

Donat De Groote, PhD

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

Professional Summary

Experienced scientific and executive professional with more than 40 years of experience in biotechnology, diagnostics and medical devices.

Specialized in regulatory affairs, quality management systems (ISO 13485), CE marking and market access strategy.

Founder of AZ Biotech Consulting (since 2011), supporting MedTech startups and SMEs in regulatory compliance, certification and product development.

Creator of ReadySet, a ready-to-use ISO 13485 quality management system, structured on Confluence, designed to accelerate the implementation of a compliant and operational QMS.

Recognized for a pragmatic approach combining scientific, regulatory and operational expertise.

Key Expertise

- Regulatory Affairs & Quality Systems (ISO 13485, MDR, IVDR)
 - CE Marking and Technical Documentation (medical devices, IVDs, software)
 - PRRC (Person Responsible for Regulatory Compliance)
 - Clinical evaluation and performance evaluation
 - QMS implementation (traditional and digital)
 - Development of ready-to-use QMS solutions (ReadySet – Confluence)
 - Support for MedTech startups
 - Project management and regulatory strategy
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Professional Experience

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

Consultant and freelance executive for companies active in biotechnology, diagnostics and medical devices.

Services:

- Regulatory Affairs & QARA
- PRRC functions
- Implementation of ISO 13485 QMS
- CE marking support (MDR / IVDR)
- Regulatory strategy and market access

Designer of ReadySet, a ready-to-use ISO 13485 quality management system based on Confluence.

Selected Assignments

- **CONTIPHARMA SA** — QA/RA Manager & PRRC (IVD): Implementation and management of ISO 13485 QMS for in vitro diagnostic devices.
- **COMUNICARE SOLUTIONS SA** — QA/RA Manager & PRRC (Telemedicine): Deployment of the QMS and regulatory compliance of medical device software according to MDR and IEC 62304.
- **HEARTKINETIC SA** — QA/RA Manager & PRRC (Cardiology): Implementation of the QMS and preparation of technical documentation for CE marking of medical devices (software and hardware).
- **DIM3 SA** — VP Regulatory Affairs, QA/RA & Clinical Affairs (Clinical Nutrition): ISO 13485 certification and CE marking of software and connected medical devices.
- **DIAGENODE SA** — Performance & Evaluation Coordinator: Responsible for regulatory affairs for CE marking of IVD PCR kits and coordination of performance evaluations.

Additional assignments available upon request.

Previous Positions

- Scientific Director — Probiox SA, Belgium (2006–2011): Research in oxidative stress and nutraceuticals.
- Deputy Director — Biotech Tools (now ASIT SA), Belgium (2003–2006): Management of research in allergology and autoimmune diseases.
- CEO & Founder — Cypro SA, Belgium (1999–2003): Creation and management of a private immunology laboratory providing services and contract testing for the pharmaceutical industry.
- R&D Director — Biosource Europe (now Diasource SA), Belgium (1996–1999): Responsible for R&D for the development of immunological reagents under ISO 9001.
- Project Manager — Medgenix Diagnostic SA, Belgium (1983–1996): Development of monoclonal antibodies and immunoassays for hormones, tumor markers and cytokines.
- Non-commissioned officer, Military Hospital — Belgian Military Service (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
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Certifications & Recognition

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

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

- Leadership and team coordination
- Strategic planning
- ISO 13485 QMS deployment
- Digitalization of quality systems (Confluence)
- Scientific and regulatory communication