic D, Fulda S, Vandenabeele P, Bertrand MJ. *ciAP1 and TAK1 protect cells from TNF-induced necrosis by preventing RIP1/RIP3-dependent reactive oxygen species production*. Cell Death Differ. 2011 Apr;18(4):656-65.
- Dejager L, Pinheiro I, Bogaert P, Huys L, Libert C. *Role for neutrophils in host immune responses and genetic factors that modulate resistance to Salmonella enterica serovar typhimurium in the inbred mouse strain SPRET/Ei*. Infect Immun. 2010 Sep;78(9):3848-60.
- Soubry A, Staes K, Parthoens E, Noppen S, Stove C, Bogaert P, van Hengel J, van Roy F. *The transcriptional repressor kaiso localizes at the mitotic spindle and is a constituent of the pericentriolar material*. PLoS One. 2010 Feb 15;5(2):e9203.
- De Koker S, Naessens T, De Geest BG, Bogaert P, Demeester J, De Smedt S, Grooten J. *Biodegradable polyelectrolyte microcapsules: antigen delivery tools with Th17 skewing activity after pulmonary delivery*. J Immunol. 2010 Jan 1;184(1):203-11.
- Van den Bossche J, Bogaert P, van Hengel J, Guérin CJ, Berx G, Movahedi K, Van den Bergh R, Pereira-Fernandes A, Geuns JM, Pircher H, Dorny P, Grooten J, De Baetselier P, Van Ginderachter JA. *Alternatively activated macrophages engage in homotypic and heterotypic interactions through IL-4 and polyamine-induced E-cadherin/catenin complexes*. Blood. 2009 Nov 19;114(21):4664-74.
- Bogaert P, Tournoy KG, Naessens T, Grooten J. *Where asthma and hypersensitivity pneumonitis meet and differ: noneosinophilic severe asthma*. Am J Pathol. 2009 Jan;174(1):3-13.
- Raes G, Brys L, Dahal BK, Brandt J, Grooten J, Brombacher F, Vanham G, Noël W, Bogaert P, Boonefaes T, Kindt A, Van den Bergh R, Leenen PJ, De Baetselier P, Ghassabeh GH. *Macrophage galactose-type C-type lectins as novel markers for alternatively activated macrophages elicited by parasitic infections and allergic airway inflammation*. J Leukoc Biol. 2005 Mar;77(3):321-7.

Authorship on international congress presentations

Bogaert P. *IVDR and LDTs - The Time to Act is Now*. ESCCA 2022 Conference, 2022, Belfast, UK. Oral presentation.

Bogaert P. *The Forest and the Trees - Challenging IVDR Requirements*. MedTech Europe Summit, 2022, Dublin, Ireland. Oral presentation.

Bogaert P. *EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)*, 2022, NVKFAZ Symposium, Leiden, The Netherlands. Oral presentation.

Schotsaert M, Ysenbaert T, Neyt K, Ibanez LI, Bogaert P., Lambrecht BN, Fiers W, and Saelens X. *M2e-based universal vaccine protects against Influenza A virus challenge and enhances heterosubtypic immunity during subsequent infections*. Keystone symposium: 'Pathogenesis of Influenza: Virus-Host Interactions', 2011, Kowloon, Hong Kong, China. Oral presentation.

Festjens N, Bogaert P., Houthuys E, Plets E, Vanderschaeghe D, Laukens B, Batni A, Asselbergh B, Parthoens E, De Rycke R, Willart MA, Jacques P, Elewaut D, Brouckaert P, Lambrecht BN, Huygen K and Callewaert N. *Disruption of the SapM locus in Mycobacterium bovis BCG improves its protective efficacy as a vaccine against M. Tuberculosis*. Keystone symposium: 'Tuberculosis: Immunology, Cell Biology and Novel Vaccination Strategies', 2011, Vancouver, Canada. Poster presentation.

Vanden Berghe T, Demon D, Bogaert P., Goethals A, Vandenbroecke J, Noppen N, Takahashi N, Cauwels A, Vandenabeele P. *Susceptibility for E. coli LPS-induced lethality is differentially regulated by caspase-1 and -3*. 18th ECDO Euroconference on Apoptosis, 2010, Ghent, Belgium. Poster presentation.

Van den Bossche J, Bogaert P., van Hengel J, Guérin CJ, Bex G, Movahedi K, Van den Bergh R, Pereira-Fernandes A, Geuns JM, Pircher H, Dorny P, Grooten J, De Baetselier P, Van Ginderachter JA. *Alternatively activated macrophages engage in homotypic and heterotypic interactions through IL-4 and polyamine-induced E-cadherin/catenin complexes*. Keystone symposium: 'The Macrophage: Intersection of Pathogenic and Protective Inflammation', 2010, Banff, Canada. Oral presentation.

Bogaert P., Boonefaes T, Serbruyns B, Raes G, Maes T, Brusselle G, Van Ginderachter J, Pauwels R, De Baetselier P, Grooten J. *Identification of new genetic markers and effector functions of alternative macrophage activation in allergic asthma*. XIXth World Allergy Congress, 2005, Munich, Germany. Oral Presentation & Poster presentation on the Junior Poster Session. Laureate of Junior Poster Prize.

Jury member of PhD examination commission

Houthuys Erica. *Transcriptome analysis of monocytes and macrophages in mycobacterial infection and chronic kidney disease*. 2010, Ghent University, Lab for Molecular Pathophysiology and Experimental Therapy. Promoter: Prof. Dr. Peter Brouckaert

Naessens Thomas. *Functional dynamics of resident alveolar macrophages in a mouse model of allergic asthma*. 2012, Ghent University, Lab for Molecular Immunology. Promoter: Prof. Dr. Johan Grooten

Vander Beken Seppe. *Mycobacterium tuberculosis bio-lipid mycolic acid and mammalian cholesterol-sensor liver X receptor in airway immunity*. 2012, Ghent University, Lab for Molecular Immunology. Promoter: Prof. Dr. Johan Grooten