

After the Audit: The Second Half of the Trust Problem

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Walk through almost any serious nutraceutical plant in India today and you will be shown the certificates first. cGMP. A third-party audit report. US FDA facility registration. ISO. The tour is well rehearsed because it works, and because for the past several years it has been the single most effective answer to the question overseas buyers were actually asking, which was whether an Indian supplier could be relied upon at all.

That question has largely been answered. Indian manufacturing has earned the benefit of the doubt it spent two decades being denied, and the recent coverage of trust-led growth in this sector reflects something real.

The difficulty is that the answer has become universal. When every credible exporter holds the same certifications, those certifications stop distinguishing anyone. They become the price of entry, and the buyer moves on to the next question.

What a certificate actually attests to

It is worth being precise about this, because the two things are routinely conflated in our own marketing.

A facility certification is a statement about process. It says the plant is clean, the batch records are intact, the raw material is traceable, the equipment is qualified, and the product in the bottle is what the label says in the quantity the label states. That is a serious achievement and it is not a small one.

What it does not say is whether the active does anything once swallowed.

Those are different claims requiring different evidence, and no amount of the first will ever substitute for the second. A perfectly manufactured, fully traceable, immaculately audited product can be clinically inert. Nothing in the audit would detect it, because the audit was never designed to look.

The question the buyer asks next

Importers, distributors and increasingly the regulators they answer to have begun asking a different set of questions, and Indian exporters should expect them to get sharper.

Does the active work at the dose you are selling, in the format you are selling it in? Is there evidence specific to this product, or to an ingredient that resembles it? Who conducted that work, was it registered before it began, and was it published whether or not it succeeded?

These are not unreasonable questions. They are the ordinary questions of a market maturing. In Japan, the Foods with Function Claims framework requires a substantiation dossier before a claim may be made. In Europe, health claims face an evidentiary assessment that most of our sector would not currently clear. The direction of travel across our export markets is towards product-level substantiation, and a facility certificate is not responsive to any of it.

Where borrowed evidence stops working

The common practice is to rely on an ingredient supplier's literature. This is understandable, it is often all that exists, and it is not always wrong. It stops working at a predictable point.

Published work on an ingredient is work on that ingredient, in that chemical form, at that dose, in that delivery format, in that population. Change any of those and the evidence weakens, sometimes to the point of irrelevance.

The microbial metabolite category illustrates this cleanly. Butyrate, the short-chain fatty acid produced when colonic bacteria ferment fibre, is the principal energy substrate of the cells lining the large intestine and acts almost entirely at the gut wall rather than in the circulation. Supply it as sodium butyrate and most of it is absorbed in the proximal small intestine, well before the tissue that needs it. Supply it as tributyrin, a triglyceride prodrug cleaved progressively by lipases, and its release profile along the gut is quite different. Same molecule, same claim on the label, materially different behaviour in the body.

A buyer who has understood that distinction will not accept literature on one as evidence for the other. Nor should they.

What product-level evidence actually requires

It is less daunting than it is made to sound, and it is more exacting than most of us would like.

Study the finished product, in the format sold, at the dose sold. Register the trial prospectively with a recognised registry before the first participant is enrolled, which costs nothing and is the single clearest signal that the result was not selected after the fact. Choose an endpoint that corresponds to the claim rather than one that is merely convenient to measure. State the limitations plainly, because every study has them and a buyer's technical team will find the ones you omit. Publish, including the studies that disappoint.

None of this requires a large trial. A small, well-designed, prospectively registered study with honest limitations is worth considerably more to a serious buyer than a large one that was never registered and reports only what worked.

Why this is a competitive argument, not a compliance one

I am aware that this reads as an exhortation to spend money. It is actually an argument about where the next decade of advantage sits.

Certification was a differentiator for the Indian companies that invested in it early, until everyone had it. Product-level evidence is at exactly that stage now. The companies generating their own data today are buying a position that will be considerably more expensive to acquire in five years, when it is expected rather than exceptional. And unlike a certificate, a clinical dataset is proprietary. Your competitor can purchase the same audit. They cannot purchase your trial.

There is also a collective dimension. A market where careful and careless companies are indistinguishable eventually gets judged by the careless, and the reputational cost of that lands on everyone exporting from the same country. We have seen this happen to Indian sectors before and the recovery took years.

The plant is clean. That argument is won. The next one is about what happens after the capsule is swallowed, and it will be settled with data rather than certificates.