Introducing Ethics

I grew up in a family that is very guided by our morals and our ethics. My parents have always refered to right and wrong as being common sense, and at this point in my life I agree with that sentiment. To me it is simple to think about things ethically, to me it really does seem like common sense. Don't lie to people, don't cheat people, don't do something that you wouldn't want done to you, and overall act in a way that wouldn't hurt somebody else. Have compassion for your fellow humans, and show that compassion in the way that you act because actions speak louder than words. These things are the foundation on which I was raised, so to me acting ethically is nothing more than taking a few minutes to think about what you are doing and how that will affect others. I think these qualities are very important for an ethical engineer. Something I had never considered before is that ethics may not always be so cut and dry, like for example in the case of an engineer. Sometimes the right thing to do is not always so easy to determine, especially when the situation is complicated.

Since I intend to work in the medical device industry I will use that industry as an example. When creating a medical device, the engineers have many things to consider. First and foremost is the safety of the device which includes things like biocompatibility. They must also consider cost, ease of production and FDA requirements. There are many members of the new product teams which ensures that every aspect is considered from the beginning to the end of a project. This includes the packaging engineers, the research and development team, the product development team, the project manager, the marketing specialist, and the regulatory affairs specialist assigned to that product. With all of these eyes on the project as well as the FDA regulation of not only the product itself, but also the process for producing the product, the devices made are as safe as they can be. Even with all of the regulations and eyes on the project no device is perfect. There will always be some side effects to putting a foreign material in the human body, but the goal is to reduce these side effects to the best of our ability.

This being said, sometimes the ethical choice isn't always the most straightforward choice. Of course the goal of the medical device industry is and always has been to help patients. However, sometimes they're put in the position where they have to decide if the side effects outweigh the actual problem itself and if the solution is worth the financial burden to the patient. Sometimes we don't know what aspects of the device will cause side effects. For example, previously we didn't know that the color of the device affects the safety of it. Sometimes there are the best intentions, but we don't

have enough knowledge to prevent adverse events. This is where ethics becomes more complicated than what I was taught as a young girl.

What it is to be an ethical engineer

Establishing the Basics

Of course there are the obvious aspects of being an ethical person as well as an ethical engineer. Many of those characteristics are described by the article *A Brief Introduction to Chinese Ethics.* This article describes ren, xin, yi,shu, and rang which are a few examples of Chinese ethics. I choose to use these specific examples because I feel that they apply directly to being an ethical engineer and they set a baseline for ethics.

Ren is the first example and it is defined as "brotherly love and sympathy between people."(1) I believe that this is very important when thinking about ethics because it allows us to have consideration for others. It allows the engineer to think about who the user is and how they can ensure that their product can be safely and effectively used by the customer.

"Xin or integrity means that people should not cheat others and everyone should be honest."(2) I feel that this is also a very important aspect of being ethical. As an engineer it is important to not cut corners and to make sure that your path is the most straightforward that it can be in the sense that you are following all the rules in place and that you're not cheating anybody. I believe that engineers should make a product to the best of their ability, which means finding a balance of making it cost effective as Jim Nankervis stated in our professional engineer interview(3), but also making the product with good quality so that it doesn't break before the customer anticipates.

Yi is described as "fairness, righteousness and justice." (4) This idea also includes that people must know what is good and what is evil in all of their actions. They must understand that every action has consequences and consider what those consequences might be and how they will affect others. "The man of honor/ Confucius writes 'seeks righteousness, while the man of disgrace only cares about profit." (5) I feel that this quote relates directly to engineering because the engineer could either care more about the quality of the end product or could care more about profit. While profit is important in the business sense, it is also important to do the right thing by your customer or they will not continue to use your business.(6)

Shu is "the practical ethics and lifelong pursuit of Confucianism." (7) This is the idea of the golden rule, do unto others as you do would unto yourself. Shu seems like the

obvious principle, and it is what we are taught from a very young age. However I feel that it is still very important to acknowledge this idea because it is one that should be used in every decision an engineer makes and maybe sometimes we forget to think about this idea because of its simplicity.

