JOB SUMMARY FOR FALL 2007 TERM

Nesos Health, Inc. is a seed-stage start-up company in the process of developing an FDA-approved Class II medical device. During my fall 2007 term, my main responsibility was to research, develop, and implement the heating component of the device. Due to the small nature of the company (I was one of five employees), I felt like I was an integral part of the team, and was involved in much more than this one project. During my time here, I was able to help refine the design requirements for not only the heating component, but also aspects of the mechanical and electrical design as well. I was given a chance to learn the CAD program, Solidworks, through the software’s tutorial, individualized instruction, and educational projects. Once I got a handle of the program, I was able to draw up device components that were later rapid prototyped for design consideration. I was also involved in contacting suppliers and ordering parts and materials that were to be later integrated into the device. For one component, I was actually able to develop manufacturing process and create a few of the parts in the office before we outsourced the production to another company. Once most of the components and materials had been chosen, many of the sub-assemblies that would eventually be part of the final device needed to be tested. I was responsible for developing the test protocol for the heating component as well as carrying out most the testing I had designed. Another large portion of my time was spent writing up documents for the Design History File that will ultimately be submitted to the FDA. I learned a lot about the documentation process and all the steps that must be followed to ensure acceptance of the device. Some of the documents I was responsible for were the Product Requirements Document, Therapy Outline Document, Risk Management Documents, and Testing Protocols.

Besides being involved in all of these processes, I was able to learn about the intellectual property and patent situation of the device as they were discussed in some of the weekly meetings I attended. During each weekly meeting I also gave an update on the status of my project and any other action items that were assigned to me the previous week. Although I was initially unfamiliar with the majority of the concepts and procedures I was involved in, I was able to use the help of my supervisors and my basic engineering knowledge to overcome these obstacles. My supervisors were very helpful with giving me just enough background information and pointers so that I could understand most of it without being directly told everything.
Housing was relatively easy to find, since the office was about a mile from the University of Minnesota—Twin Cities campus. There was an area similar to Collegetown just off-campus that I ended up living in with a few students who were taking classes at the university. A car would have been great to have, but I was able to get to work without much trouble. I initially borrowed a bike from my supervisor and biked to work while the weather was still warm. When it turned colder I was able to take the bus into work or get a ride from my supervisor. The students I was living with did have cars, which helped with grocery shopping and exploring the cities on the weekend. The main drawback to working for such a small company was that I was usually the only person in the office during the day and there were no other co-op students that I knew of in the area. However, this was balanced by living close to the university and I was able to meet people through the students I was living with. I was also able to find a group of students that played pickup ultimate Frisbee during the week.
During the summer term of my co-op at Nesos Health, Inc. we continued to develop and test the company's first generation device as well as determine the feasibility for a second generation device. The first device is a reusable knee brace that delivers electromagnetic and thermal therapy to ease pain in patients suffering from osteoarthritis. The second device looked to expand upon this technology to treat other joints in the body. These devices are to be classified as Class II medical devices by the FDA, so ensuring the proper documentation and incorporating a quality assurance system was a high priority. When I arrived in June, the design had been finalized and prototypes were being manufactured for testing. At this point we were working on getting our documentation up to speed. Specifically, I worked on writing up the test protocols, developing a risk management plan, and initializing a risk assessment of the design. Then, in July, we started the background research on the second generation device. For this we looked at the size of the market, competitors who had treatments that targeted this market, and what the cost would be to make our device. I also used the CAD program, Solidworks, to draw up an embodiment of the new design. During my last week, I was assigned to pick out potential materials that could be used to manufacture the device.

Housing was easy to find again, due to the close proximity to the University of Minnesota-Twin Cities campus. I was able to find a nice apartment off campus with another student taking classes over the summer. I was near a bus stop that could take me to work, but I was close enough that I would often walk home. I was lucky to have a gym in my apartment complex, but I was also able to find a summer Ultimate Frisbee
league and some pick-up games around the cities. One weekend I was even able to join a team and play in a nearby tournament.