



## How do we get rid of the endotoxins? Birmingham's BioDtech has the solution

As you can probably imagine, drug development is tricky business.

And despite what your Anti-Vaxer coworker may loudly and dangerously espouse, the process is long, thorough, and rigorous.

The injectables that make it to market have been carefully tested and developed by people who know what they are doing.

An important part of that process, especially when it comes to large molecule drugs, is finding a suspension solution for the drugs that will keep it from breaking down before it gets to the patient. That's what Soluble Therapeutics does.

[Go read my piece on Soluble Therapeutics to learn more about that.](#)

Another part of the development method is making sure that the drug only contains the things that are meant to be there. In other words, the solution that's injected into patients must be free of any extra materials, especially any materials that could cause harm.

This is the field that another Birmingham biotechnology company specializes in: Innovation Depot-based company, BioDtech.

One very common but potentially harmful material are endotoxins.

Endotoxins are also called Lipopolysaccharides, but I'm not going to call them that here because I want you to keep reading.

"Endotoxins" sounds like something The Scarecrow might threaten to unleash on Gotham, so we're going to go with that name.

In the real world, endotoxins are what makes up most (around 70%) of the outer 'shell' of [Gram-negative bacteria](#).

Because the presence of endotoxins usually means the presence of bacteria, animal immune systems tend to freak out when they sense that they're around.

Most septic shock, in fact, happens because the immune system is overwhelmed by a [rush](#) of endotoxins, usually through an open wound of some kind.

It goes without saying that we want to remove most if not all endotoxins from solutions that we inject into sick people, especially since they may have immune systems that are already compromised.

If you're wondering why there's ever bacteria in or around drug solutions, it's because a lot of the proteins used to make the drugs are literally manufactured by bacteria. It's called recombinant protein and it's a pretty fascinating process. [You should go read about it.](#)

Clearing these drug solutions of any endotoxins is a complicated and important process. Some material separators get rid of a lot of them, but there are still some present, and that's where BioDtech comes into play.

BioDtech has developed a "chromatographic media" that injectable drugs are filtered through, thereby removing endotoxins.

Here's how it works: The company has on hand specially-made sugar pellets. Each pellet has a kind of rough spot that bonds well with particular molecules.

BioDtech has developed a molecule that will attach to these sugar pellets, but is also a perfect match for endotoxins. That is, this molecule is attractive to the chemical makeup of endotoxins and will attach to them if they are around.

A group of these sugar pellets - with molecules attached - is placed at the bottom of a syringe or IV drip so that the drug must flow through the field of endotoxin-attracting molecules before it goes into the patient.

How can they be sure that this process removes all of the endotoxins from the drug? Why, they use crab blood, of course!

Horseshoe Crabs' blood contains things called amebocytes, which cause the blood to quickly clot in the presence of endotoxins.

For this reason, all injectable drugs are tested with Horseshoe crab blood. That's a lot of blood. There's large-scale, but seemingly sustainable, harvesting going on around the East Coast.

Their blood is baby-blue because of the presence of copper, which is interesting and kind of alien. They're an incredibly old species (450 million years or so) and definitely look the prehistoric part.

[Go read this excellent article on the mass blood harvest from The Atlantic a few months ago.](#)

I went to check out the BioDtech labs at Innovation Depot last week and met up with Dr. Keith Champion, BioDtech Director of Operations for a tour and explanation.

You can see some pictures I took in the gallery above.

"We're in the business of detecting and removing endotoxins from liquids." He told me. The company has three product lines available at the moment.

Apart from the chromatographic media I talked about above, BioDtech also offers kits for detecting endotoxins in different environments. One is called EndoPrep, which will help researchers find endotoxins in protein and peptide samples. The other is ESP, which detects the presence of endotoxins in human blood plasma.

With the award of a new NIH grant, the company has begun research on a round of assays involving the testing of human blood not just for the presence of endotoxins, but for the amount of endotoxins.

They think that the level of endotoxins may be a reliable biomarker for some diseases. They've already looked at patients suffering from Crohn's Disease and are about to start testing with the HIV virus.

Dr. Champion is very careful to point out, however, that the trials are still in the very early stages.

The company was drawn to Birmingham from Nashville several years ago by the [Birmingham Technology Fund](#).

You can go read more about BioDtech at [www.biodtechinc.com](http://www.biodtechinc.com)

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