Donat De Groote, PhD

Expert in Biotechnology, Diagnostics & Regulatory Affairs
Founder & Managing Director — AZ Biotech Consulting

Waterloo, Belgium | +32 473 33 71 13 | donat.degroote@azbc.be | www.azbc.be

Professional Summary

Senior executive and scientist with over 40 years of experience in biotechnology, diagnostics, and medical devices. Specialised in Regulatory Affairs, ISO 13485 Quality Management Systems, CE marking, and strategic consulting for MedTech, IVD, and SaMD companies. Founder of AZ Biotech Consulting (since 2011), Donat provides executive and freelance consulting services to start-ups and SMEs, helping them achieve regulatory compliance, certification, and market access. Recognised for his dual expertise in science and business management, he has supported numerous organizations in the implementation of QMS, CE marking, and clinical and performance evaluation processes.

Key Expertise

- Regulatory Affairs & Quality Systems (ISO 13485, MDR, IVDR)
- PRRC (Person Responsible for Regulatory Compliance) functions
- CE marking and Technical Documentation (hardware, software, IVD)
- Clinical and Performance Evaluation
- Start-up mentoring, business creation and strategic planning
- Project management, grant writing, funding and partnerships
- Integration of digital QMS (e.g. Confluence-based systems)

Professional Experience

Founder & Managing Director | AZ Biotech Consulting, Belgium (2011 – Present)

Freelance executive and consultant for biomedical, diagnostic, and medical device companies. Services include Regulatory Affairs, QA/RA Management, PRRC responsibilities, Medical Affairs, QMS implementation, grant writing, and start-up support.

Selected Missions (2011–2025):

• CONTIPHARMA SA – QA/RA Manager & PRRC (IVD): Implementation and management of ISO 13485 QMS for IVD devices; PRRC responsibilities.

• CONTIPHARMA SA – Project Management Support: Steering committee member for R&D projects in molecular diagnostics.

• COMUNICARE SOLUTIONS SA – QA/RA Manager & PRRC (Telemedicine): QMS implementation and regulatory compliance for telemedicine software under MDR and IEC 62304.

• AFEC SRL – QA/RA Manager & PRRC: QMS management for PPE manufacturing and medical device distribution.

• HEARTKINETIC SA – QA/RA Manager & PRRC (Cardiology): Implementation of QMS and preparation of CE marking technical documentation for software and hardware medical devices.

• DIM3 SA – VP Regulatory Affairs, QA/RA & Clinical Affairs Manager (Clinical Nutrition): ISO 13485 certification and CE marking of software and connected devices.

• CERHUM SA – Regulatory Affairs Consultant: Verification and validation of the technical file for a class IIb implantable medical device.

• LaCAR DMX SA – Scientific Consultant: Grant writing and project support in molecular diagnostics.

• SPQI (France) – Scientific Consultant: Market access study for an ELISA kit (Boost4Health voucher).

• DIGITAL ORTHOPAEDICS SA – Regulatory Affairs Consultant: Verification and validation of the technical file for CE marking of a Software as a Medical Device (SaMD).

• BIO-LINK Project – Entrepreneurship Consultant: Support for funding and company creation in tissue repair.

• VitriCell SA – Entrepreneurship Consultant: Business and financial planning, company launch in cell preservation.

• Zentech SA – Regulatory Affairs Consultant: Verification and validation of the technical file for CE marking of an IVD medical device.

• ABAXYS SPRL – Entrepreneurship Consultant: Support for funding and business creation in neurodegenerative diseases.

• PROGENOSIS SA – Senior R&D Project Manager: Setup of a biotech platform for human monoclonal antibody development.

• DIAGENODE SA – Performance & Evaluation Coordinator: Regulatory Affairs lead for CE marking of PCR-based IVD kits and coordination of performance evaluation.

Earlier Positions

- Scientific Director – Probiox SA, Belgium (2006–2011): Research in oxidative stress and nutraceuticals.
- Deputy Manager – Biotech Tools (now ASIT SA), Belgium (2003–2006): Research management in allergy and autoimmune diseases.
- CEO & Founder – Cypro SA, Belgium (1999–2003): Founder of a private immunology laboratory providing contract research and testing for pharmaceutical clients.
- R&D Director – Biosource Europe (now Diasource SA), Belgium (1996–1999): Head of R&D for immunological reagents under ISO 9001.
- Project Manager – Medgenix Diagnostic SA, Belgium (1983–1996): Development of monoclonal antibodies and immunoassays for hormones, tumour markers, and cytokines.
- Sub-Officer, Military Hospital – Belgian Armed Forces (1982–1983).

Education

- PhD in Sciences (Immunology) – Université Libre de Bruxelles (ULB), 1983
- Master's Degree in Biology – Université Libre de Bruxelles (ULB), 1978
- Postgraduate Diploma in Management (Business Creation & Support) – Solvay Business School, Brussels, 1999

Certifications & Recognition

- Accredited Expert – Wallonia Public Service ("Chèques-Entreprises" Program)
- Independent Expert – European Commission (FP6, FP7, H2020)
- Author / Co-author of more than 100 peer-reviewed scientific publications

Languages

- French – Native
- English – B2
- Dutch – A2

Core Competencies

- Leadership and team coordination
- Business administration and strategic planning
- Grant engineering (BioWin, Wagralim, EU programmes)
- Intellectual property management (patent applications)
- Coordination of industrial, scientific, and outsourced partners
- Excellent communication in scientific and regulatory environments