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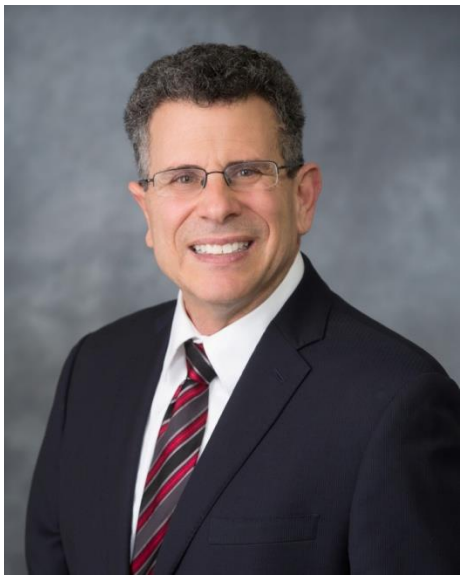
# FreeThink Technologies – With the Software and Laboratories that Enable Pharma Companies to Bring Life Saving Drugs to the Market Faster



**Dr. Kenneth C. Waterman**
**President/Chairman**

**FreeThink Technologies**

**Interview conducted by:**
**Lynn Fosse, Senior Editor**
**CEOCFO Magazine**

**CEOCFO:** ***Dr. Waterman, what is the concept behind FreeThink Technologies?***
**Dr. Waterman:** We do several things mostly for the pharmaceutical world. We are most known for the technology that enables companies to get drugs to market faster. In traditional drug development, companies have to set an expiration date for new drug products. Typically, companies like to get at least two years if they can. To do that it is not arbitrary; they have to have data that they submit to the health authorities like the FDA in the US and other similar agencies globally. It takes more than a year to generate the data needed. We figured out how to do it in about three weeks. Companies prefer three weeks to one year and now most of the major pharma companies worldwide are using our stuff. We both produce software and have laboratories that do the work needed.

In addition, we develop new technologies and help companies with complex formulations. Those are our major areas of focus. Sometimes we do veterinarian medicine or OTC medicines. It is all related to the medical world.

**CEOCFO:** ***How can you do it in three weeks when others cannot?***
**Dr. Waterman:** There are a couple of principles. The first, in traditional stability things are put at a standard set of conditions and then they are left there for months. Every few months a sample is taken and analyzed to see how much it has changed and of course hopefully nothing has changed during this time. What we do is the opposite. We want the product to fail so we push it to its failure by hitting it with accelerated higher temperatures, humidity, and sometimes oxygen to make it fail at a known condition at a known time. We use all those times to fail to propagate them. We had to develop some new equations for moisture and oxygen sensitivity with the temperature sensitivity being well-known, and how these factors affect rates. Combining these all with a bunch of statistics allows us to say not just whether it will pass or not but whether there is at least a 95% probably that the product will be acceptable at the end of the shelf-life period and this accelerated stability process has been accepted by health authorities pretty much around the world.

**CEOCFO:** ***What has changed in your approach over the last fifteen years?***
**Dr. Waterman:** Originally, we focused almost entirely on small molecule drugs and only on their chemical stability. Over time we broadened to include large molecules, biological molecules, physical changes such as the dissolution of tablets or capsules, and physical changes like how an amorphous drug might become crystalline over time. We have even been able to expand to include the stability of probiotics. Meanwhile we have pushed to say not just that a product is not stable enough, but to also figure out what we can do about it. We have also been in the fields of packaging. We have our own packaging technology and formulation ideas.
FreeThink Technologies interview continued on page 3.

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**CEOCFO:** ***Why would anyone do it the old way?***
**Dr. Waterman:** If you are very patient you can do it the old way.

**CEOCFO:** ***Is this now the industry standard and if not, why not?***
**Dr. Waterman:** The pharma industry is incredibly slow to adopt anything new, using in many cases things that we know do not work. Because of the highly regulated nature of pharmaceutics, it keeps people from using this best science; they are always trying to guess what a regulator might say. In this case, the health authorities in the world have this International Committee for Harmonisation (ICH) and they have been meeting to discuss this topic for the last three years to come to some consensus on what they are going to do. Even with things pretty well established it still takes quite a bit of time for the wheels of the regulatory world to turn.

There is a lot of feeling in the pharma industry that it is far more important to be compliant than to do something that makes sense scientifically. What happens therefore is that a lot of companies are forced or feel they are forced to use things that do not make sense because that is the way it has always been done and things cannot modernize.

**CEOCFO:** ***What have you learned to break through that barrier?***
**Dr. Waterman:** In many places, champions will join to make things happen. There will always be people against things wherever you go and there will be people in many cases that will say, "Yes this makes sense" and will be one of the ones to push it and that has helped push through barriers.

**"The pharma industry is our main industry. However, we are affecting everybody. Many drugs that hit the market got out there faster because of us." Dr. Kenneth C. Waterman**

**CEOCFO:** ***Is there a typical size of company or geographic location that seems to understand more than others or is it across the board?***
**Dr. Waterman:** The distribution of how they work with us is different. The large pharmaceutical companies are typically setting up laboratories with specialists to use our stuff. It is called the ASAP (Accelerated Stability Assessment Program). The big companies license ASAP*prime*®.

