**Your name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Active Learning partners**:

***(your last two chances to meet somebody new)***

|  |  |  |
| --- | --- | --- |
|  | Person on your left **🡨** | * Person on your right |
| April 12, 2018 | Michelle Lui | Ravyn Ogden |
| April 19, 2018 |  |  |

**IMPORTANT NOTE:** please remember that you should not share any electronic files with classmates. This includes not sharing the **SolidWorks** files or technical drawings that you will be working on in this assignment. You can verbally ask your classmate about how to do something, but you should not accept or give an electronic copy of a SolidWorks file, drawing, etc. And the **Business Plan** you submit should be your own work, too.

**Summary of design process**:

1. In this step of the process, you will design the physical casing for the device and test-strip layout. Using SolidWorks, design the case for your blood glucose meter (the part users would hold when using the device) and the test-strip that the user will place the drop of blood on (this is where your enzyme is).

a) Design the bottom of the case. This should include the circuit board that includes your working electrode, resistor, op-amp, battery, and “Arduino”-style output measurement chip (size doesn’t have to match a real Arduino which are larger than you need). You do not need to put those details on your circuit board (just make it big enough) EXCEPT you need to specify the location of your working electrode contact because it MUST assemble correctly with the working electrode on the test strip. Also include a position for the battery needed to power the op-amp (look up specs for the battery you chose back in Assignment #6 to see how big that battery is). Make sure the position is the right size and dimensions for your battery.

[Include the “Technical Drawing” of part here – see attached information about how to create the technical drawing for your part]

b) Design the top of the case. This should include a location for the LCD display to read out. It should also mate with the bottom of the case.

[Include the “Technical Drawing” of part here – see attached information about how to create the technical drawing for your part]

c) Design the test-strip. This should include the working electrode (where your enzyme is). It should also include a mechanism for getting the blood spread on the working electrode properly (can be a capillary tube running from the side, or a defined dimension opening on the top of the strip). The test-strip needs to “assemble” properly with the rest of your device by inserting into a hole in the case so that the working electrode on the test-strip assembles by matching up with the contact for the working electrode on your circuit board.

[Include the “Technical Drawing” of part here – see attached information about how to create the technical drawing for your part]

d) “Assemble” these three pieces together so that the top of the case mates with the bottom of the case and so that the working electrode on the test strip mates with the contact for the working electrode on the device’s circuit.

[Include the “Technical Drawing” of your final assembly here – see attached information about how to create the technical drawing for your assembly]

1. Make a simplified business plan for manufacturing and selling your device.
2. Estimate the costs of each of your components required per device (including but not limited to: resistor, op-amp, battery, voltage sensing “arduino”, LCD display, casing material, etc) and test-strip (including but not limited to: enzyme, cellulose acetate, Nafion, other chemicals needed for making working electrode, test strip backing material, etc.).

[Include list with itemized costs per measurement device here]

Resistor: $

Op-amp: $

Battery: $

Voltage sensing “Arduino”: $

LCD display: $

Casing material: $

Test-strip: $

Enzyme: $

Cellulose: $

Nafion: $

Other Chemicals: $

Electrode Materials: $

Test Strip Backing Material: $

[Include list with itemized costs per test-strip here]

Cost per test strip: $

b) Estimate the cost of capital equipment needed to make each device or test strip. Make sure to keep in mind the total number of users you estimate will own your device and how many test strips they’ll need to buy per month. Scale your equipment needs to match that production capacity. Amortize by dividing cost of the items by 10 years to calculate an amount per year to count against your profits. Include cost of real estate for housing your manufacturing facility and corporate offices here (or include in 2a if you will be renting rather than buying the property).

[Include cost of equipment with itemized costs here]

Cost of equipment: $

Cost of Real Estate: $

Cost of Electric Bill: $

Cost of Water Bill: $

Cost of Trash: $

c) Estimate the time you will need to pay workers to:

(1) manufacture a single device

(2) perform your calibration tests (each batch of test-strips requires its own calibration)

(3) perform all quality control and regulatory documentation

(4-∞) any other labor costs you will need to pay including marketing, legal, customer service, etc.

Multiply each by an estimate of $30/hr

[Include the annual cost of each of these items here (at $30/hr)]

d) Estimate the selling price (manufacturer’s whole-sale price) for your device and test strips (remember the 1-3-9 rule, which says that the retail selling price is 3 times the manufacturer’s whole-sale price, which is 3 times the manufacturer’s cost). Multiply by number of devices and test strips you expect to sell each year. Add these together to get your annual sales.

[Include the information for these items here]

e) Calculate the following:

(1) Capital required: add up all parts needed for the first year of production, cost of all equipment (not amortized), and cost of all labor needed for the first year of production.

(2) Annual expenses: add up all parts needed for the first year of production, cost of all equipment (amortized), and cost of all labor needed for the first year of production.

(3) Annual revenue: add up revenue from sales of devices and test strips

(4) Annual profits: subtract annual expenses from annual revenue.

[Include the information for these items here]

1. Most likely, the simplified business plan you just created says that you will make millions of dollars in profits during your first year in business. That never happens in the biomedical industry. The typical biomedical start-up requires a minimum of approximately $50,000,000 in start-up costs and a minimum of about 5 years before ever turning a profit.

Identify as many omissions and underestimates you can find in your above business plan. List them here with a brief (~ a sentence) description and how much difference in your plan this is likely to make (dollar amount difference in expense or income).

[Include list here]

**Instructions for turning in Assignment 7:**

1. **Upload** your worksheet in either Word or PDF format to Blackboard (**due before class begins, Thursday, April 26th**)
2. **At the beginning of class on Thursday, April 26th**: **Turn in** a hard copy of the worksheet (PDF or Word format), your explanatory essay (if you want to submit one) AND a copy of the pages in your notebook for this assignment.