A One-Stop Service Provider to Medical Device Conceptualization, Prototype Development, Analytical Testing, Preclinical, Clinical & Regulatory Road Map to Market

Radboud Universiteit Nijmegen UMC St Radboud Regulate BV LifeNet Health HCM Medical

Mission and Vision

Medical device Product Development requires deep expertise in conceptualization of ideas, planning and design of product, prototype development with numerous tests of the medical devices, validation and technology transfer with a clear regulatory and clinical pathway according to **ISO 13485** towards **CE/FDA Approva**l. More often, companies which develop these products spend significant amount of time in searching for individual service providers. Regulate B.V has an expert team with over 30+ years of experience in developing implantable medical devices right from idea conceptualization to market launch. Regulate B.V provides a **"one stop product development"** by product testing and advisory services for product development, all intermediate -to-final product testing using state of the art technologies for mechanical testing, biochemical analysis, cellular and molecular assays, histology, and preclinical -to-clinical road map with regulatory services. In specific, the team has in-depth expertise in dental, orthopedic, wound care, bone graft substitutes -derived from xenografts, allografts including bioactive ceramics, calcium phosphates and composites.

Regulate B.V Offers

Biochemical / Molecular/Cell Biology assays

- Total DNA assay
- Alkaline Phosphatase Assay
- Total Calcium assay
- ELISA, PCR, Flow Cytometry
- Antibiotic, Growth Factor coating and release assay
- Antibiotic release kinetics (HPLC)
- Cytotoxicity
- *In Vitro* Osteo-inductivity assay

Histology and Microscopy

- Hard and soft tissue processing
- Paraffin, MMA /GMA embedding, staining and microscopy
- Image analysis and reporting
- Immuno-staining of soft and hard material such as bone, enamel, metals, polymers, ceramics

Mechanical Property testing of Medical Devices

- Physico-Chemical Characterization of materials
- HPLC, EDX, EM, XRD and FTIR
- Mechanical characterization of materials: Tensile strength, Rheology etc.
- Injectability analysis (Extrusion force)
- 3D printing (SLA/SLS)

Prototype –to production with regulatory, CE/FDA road map

- OEM Production of Medical Devices Pharmaceuticals; and human Tissues and Xenograft products
- Batch production for clinical studies or product registration under GMP Conditions
- Test method development and production process validation, Product registration, Quality control for manufacturing and related

The Team

Dr. Frank Walboomers: Associate Prof at Regenerative Dentistry, Radboud Med Center. 25+ years of experience dental and orthopedic research.

Ms. Henriette Valster: A serial entrepreneur with over 30+ years of experience in bone allografts, xenografts, Collagen and has successfully market launched many implanted medical devices.

Mr. Christian van Munster: HCM-Medical (LifeNet Health), 25+ years of experience in QA, QC & Regulatory process of medical devices

Dr. Ram Siddappa: Biomedical scientist with 15+ years experience in Bone Graft Substitutes, allografts, xenografts & collagen tissues.

Mr. Koen Dijkstra: Certified expert of tissue handling, assay validation, QA/QC, and manufacturing of OEM and IMD batches.