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CUSTOM SYNTHESIS ORGANIC COMPOUNDS MANUFACTURING COMPANY OF THE YEAR IN CANADA 2025

TLC PHARMACEUTICAL STANDARDS

THE ANSWER TO ALL CUSTOM SYNTHETIC REFERENCE STANDARD NEEDS

Alex Kazandjian,
Vice President of Sales and Marketing

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TLC Pharmaceutical Standards

*This award is in recognition of **TLC Pharmaceutical Standards**' stellar reputation and trust among customers and industry peers, evident in the numerous nominations we received from our subscribers. **TLC Pharmaceutical Standards** emerged as the **Custom Synthesis Organic Compounds Manufacturing Company of the Year in Canada 2025** after an exhaustive evaluation by an expert panel of C-level executives, industry thought leaders, and our editorial board.*

Awarded By

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CUSTOM SYNTHESIS ORGANIC COMPOUNDS MANUFACTURING COMPANY OF THE YEAR IN CANADA 2025

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THE ANSWER TO ALL CUSTOM SYNTHETIC REFERENCE STANDARD NEEDS

Analytical delays, regulatory setbacks and supply chain disruptions cost the pharmaceutical industry billions of dollars each year. But these losses rarely stem from formulation errors alone. More often, they trace back to a missing link in the validation chain – the reference standard.

As drug compounds become structurally more complex and impurity profiles become harder to predict, regulatory agencies from the FDA to EMA and Health Canada are raising the bar. Developers must now deliver full-spectrum characterization, not just the active pharmaceutical ingredient (API), but every impurity, degradant and metabolite associated with it, across the drug's lifecycle. The absence of even a single standard can trigger regulatory hold-ups and stall production.

TLC Pharmaceutical Standards was built for this moment.

Far beyond its role as a reference standard provider, TLC functions as a critical synthesis and risk mitigation partner for labs navigating increasingly stringent compliance environments. Its model is grounded in speed, scientific precision and anticipatory scale—traits that have cemented its leadership in the manufacture of high-purity, custom-synthesised organic compounds.

A catalog of more than 20,000 reference standards—with over 2,000 new compounds introduced annually in response to emerging industry demands—lets TLC offer both breadth and relevance. Its portfolio spans rare and hard-to-source impurities, stable-labeled isotopes and custom-synthesized compounds that align with where drug development is heading. Every molecule is manufactured under tightly controlled conditions, fully characterized and dispatched with the urgency demanded by modern regulatory cycles.

"It's all about earning trust," says Alex Kazandjian, vice president of sales and marketing. "Clients rely on us not just for our chemistry, but for the certainty that their timelines won't stall because a critical standard is missing. We've built our reputation by showing up when it matters most."

That trust is assured by keeping everything in-house. A team of seasoned chemists and analysts operates across 14 operational production labs, including dedicated labs for peptides and antibiotic synthesis, and two fully equipped analytical labs, giving the company total control over speed, quality and regulatory rigor. All work is performed to ISO 9001, 17025, and 17034 standards, ensuring that every compound leaving the facility is audit- and submission-ready. Each molecule undergoes orthogonal analytical characterization to satisfy agencies such as the FDA, EMA and Health Canada. And if an issue arises, in-house experts resolve it in real time using their scientific expertise, equipment and regulatory knowledge.

TLC's reputation was recently tested during the global nitrosamine rush, following the FDA's updated guidance in September 2024 (Rev. 2) on controlling impurities in human drugs. This revision was initially based on the September 2020 directive, which had deadlines culminating in 2023, and called for urgent action on both small-molecule nitrosamines and nitrosamine drug substance-related impurities (NDSRI). Now, by August 1, 2025, manufacturers must assess their products and meet intake limits using validated reference standards. Many labs were still

Alex Kazandjian,
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unprepared and lacked the required compounds. TLC responded quickly, using its agile synthesis platform and expert chemists to synthesize more than 1,000 nitrosamine standards within a five-year period, meeting the industry's very high and urgent demand for nitrosamines and helping clients stay compliant under tight deadlines.

Solving the Science Behind the Submission

TLC is all about molecular-level problem-solving.

When pharmaceutical teams encounter unknown impurities or degradation products, often without a defined structure or documented synthetic route, the question is no longer "where do we source it," but "how do we even begin?" That's when they call TLC. With decades of experience in structure elucidation and route design, TLC's scientists reverse-engineer synthesis strategies from fragmentary analytical data, then build, isolate and fully characterize the compound.

