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Company Overview

CH-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. **CH-Regulate** 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 Strength: 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.