ASSIGNMENT 04: Conceptual Design Process

Due Date: Fri 3 May 11:59 p.m.
Points: 100

*This assignment asks you to finalize the Design Concept that you drafted during class, and **prepare a Conceptual Design Process** that embodies all the elements of engineering design. The outcome of this assignment will rigorously assess the implementation of the design process you have developed to achieve your specified bioengineering solution. Remember, **design** is a process that **ensures success** to large-scale and complex problems. Engineering design **guarantees** that a functional solution or outcome emerges based on **an iterative process for optimizing and selecting** the "best" form of the outcome/process given the required function. For your Conceptual Design Process, I will be looking for you to identify clearly: (1) Functional requirements of the output/process, (2) Design constraints, (3) Acceptance criteria and validation testing, and the (4) Iterative decision making process to evaluate sub-system level feasible alternatives to select the "best" form of the solution to achieve the required function.*

Purpose: To implement a design process as an engineering tool to solve large-scale, complex and sometimes ill-defined problems of biomedical health significance. The Conceptual Design Process will be included in your Capstone Proposal if it is being proposed as a solution to your Bioengineering problem and is part of your Project Plan (required for 402 Track).

Assessment: Submit to Drop Box your Conceptual Design Process with the content specified below and requested in the attached figures and tables.

Approach: The following materials are requested for successful completion of this assignment.

- **Design Narrative:** In the space provided below, provide a narrative of the design process being implemented to achieve the form of an output/process that meets specified functional requirements for what is being designed.
  - **Page limit**: 1 page maximum
  - **Formatting**: Margins (top, bottom, left, right): 0.5-1"; Font size: 11-12 point font; Typeface: Arial, Helvetica, Palatino Linotype, or Georgia; Type density: 1.5 – double space.
  - **Content** must include/address: (1) Problem statement, (2) Functional requirements of output/process (what constitutes a feasible design), (3) Design constraints and acceptance criteria, and (4) integration and testing plan to evaluate alternatives and select best design outcome.
  - **Ensure success**: The design process must demonstrate that at least one feasible outcome/process will emerge to satisfy all the specifications.

- **Figure 1:** Provide a diagram of the output or process being designed. From your figure, it should be clear the iterative activity analysis that will be used to meet the defined specification in Table 1.

- **Table 1:** Define the specifications, acceptance criteria and validation tools. These specifications should allow you to measure success and be as quantitative as possible.

Design Narrative:

Cellular apoptosis is known to be a major factor in tissue remodeling, cancer elimination, aging, and age-related diseases. Determining the level of apoptosis and DNA damage in a given sample of cells is an important diagnostic for genotoxicity and health status. Current techniques in apoptosis evaluation suffer from a variety of functional issues, such as requiring large numbers of cells, insensitivity to low levels of apoptosis, artifact labeling, loss of detection of some cell types, and false positive results. Many of these issues can be immediately resolved by analyzing apoptosis at the single cell level, with a trade-off being a much longer and more tedious post-lab analysis required to individually assess each imaged cell.

This project will deliver a platform for the systematic analysis of apoptosis at the single-cell level. An assay, image algorithms, and an analytical software will be designed to work seamlessly together to meet this end. Users will have the ability to analyze a large volume of cellular imagery with good confidence in results, with the benefit of evaluating both apoptosis and DNA damage levels using differing algorithms. In addition, the assay will run at a lower price than many current techniques, as enzymes and antibodies will not be required.

To be acceptable, the assay must require no more than 10,000 total cells per slide to maintain repeatability of results. The image analysis algorithms must analyze one picture in 15-30 seconds with a sensitivity of 98% or better per desired cell type. False positive results must only occur in 1-2% of positive results. For the DNA damage algorithms, the normalized level of damage as measured by the intensity moment of the halo must be insignificantly different than that given by the tail moment in a paired comet assay analysis ($p > .05$). The analytical software must be able to run on Windows XP through 8 operating systems; a strong design will also run on Mac OSx 10.0 and above. The software must accept PNG, JPEG, GIF, and TIF image types, permit data export to spreadsheets, and include histogram creation, statistical tests, image queues, and algorithm selection and comparison tools. A strong software design will include instant results during analyses, pixel intensity threshold settings, and intensity dependent pseudo-color image results.

Significant direct testing will be required to meet the specified goals. The minimum cell requirement will be evaluated by comparing experimental repeatability with differing cell densities, which is the most important factor in determining assay success. During development, several algorithms will be created which will undoubtedly complete analyses in different time scopes and with varying degrees of accuracy, as determined by comparison with manual scoring. Algorithms that can provide the greatest level of accuracy in the shortest amount of time will be included in the software. The algorithmic sensitivity and false positive generation rate must meet the specifications above, unless the algorithmic speed is deemed great enough to offset these fallbacks by handling a significantly larger volume of images. The analytical program will add functionality piece by piece in order to control and test variations of each feature for computational efficiency, processing speed, and operating system compatibility.

