

UNC Charlotte College of Engineering Senior Design Program Senior Design Project Description

Company Name	UNCC	Date Submitted	December 31, 2017
Project Title	Microneedles Test Kit	Planned Starting	Spring 2018
	(UNCC_NEEDL)	Semester	

Personnel

Discipline	Number	Discipline	Number
Mechanical		Electrical	
Computer		Systems	
Other: Biomedical	1		

Project Overview:

The objective of this project is to identify and statistically validate a series of experimental tests that can be conducted to determine the effectiveness of different formulations for Dissolving Microneedles (DMs). DMs, which are arrays of small needles with a lengths less than 100 microns, are being investigated as a pain-free alternative to hyperdermic needles for delivering drugs systemically. These needles are prepared from water-soluble and biocompatible materials such as cellulose derivatives and sugars, and can be administered without specialized medical training. Although the first generation of microneedles are now entering clinical trials, the mechanical strength of the needles needs to be optimized, without compromising the ability to deliver an effective dosage of the drug over the desired time window. The Biostability lab has been investigating the physical properties of trehalose and organic salt compositions, including glass transition temperature, hygroscopicity, and metastability in a supersaturated solution. These compositions exhibit characteristics that may be beneficial for MN fabrication. In order to discriminate between formulations for the purpose of fabricating MNs, a series of tests will need to be selected and statistically validated, to demonstrate relative effectiveness in terms of manufacturability, mechanical robustness, and ability to deliver an effective dose of a selected therapeutic. Methods, controls, and equipment will be selected based on a review of existing literature, and the availability of resources at UNCC. The effectiveness of each test will be determined based on the statistical reproducibility of repeated measures with current gold standard formulations.

Initial Project Requirements:

The student will initially be required to: a) review the existing literature to determine current best practices for preparing MNs, and b) identify resources that are available or easily acquired for testing the effectiveness of formulations, and c) deliver a proposed manufacturing method and test series, including a 'next-best' alternative in each case. This proposal should be evidence-based and well-justified with appropriately documented literature references. Upon approval of this initial proposal, the student will then acquire the resources and begin to statistically validate each test.

Expected Deliverables/Results:

- A comprehensive review of existing literature that summarizes the state of the art for preparing and testing the effectiveness of DMs.
- A statistically validated minimum battery of tests, with detailed methodologies, that can subsequently be used by others to identify desirable formulations for further testing, and to rule out undesirable formulations.

Disposition of Deliverables at the End of the Project:

A series of well-written and statistically validated test methods, including comprehensive methodologies that can be easily reproduced by others, should be presented to the sponsor at the end of the project.

<u>List here any specific skills, requirements, knowledge needed or suggested (If none please state none):</u>

Should be a self-starter, and willing to seek out necessary resources to solve problems as they come up in the design process.