CS ANALYTICAL

CONTAINING QUALITY

"THE EXECUTIVE THREE"

Three questions for the company executive that establishes their vision and leadership style.

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You are considered one of the world's leading authorities on container qualification testing and container closure integrity testing. Over the past three years you have you have advised dozens of clients on their container issues working as an independent advisor and consultant. What was your motivation to join the CS Analytical Leadership Team?

My motivation for joining CS Analytical was actually quite simple. Over the past 3 years operating as an independent consultant to industry, I gained a new perspectives on contract laboratories and the work they perform working from the client side. This took shape in two ways.

On one hand, I gained deeper insight into why organizations contract work to 3rd party laboratories. Naturally, there is the high-level business case – it is more cost-effective for most companies to outsource work than to perform it internally. However, in discussions with clients, whether it be at my last contact lab position, or as consultant, this is hardly ever the main driving force behind samples actually coming through the laboratory door. Instead, as regulations and best practices surrounding package testing continue to increase in complexity, volume, and demand, the value of a contract laboratory expands. A custom-tailored test approach that closely considers internal and external requirements is required for success. Clients aren't looking for the cheapest avenue to sending a sample and generating data, they're looking for a solutions provider; a partner acting as a natural extension of their team with areas of expertise that complement internal knowledge to achieve results. A test is only worth it if it's the appropriate test to perform and performed properly. Leveraging the experience and knowledge of a contract laboratory is the true value of a contract lab. The Science and experience that a contract laboratory brings to the table matters.

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On the other hand, I saw how the operations at contract laboratories directly impact operations of the companies they work for. I saw how critical contract lab operations can be to the success of the client organization. An HDPE bottle waiting for a <661.1> ID by IR analysis may be one of dozens sitting in a bin waiting to be analyzed at the lab, but for the client, that same bottle and test result may be the difference between releasing a lot of components or product. In other high-stakes situations, a test result is the difference between having data for your next FDA meeting, or appearing woefully unprepared. The Service that a contract laboratory provides matters.

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If one thing has become clear during my time as an industry consultant, it's that in the current contract laboratory landscape, there has been a substantial decline in competency and customer service in recent years. There is a demonstrable need for high-quality, cGMP, FDA-registered and inspected container and package-related testing. So, to get back to your question, my motivation was simple: I want to be part of the solution that brings science and service back to the contract lab space. My aim is to provide clients with the best, most comprehensive container qualification programs, inclusive of CCIT, that meet internal requirements, implement current best practices, and meet or exceed regulatory requirements.

What are the current challenges that the pharma, biotech and medical device companies face with regard to container and package issues?

Over the past 10 years or so, there has been an explosion of activity when it comes to regulatory expectations surrounding primary and secondary packaging in these regulated industries. This, ironically, is both in response to a challenge, and a challenge in and of itself.

If we rewind to the early-to-mid 2000s, before the release of the modern USP <1207> and the revisions to USP <671>, <661>, and <381>, the industry was in a bit of an odd state when it came to package systems and the testing they were subjected to. For decades, many of the pharmaceutical products entering the market were, for lack of a better word, similar. So were the packages: pills and capsules in HDPE bottles, liquid and lyo small molecule parenterals in glass vials closed with rubbers stoppers. As such, compendial test methods employed to evaluate the quality and safety of these materials and components, like those in the USP, had been around for decades with established specifications for their traditional use.

However, at the same time, the advent of biologics and other complex therapies, along with their unique distribution, storage, and dose delivery requirements, pushed the bounds of traditional packaging systems to their limits while concurrently spurring the use of new packaging materials and configurations.

A great example is what's going on right now with the COVID vaccine – take a glass vial and rubber stopper that had been developed and used for years at "normal" storage conditions, putting a new drug (vaccine) in it, and try to force it to keep integrity during distribution and storage at -80C vs developing a new type of package system expressly designed to accommodate this use. Holding the vaccine's package to standards required of saline solution stored at 2-8C does nothing to prove its suitability for this intended use. Examples of this are myriad, with the use of plastic packaging components for parenteral products being another. In this case, the plastic needs to be held to a much higher standard when housing a parenteral vs a month's worth of Dad's Nexium.

The novel use of existing package systems, concurrent with the expansion of new materials and package configurations, resulted in a great disconnect between testing requirements and actual risk to product quality or safety. The most detailed and in-depth testing was done for materials and components the industry had used for years, those HDPE bottles for solid oral dosage forms, the Type 1 glass vial, etc. The new, less-proven and well-characterized materials, such as cyclic olefins, PVC / PVDC, were subjected to reduced testing under USP standards, largely due to the lack of material-specific methods and specifications. The actual USP methods were the "challenge". Industry was forced to use and apply test methods that were not ideal nor specific to the advanced package systems that are now being used.

In an effort to reduce the prescriptiveness of these chapters, the USP began to revise test procedures. The resulting revisions included a host of new materials, packaging configurations, use cases, along with more rigorous test methods, and many of the one-size-fits-all specifications were removed.

From a quality perspective, setting the specifications with respect to final product requirements (intended use) is the right way to do things. However, for an industry used to qualifying packaging components and systems in an almost check-box fashion, this was a massive shift. A shift so massive that in the case of <661.1> and <661.2>, implementation has been delayed for almost a decade as industry works to interpret and implement the new standards. Similarly, <1207> remains a guidance chapter, but one selectively enforced by FDA.

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Thus, where we are today is a confusing matrix of best practices, guidance, and regulatory requirements both current and pending. Now, I see the main challenge as follows: understanding how your product dictates the requirements of the package, and then choosing the appropriate test methods and specifications to demonstrate the suitability of that package for its intended use.

Can you explain how your role as Chief Scientific Officer for CS Analytical will enable you to better serve your clients?

On a personal level, being named CSO at CS Analytical brings my career full circle. When I ran the container testing division at a contract lab, I developed and implemented testing strategies case-by-case, but across hundreds of companies and products. As an advisor and consultant to industry, I helped design broader container testing strategies client by client that included testing requirements, risk mitigation, and control strategies across many product configurations and portfolios. At the same time, both this data and the interpretation of this data were used to support regulatory filings.

As CSO of CS Analytical, I am joining the only team uniquely and specifically dedicated to advising AND implementing container and container closure integrity testing strategies to a standard not met in the current contract laboratory landscape. With a team comprised of experts in their respective fields, at CS Analytical, we aim to bring this level of expertise, commitment, and service back to the contract lab market. Our comprehensive service offerings will include CCI method development, validation, and analysis, as well as USP/EP/JP physical performance tests and physicochemical tests for all common or unique primary packaging components and systems.