Rang is defined as "modesty and self effacement. Rang does not mean giving away everything blindly but acting altruistically and fulfilling one's duties and obligations. Rang is respect and consideration for others." (8) I felt that rang was also an important principle to consider when defining an ethical engineer. This idea is similar to shu because both seem to refer to having consideration for your fellow man, but it is different in the sense that it acknowledges the idea of respect. When you have respect for your customer, it is much more likely that you will treat them correctly.

Of course these aspects of being an ethical engineer are not the end all be all. As I said before, these principles set the baseline for ethics and can be used as such. These principles can be expanded upon in order to better define an ethical engineer. On top of the Chinese ethics, engineers must consider ease and cost of production. (9) There must be a balance between the ease and cost of production and the integrity of the product. The user is the most important part because without them, the product is rendered useless.

Considering the User
One of the most important aspects that engineers should focus on when designing a new product is the user. The user is a very important part of the process because for example if the product works perfectly but the user doesn't know how to operate it then the product becomes useless. As is stated in *Engineering for Problems of Excess,* "the human element is fundamental." (10) The engineers must keep in mind the end goal of their product and consider this from the beginning stages of the design. They must also consider the safety of their design. "To me an ethical engineer considers safety to be a top priority in every design. A well-engineered design must never knowingly do harm to a person or the environment." (11) User testing is extremely important in the design process because it allows the engineers to identify where users could go wrong and how the engineers can design the device better. It also allows engineers to see what could potentially be unsafe about their product and adjust the design to create a safer and more effective product.

Considering the Environment

Another very important aspect to being an ethical engineer is the environment. This idea relates to Shu because it refers to considering how we would want to be treated. Engineers must consider that the earth is not just ours, but also the generations that will come after us. Sustainable development is a term that was coined in the early 1970's and was used in *Ethics, Engineering and Sustainable Development.* This term refers to the fact that human populations as well as industrialization cannot grow indefinitely because if they did then eventually we would run out of resources and space. (12) Engineers must always consider how what they're doing will affect people and the environment. "Some critics tried to ignore the message, simply sticking to the old but entrenched belief that nature possesses inexhaustible resources, permitting it to bounce back from even the most severe depletion and contamination."(13) If people, or specifically engineers, operate under this unfounded belief, then we will leave future generations without the quality of life that we have been so fortunate to have.   The following is a list of quotes from *Ethics, Engineering and Sustainable Development* and looks at the sustainability aspect of engineers.

The idea of being environmentally friendly has caught on at many corporations because it makes good business sense. This is mostly due to the image that an environmentally friendly company creates. People are warming up to the idea of sustainable development, and like to see when companies act in a way that is positive for the future of mankind. "Indeed, it is becoming more and more evident to corporate leaders that environmental responsibility is the next step in total quality management — some call it total quality environment management (TQEM) — a step that is becoming increasingly necessary in order to ensure their companies' continued competitiveness and profitability."(14) An example of this is Boston Scientific. Not only are they a major competitor in the medical device industry, but they have made great efforts to make themselves more environmentally friendly and compete with other medical device companies in that aspect as well. Even as an intern at Boston Scientific, we were given training on how to dispose of utensils in the cafeteria because they are all recyclable. I felt that the fact that Boston Scientific used time to cover this topic showed just how important being environmentally friendly is to them. This is a smart move for Boston Scientific because it allows them to have an edge on any competitors that might have a larger portfolio, but aren't quite as environmentally aware.

Of course there are other companies that put a good amount of time and energy into ensuring that their company is environmentally friendly. For example, 3M has the "3P" program ("Pollution Prevention Pays"), which has not only saved the company money, but has added credibility to their already impeccable reputation. (15)

The following principles from the *Ethics, Engineering and Sustainable Development* article give a great description of how engineers should act in order to protect our future.

