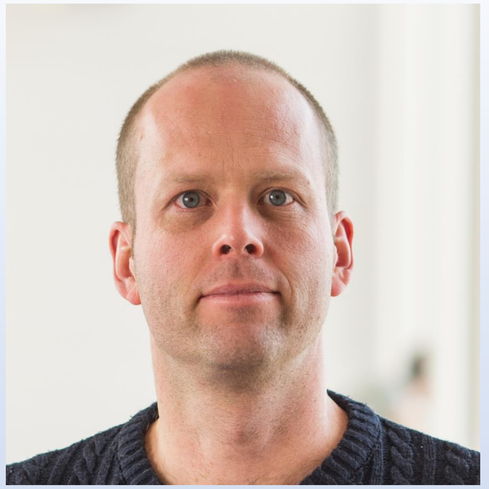

Frank Walboomers, PhD

HCM Regulate

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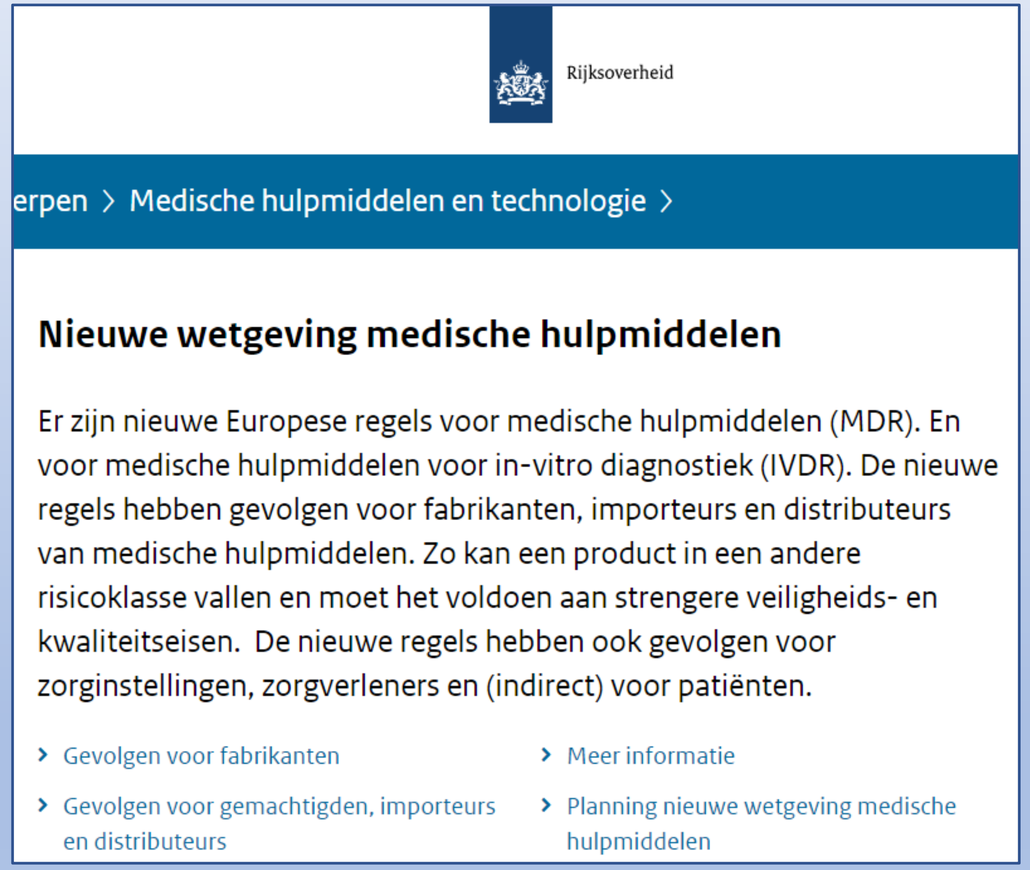
New MDD / MDR will have drastic impact on medical device translation from R&D to market

- May 2020 → new MDD (93/42/EEC) & Directive on Active Implantable Medical Devices (90/385/EEC)
- Implementation new MDR, stepwise, … ?
- Unclear to most MD manufacturers
- Expectation that the number of lab test in MD will drastically increase, or even quest for development of new test methods



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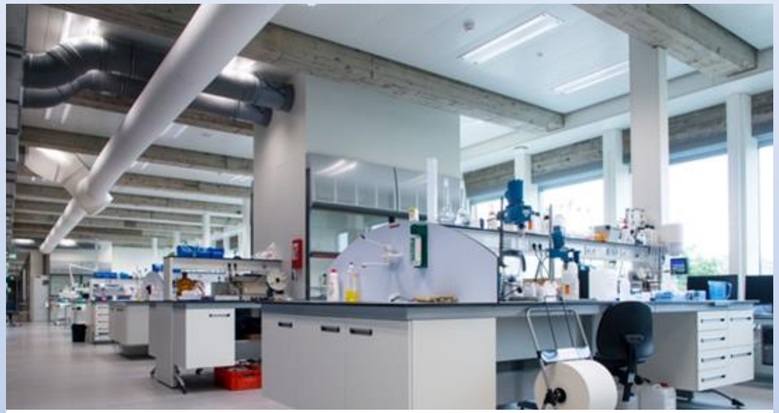
HCM-Regulate B.V.

