Regulate BV

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Company Overview

Regulate B.V., based in Nijmegen, The Netherlands, is a specialized provider of **"End-to-End Medical Device Product Development services"**. With a combined team experience of over 30 years in developing implantable medical devices, the company offers a **"one-stop product development"** model—from idea conceptualization through design, prototyping, testing, validation, regulatory strategy, and preparation for CE/FDA approval. It's integrated service model, advanced testing capabilities, and GMP infrastructure (ISO:13485) give it a competitive advantage in accelerating product development cycles and ensuring regulatory-ready outcomes.

Value Proposition

Medical device companies often face fragmented workflows, relying on multiple service providers for testing, regulatory planning, clinical pathway design, and GMP manufacturing. **Regulate B.V** solves this challenge by integrating R&D, testing, regulatory consulting, and GMP production under one roof, significantly reducing development timelines and improving quality consistency.

Key differentiators include

- Deep expertise in **Dental**, **Orthopedic**, **Wound Care**, and **Bone Graft Substitute** (BGSs) technologies—including **Xenografts**, **Allografts**, **Metals**, **Bioactive Ceramics**, **Calcium Phosphates**, and **Composite materials**.
- Ability to support both medical device and Investigational Medicinal Product (IMP) development under GMP conditions.
- Access to state-of-the-art testing technologies, providing comprehensive **Analytical**, **Biochemical**, **Cellular and Molecular assays**, **Histological**, and **Mechanical Testing** capabilities with validated ready protocols or co-develop a validation protocol with the client.

Service Portfolio

Product Development & Testing

Conceptualization → Design & Development → Prototype → Testing & Validation→ Manufacturing

Mechanical testing:

- Tensile strength, Tear strength, rheology etc.
- Physical-Chemical characterization (HPLC, EDX, EM, XRD, FTIR)

Biochemical and cell biology assays: DNA, ALP, Calcium assay, ELISA, PCR, flow cytometry, all Collagen -based assays, antibiotic/Growth Factor coating & release profile assays.

Histology: Hard & Soft tissue Paraffin, MMA/GMA embedding, immunostaining, microscopy, image analysis, data acquisition and reporting.

Regulatory & Clinical Pathway Support

- Full CE/FDA roadmap development
- Test method development, process validation & OEM production
- Quality control and product registration support

GMP Production Capabilities

- GMP-licensed production of clinical batches for medical devices, pharmaceuticals, and tissue-based Xenograft & Allograft products
- IMP development and manufacturing for clinical studies
- Target Market & Opportunity

Team: The company's multidisciplinary leadership

Dr. Frank Walboomers: 25+ years in dental & orthopedic research
Ms. Henriette Valster:30+years in BGSs, allografts, xenografts, collagen, and medical device commercialization
Mr. Christian van Munster: HCM-Medical B.V (LifeNet Health): 25+ years in QA/QC & regulatory processes
Dr. Ram Siddappa: 15+ years in bone graft substitutes, allografts, xenografts & collagen technologies
Mr. Koen Dijkstra: Certified expert of tissue handling, assay validation, QA/QC, and manufacturing of OEM and IMD batches.