In one instance, a client running a long-term stability study flagged an unidentified peak during routine analysis. The compound hadn't been previously reported and no structural data existed. Yet its presence had to be resolved to advance the drug's regulatory filing. TLC was brought in at the investigative stage. Working in close collaboration with the client's analytical team, TLC proposed a structure, mapped out a viable synthetic route and produced the compound in-house. The final output was synthesized at high purity and accompanied by full analytical documentation, ready for regulatory submission without additional delay or outsourcing.

Such upstream involvement is becoming increasingly common. Where clients once approached TLC after defining their targets, many now engage at the pre-characterization phase, especially in early development programs or when faced with ambiguous impurity profiles. The company's chemists are often among the first to see an unknown peak in drug impurity profile and help translate it into a compound that can be synthesized, validated, and submitted.

Whether working under confidentiality agreements or navigating tight timelines ahead of new drug application or abbreviated new drug application submissions, TLC supports regulatory teams in moving from analytical uncertainty to actionable solutions.

Readiness That Precedes Demand

Long before GLP-1 analogs like semaglutide and liraglutide became the focal point of therapeutic pipelines and media cycles, TLC had already started building for that future. The company established a dedicated peptide lab, onboarded scientists with deep expertise in solid-phase peptide synthesis and began developing the infrastructure needed to support a new class of regulatory submissions.

That foresight is now paying off. As interest in GLP-1 receptor agonists continues to surge across diabetes and obesity, TLC is already equipped to deliver what clients now urgently require—well-characterized peptide reference standards, stable-labeled analogs and hard-to-source impurities that meet regulatory-grade standards.

What makes TLC so responsive is institutional awareness. The team operates with an unusually tight feedback loop, where chemists, regulatory experts and client-facing teams are constantly in dialog about emerging compound classes, shifting regulatory signals and client pain points. There's no waiting for quarterly planning cycles or layers of internal approvals. TLC moves fast because it listens and acts before urgency becomes a crisis.

The readiness was evident as regulatory scrutiny grew around extractables and leachables. With increasing concern over the migration of chemical species from container closure systems, elastomers and processing components into finished drug products, pharmaceutical companies needed access to highly specific and often hard-to-source materials. TLC again stepped forward, synthesizing a suite of complex rubber oligomers and related compounds, allowing labs to execute risk assessments using well-characterized, fit-for-purpose reference materials.

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A Culture Built on Doing What's Hard

Clients often turn to TLC with the kind of projects others decline. The willingness to take on complexity is part of the company's DNA. From senior leadership to bench-level chemists, the culture is built around scientific integrity, intellectual curiosity and a deep respect for doing things the right way, even when it takes longer.

That mindset has shaped TLC into a trusted partner for high-stakes, high-complexity synthesis work. Clients don't just return because the compound was delivered. They return because the team didn't treat their request as a transaction. They treated it like it mattered. When timelines are tight or data is incomplete, TLC leans in, asks the right questions and works the problem until it's solved.

Adaptability is what ties it all together. TLC stays close to where science meets reality. What are clients running into in the lab, what are regulators prioritizing and what therapeutic areas are shifting?

"We're lean, we're agile and we're listening," says Alex. "Weekly internal reviews keep us in lockstep with what's happening on the ground, not just what's forecasted."

Going Where the Science Goes

TLC's recent expansion into Hyderabad, India, is more than a geographic move. The new office, launched in late 2023, strengthens the company's ability to support one of the fastest-growing life sciences ecosystems in the world. Embedding sales, marketing and customer support from India has helped TLC offer clients in the region with faster turnaround times, on-the-ground coordination and real-time responsiveness.

The company is also rethinking how it connects with clients across all regions. By investing in digital infrastructure, it has rolled out tools that make interactions smoother and more self-sufficient, from secure file sharing to instant access to pricing, inventory and certificates of analysis. Clients no longer have to wait for email replies. They can simply log in, pull what they need and move forward.

At the same time, TLC is embedding itself earlier in clients' development cycles, stepping in during the critical planning phases to help shape strategy and accelerate decision-making. This combination of geographic access, digital enablement and upstream collaboration reflects a deeper shift where TLC isn't just expanding its reach but expanding its role as a strategic partner in helping pharma companies move faster and with greater confidence.

That's how TLC lives up to its promise, fulfilling the role of a true synthesis partner, trusted not only for reference standards, but for advancing the critical work that earns confidence from regulators and clients alike.

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