- Founded 21/09/22
- Operational per 2023

HCM Medical



Radboudumc

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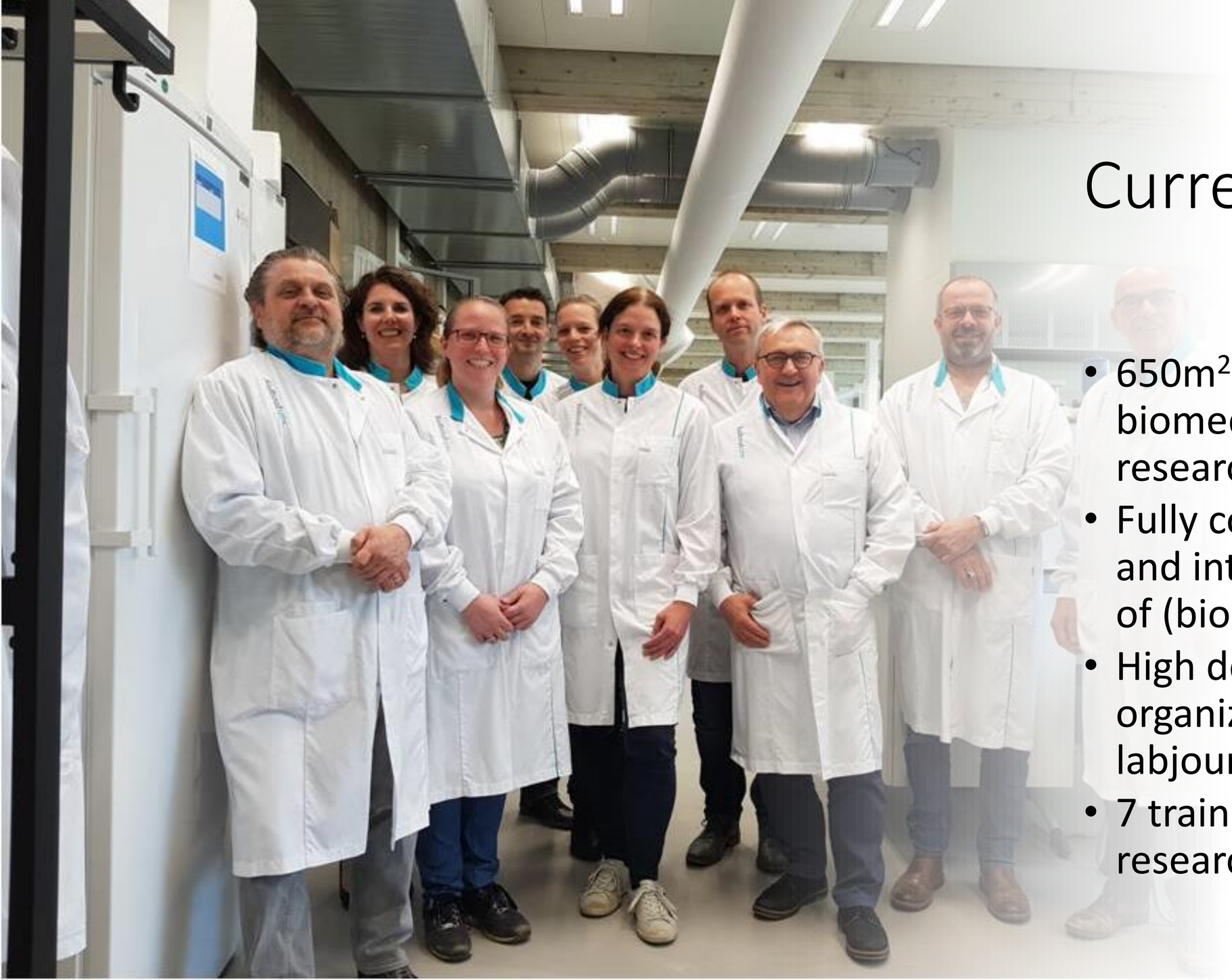
HCM Medical B.V.

- Hightech Contract Manufacturing Medical
- Contract Manufacturing Organization (CMO) specialized in the development and manufacturing of biological and biomaterial products.
- Licences: ISO 13485 (Medical Device), Tissue Establishment (allografts), GMP for Investigational Medicinal Products (IMP).
- Facilities: GMP class A/B/C cleanrooms
- Core technologies: supercritical CO_2 technology, aseptic processing, Freeze drying, filling and packaging



Current capacity

- 650m^2 state-of-the-art biomedical device materials research lab
- Fully compliant to national and international standards of (bio)safety etc.
- High degree of work organization (Digital labjournals, SOP’s, ISO/GLP)
- 7 trained and skilled research technicians

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Technical capacity (& this is even partial …..!)

- **Materials synthesis and processing:** Organic/ inorganic scaffolds, gels, cements, dental materials, fibers, coatings, membranes, suspensions, nanoparticles, composites, etc. Thin film deposition (Magnetron Sputtering, Electrodeposition, electrospinning, emulsification, ultrasonication, sintering, plasma treatment, …
- **Physico-chemical characterization:** HLPC, electron microscopy (scanning and transmission),DLS, elemental analysis EDS, molecular analysis FTIR, XRD
- **Mechanical characterization:** Tensile benches static/dynamic from 10 to 20.000 N, rheology, profilometry, surface properties (roughness, scratch tests, etc), erosion/ageing/wear simulation, …
- **Cell & Molecular Biology:** GMO-certified cell culture lab, live imaging, mechanical loading, molecular biology including (q-PCR , ELISA, blotting, etc.)
- **Preclinical studies & Histology:** (small & large in vivo models), paraffin embedding + immune stainings, PMMA embedding and diamond blade sawing microtomes to section hard matter, automated microscopy & DIA
- (clinical studies)

→ over 100 machines / techniques operational; many unique to medical device research

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What can HCM Regulate do for you