HSLU Hochschule Luzern

IMPLNZ

Lucern University of Applied Sciences and Arts
Hochschule Luzern - Technik & Architektur

Bachelor-Thesis Wirtschaftsingenieurwesen | Innovation

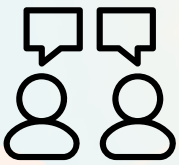
Qualification of a Non-Clinical Assessment Model for Dental Implant Stability: A Case Study for MDDT Accreditation of IMPLANZ

Purpose

The purpose of this thesis is to demonstrate how advanced engineering methods and regulatory strategy can be combined to accelerate innovation in dental implant development. In collaboration with a start-up developing a finite element (FE) simulation tool for assessing dental implant stability, the thesis translates a technically complex product into a structured pathway toward FDA qualification as a Medical Device Development Tool (MDDT).

The goal of this thesis is to define and execute a practical roadmap toward FDA MDDT qualification for a simulation tool that supports the assessment of dental implant primary stability.

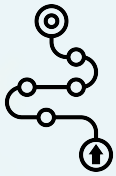
Applied Competencies


Interview


Literature Analysis


Value Proposition

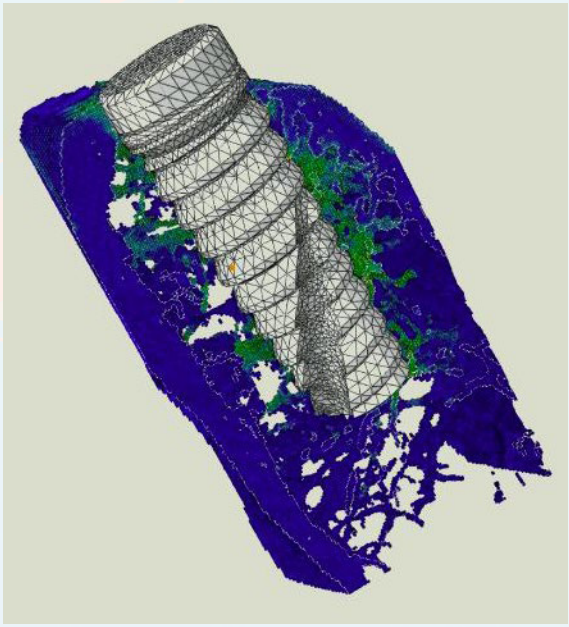

Regulatory Alignment


Project Management

The goal was achieved by combining a structured review of FDA MDDT requirements with targeted literature research and continuous alignment with the start-up. Based on this, a clear context of use and an evidence and documentation roadmap were defined to connect the simulation approach with regulatory expectations. This was complemented by sharpening the value proposition through a customer interview.

Results

The main result of this thesis is a structured and proposal-ready roadmap toward FDA MDDT qualification for a finite element simulation tool that supports the assessment of dental implant primary stability. Key deliverables include a clearly scoped context of use, a set of defensible performance claims and endpoints (ultimate force, initial stiffness, insertion torque), and a qualification evidence strategy with correlation-based acceptance criteria (e.g., R^2 thresholds) grounded in reviewed studies comparing experiments with simulation results. This is reflected in a rigor proposal package document, which will allow IMPLANZ to have a strong entry point for discussions with FDA at hand.



Student: Carl Schmidt