The smaller companies will outsource the work, typically to our labs. That creates a different dynamic. The distribution globally, for the software is about a third US and Canada, a third Europe and a third Asia and some in South America as well. Distribution varies.

Typically, we find that drug discovery companies sometimes called Ethical drug companies are more likely to use something more scientific like our stuff. We also get a lot of biotech customers who just have a single drug and want to get it into the clinic fast. They are used to taking more risk.

**CEOCFO:** ***When testing for the different conditions, how do you put the data together?***
**Dr. Waterman:** It is important that the analytical method be what we consider stability indicating and we do a lot of work to develop such methods. That is not where we are innovative, meaning this is something that everybody knows how to do which is develop methods that are supposed to detect the things that are important. Now and then things come up, a few years ago somebody "discovered" that there are these things called nitrosamine at extremely low levels in some drugs; so many drugs were moved off the market. These levels are much lower than in some foods but that did not matter, they were pulled off the market. Our key is making stability determinations go faster and determining the packaging needed. What is being tested is often the same as with traditional stability.

**CEOCFO:** ***Would you tell us about the packaging side of FreeThink?***
**Dr. Waterman:** I will start with how I got into packaging. I had been doing things involved in stability for 25 years. Companies in general do not want to change anything because they may have clinical trials they have already done with that particular product. With any change, they would have to redo those clinical trials. Packaging changes do not affect the regulatory filing concerning the efficacy and safety of the drug. I started getting involved in the packaging side to help stabilize drug products without changing the fundamentals of those products in terms of process and formulation.
FreeThink Technologies interview continued on page 5.

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Most of the protection the packaging provides is limiting the rate that moisture can come into the package. Before I started a lot of people thought you had to put things up in packaging and just wait and see what happens. It turns out the science was already well established for how this works, and just needed someone to put it together. So we know exactly the humidity inside the package and the storage conditions over time. Once we know that we can say whether any particular packaging option will be acceptable for the desired shelf life. Typically, the more expensive the packaging the more protective. There is an incentive to not overdo it in the sense that you are going to be paying for years to come for a package that is over-protective.

There is another big factor happening in the world which is not so much in the US but in Europe. There is a big push in Europe now to use more sustainable packaging. Unfortunately, most sustainable packaging options are less protective than non-sustainable packaging depending upon how we define sustainable. It is getting us a fair amount of business on how to replace packaging and whether we can justify acceptability. That has created a new opportunity for us but a challenge for the companies needing to do this.

**CEOCFO:** ***What does the next year or two look like for FreeThink Technologies?***
**Dr. Waterman:** Our biggest thing is we are trying to consolidate in a new laboratory we just started renting but we are having to put a lot of resources into fixing up the lab and it is taking many months. Before anything else, we have to get the lab fixed up to get everybody into one place. Our other challenge is always getting people hired when we need to hire, trained, and ready to go for projects. I think these are some of the common challenges of companies.

**CEOCFO:** ***How do you know when somebody is a good fit?***
**Dr. Waterman:** When it comes to hiring people, I wish one question would answer it. I will sometimes try to make a judgment. We have a group that interviews and we do our best to find the right match. We do a very good job but we are not perfect. Sometimes we turn down people who would have been great and sometimes we hire people who just do not work out, but we do a pretty good job. Almost everybody we have hired has turned out to be great.

**CEOCFO:** ***What are some of the challenges in getting the lab ready the way you want it?***
**Dr. Waterman:** There is this thing called HVAC. It is a thing that seems to take forever and costs a fortune. Everything else is challenging but that overwhelms everything else. It seems there is a shortage of people in the trades these days. You try to get an electrician or plumber sometimes and they get busy somewhere else and do not show up.

It is difficult for small companies like ours to deal with sponsorship for immigration, but a large percentage of our applicant pool are not permanent residents. We have nothing against people wherever they are from, but we have to hire them with permanent residency, and it is very difficult for small companies to manage that issue.

**CEOCFO:** ***Why is FreeThink Technologies important? Why pay attention?***
**Dr. Waterman:** The pharma industry is our main industry. However, we are affecting everybody. Many drugs that hit the market got out there faster because of us. We are not the ones who came up with the drug; those people I think are great, but in many cases, a lifesaving or helpful drug got on the market because of something we did months or even years earlier than it would have without us. For a lot of people that can make a big difference. In some cases maybe it will not make much difference. Also because of the speed we can go, we can get things faster into the clinical trials which means that sometimes they fail faster but it means the companies can go back and get more rounds to get something that will work without having to wait as long and cost as much money.

We are in the background, we do not sell anything to consumers but our work impacts people indirectly throughout the world. We do a lot of work and big projects that help with lifesaving drugs in Africa where the climate makes it difficult with packaging and shelf life. Again, it is all stability.