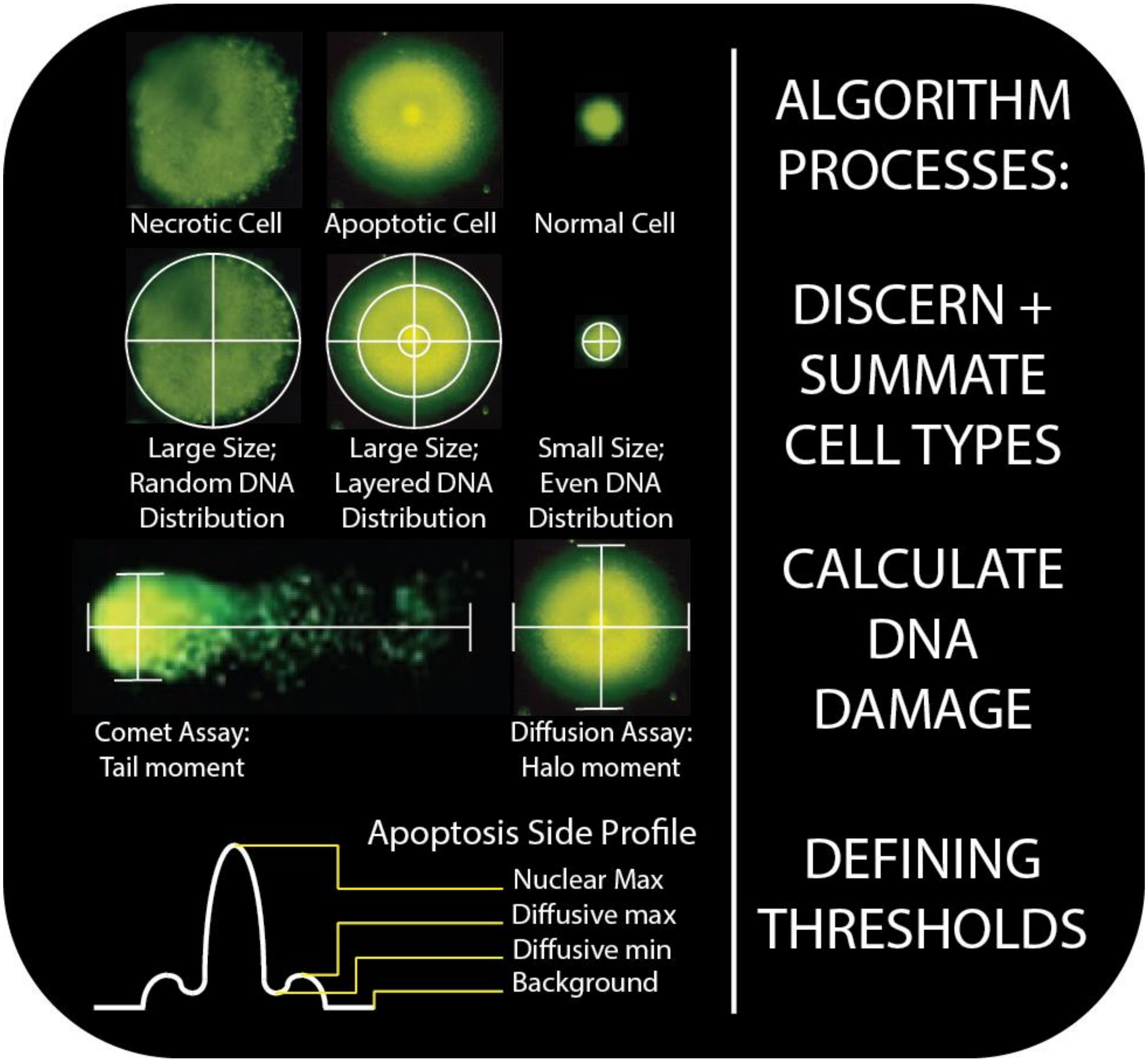

Figure 1: Design concept for [define output or process]. A feasible design of [output/process] will [achieve/show/lead to what?] by meeting the specifications listed in Table 1.

Table 1. Acceptance criteria for [define output or process]

Design Specification	Target values and tolerances or go/no-go decisions	Validation Tool
Minimum number of cells	10,000	Hemocytometer
Image analyzing time	15 - 30 sec	Internal timer
Algorithm sensitivity	98%	Manual scoring
False positives	1-2%	Manual scoring
DNA Damage Comparison	P > .05	Comet Assay + VisCOMET
Software OS compatibility	Windows 5 - 8	Feature testing
Image formats accepted	PNG, JPEG, GIF, TIF	Feature testing