

# pharma

**TECH OUTLOOK**

[WWW.PHARMATECHOUTLOOK.COM](http://WWW.PHARMATECHOUTLOOK.COM)



**Chemtos**

A gold award badge with a shield-shaped center. The shield contains the text "TOP ANALYTICAL Services Companies 2021" and "Recognized by pharma TECH OUTLOOK" with the "pharma" logo in red.

*The annual listing of 10 companies that are at the forefront of providing Analytical Services and transforming businesses*

# Chemtos

## Deliver High-Purity Compounds with a Comprehensive Certificate of Analysis



**R**egardless of their size, CROs, bioanalytical laboratories, and pharmaceutical companies often struggle to determine which chemical analysis should be included in a Certificate of Analysis (CoA) for an organic compound. This is primarily due to the absence of any single analytical tool that can detect everything that can be present, preferably with a weight proportional response. For example, one needs to weigh (or administer) an accurate amount of active ingredient while

disregarding impurities and/or salts/counterions that might be present and contributing to its weight. This is commonly referred to as the potency of a compound.

To this end, Austin, Texas based, Chemtos, offers single-use reference standard solutions, including DEA Exempt formulation products, for diagnostics, forensics, and drug screenings, which are accompanied by a comprehensive CoA that includes copies of the analytical data. "We started out in 2006 with our primary clientele being those conducting



All of our products require accurate CoAs and our knowledge and skills in analysis give our clients greater confidence in our products



clinical trials. Since 2017, we are leveraging our qNMR capabilities to differentiate from our competitors and gradually expand into reference standard solution ampoule business targeting Diagnostics and Toxicology studies," says Khalid Thakur, President, Chemtos. The company expanded to an additional site in 2016, where a 500 MHz Bruker NMR and a 300 MHz Agilent NMR were installed. They have been optimizing qNMR (Nuclear Magnetic Resonance) process to minimize errors and increase accuracy and precision. Chemtos entered this market with a logical process to tackle the challenge of analysis for CoA generation – break it down to three major categories and analyze based on the application of the compound.

Category 1 is to confirm the identity of the compound, using at least two different analytical techniques. For the uninitiated, this is a minimum requirement and easy part of the analysis for CoA.

Category 2 is to determine the potency of the active ingredient in the compound — which is considered to be a major source of problems in a CoA. Traditionally, multiple analytical techniques are used to detect the presence of residuals such as water, solvents, salts, organic impurities, presumably in a weight proportional response. But there are numerous problems with this approach which is comparable to trying to detect the size of an elephant by independently detecting the size of each of its body parts using different techniques. Chemtos offers the alternative of directly detecting the size of the elephant (a.k.a. determining potency) using qNMR methods. Accurate analysis by qNMR is non-trivial, and the company has spent the last five years optimizing and minimizing sources of error while still using only a few milligrams of sample for analysis.

Lastly, Category 3 is to confirm the absence of toxic or biological impurities that can have an outsized biological response, especially if the compound is to be administered to humans or animals. These include bacteria, virus, fungus, heavy metals, and other toxic materials present in trace levels. This is not required if a compound is not to be

administered to humans or animals – or only used as an analytical reference standard.

"With our comprehensive certification, you will never need to doubt the authenticity or purity of our reference standards. Every compound provided by Chemtos comes fully certified with Diode Array HPLC purity analysis, proton NMR analysis, LC/MS and all of the supporting data. All analytical work is done under GLP conditions," says Thakur.

Most of the company's analytical services are fixed price (no ambiguity in pricing) with a streamlined process of web-based request submission and quick analysis upon receipt of the sample. "Our major business is a service offering of 'Custom-Synthesis of Analytical Reference Standards that are not available at any other vendor'. We also offer accurate qNMR analysis using <5 mg of sample (which are often high-value reference standards). That's not all! The company provides in-stock analytical reference standards in neat and solution ampoule form whose potency has been accurately determined using qNMR. Most of the solution ampoule products are US DEA Exempt products that are used in drug screening, forensics, and Toxicology studies." Thakur says, "all of our products require accurate CoAs and our knowledge and skills in analysis give our clients greater confidence in our products."

To put this into perspective, one of Chemtos's clients spent months trying to quantitate all the metabolites to account for the administered amount of API in a clinical trial but kept coming short. FDA requires that at least a certain fraction of API is excreted from the body within a certain time frame so as to not accumulate in the body. "Our qNMR showed that the potency of the reference standard they were using was 10 percent less than expected," says Thakur. With the correct potency value of the metabolite reference standard, all -API was accounted for. The client mentioned to Khalid that had they initially analyzed the reference standard by qNMR for accurate potency, they would have saved many months of effort struggling to account for all of the API.

With many such instances of client success, Chemtos actively seeks new avenues to grow. For the past 4-5 years, Chemtos has been developing and adding products for Diagnostics, Toxicology studies, and Drug screenings. Meanwhile, they continue to improve Analytical services which are different from the traditional way of analyzing compounds for their CoA generation. "We will be looking to get ISO certifications once the Pandemic is under control – even though our processes are a little different from the traditional methods of CoA generation," concludes Thakur. 