> "Act so that the effects of your action are compatible with the permanence of genuine life. Act so that the effects of your action are not destructive of the future possibility of such life. Do not compromise the conditions for an indefinite continuation of humanity on earth. In your present choices, include the future wholeness of Humanity among the objects of your will." (16)

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My Role in Ethical Engineering

My internship this summer was with Boston Scientific as a Regulatory Affairs, Clinical Trials, and Medical Affairs intern. Throughout this internship I learned a lot about the process for creating a device as well as how a company such as Boston Scientific operates. Throughout the experiences I had as an intern, I learned that Boston Scientific holds themselves to a very high standard. They not only have a high regard for the patients and the environment, but also for ensuring that they complete all of the processes by the books. I was very fortunate to have had my first internship with a company that has such a great reputation and I was not disappointed by my experience with them.

When working for a company such as Boston Scientific, everybody plays a role in ensuring that everything is done with integrity and honesty. My role in this was as an intern for three different departments. For each department I had a different project, however all contributed to ensuring the safety and integrity of the devices.

My main project as a Regulatory Affairs intern was to write a 30 Day Notice for manufacturing changes. Throughout this process I learned what the FDA requires to make these changes. I also learned that it was my responsibility to ensure that the process change was up to standards before sending the 30 Day Notice to the FDA. Throughout the summer I attended a couple of new product team meetings with my mentor who is a Regulatory Affairs Specialist. During these meetings I learned that it is the responsibility of the Regulatory Affairs Specialist to tell the engineers if an aspect of their design will not be approved by the FDA. For example, one specialist had to tell the engineers to change the colors they were using for a device because as it turns out, there are only a select few colors that are biocompatible. It is the responsibility of the Regulatory Specialist to know what the FDA requires and to make sure the engineers are creating a device that falls within these constraints.

As a clinical trials intern my role was to edit the informed consent form for the clinical trials that would be conducted in both the U.S. and the EU. This project allowed me to see the level of safety that the devices are held to especially throughout the clinical trials.

Throughout all of these experiences, every aspect of these projects were to ensure the safety of the devices for patients. While writing the informed consent forms the goal was to make sure that patients had a clear understanding of potential issues with the trial as well as where to report if something did go wrong. This process shows that not only is the design of the device important, but also the successful outcome of the clinical studies. While writing the 30 Day Notice, every aspect of this document was to ensure safety of the device and safety of manufacturing.

How Ethics Applies to Technical Writing

Engineering is not the only profession that requires ethical behavior. Everyone should be ethical in their jobs including Doctors, Lawyers, and even Technical Writers. I will focus here on why it is important that Technical Writers make ethical decisions and how they should go about doing so.

Technical writing may not seem like something that ethics plays a role in, but it certainly is. It is very important as a technical writer to be sure to include all of the information available to you in a way that the intended audience would understand. This means writing so that the message is straightforward and clear. There is one very important example of poor technical writing that is constantly used in the Scientific and Technical Communications courses. This example is the Challenger. Something that I've heard many times is that if the memo had been written in an active tone rather than a passive tone then maybe the O-Ring failure would have been caught much sooner than the day before the launch and the issue could have been resolved.

This is very applicable to me because my role will be to tell the FDA about a new product or changes to a product. In order for them to approve the product or changes they will need to fully understand every aspect which means that what I write to them must include details, it must be clear, and it must be to the point.

Of course like I mentioned before ethics isn't always black and white and the same goes for technical writing. If someday I encounter a situation where the company I work for would like me to try to get a controversial device approved, I will do my best to do just that. However, I will be sure to include in my submission why it is controversial so that

all of the potential risks are upfront and in the open. I think that this would be the best way to approach this situation because it would not only protect the company in the case that the FDA approves the product and something goes terribly wrong, but it would also protect the patients which is what my job is ultimately about.

Conclusion

I was raised in a house that took ethics very seriously. I still believe that ethics is about having knowledge of right and wrong and that this is typically common sense. However, I do know that not everything is a black and white situation and sometimes ethics can be a question of what is the least harmful solution.

Having the Chinese principles are a great baseline for ethics, but of course there are many other aspects to consider. Engineers as well as technical writers must consider not only the safety of the device, but also the user and the environment.

Even though I am not directly involved in the design process, I am still responsible for ensuring the safety and efficacy of a medical device. I think that it is very important for other people to double check engineers work and ensure that they are acting ethically and also to continue to act ethically themselves. I am excited that this will continue to be my role in the future.

Citations

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