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Pharma manufacturing is data-rich and decision-poor

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Bengaluru-based Pivot Path has just launched as an independent pharmaceutical technology company following its demerger from Strides Pharma. Pivot Path emerged from inside Strides Pharma's regulated manufacturing operations, evolved from an internal operations hub into a platform that now serves 70+ pharmaceutical companies across five continents. The company recently secured Rs 100 crore in investment from Ascent Capital, valuing it at Rs 230 crore. BioSpectrum took this opportunity to interact with Shashidhar KL, Chief Executive Officer, Pivot Path, and find out about the company's growth plans in the coming years.



Pivot Path recently secured an investment of Rs 100 crore from Ascent Capital. What are your strategic priorities for deploying this capital, and how will it support the company's next phase of growth?

The investment is concentrated where the regulated workload is heaviest and the manual effort least defensible. In pharmacovigilance, that is NovaVigil: extraction, data entry etc. consume qualified people on work that does not need their judgement. In quality and compliance, it is NotelQ, because validation and controlled documents are where a change gets stuck for months.

AnomIQ, because audit-trail review is done at defined intervals by sampling, rather than through continuous real-time monitoring. Issues may remain undetected for extended periods, limiting the ability to take prompt corrective or remedial actions on batches.

InvestigationIQ, because root-cause analysis is done by scarce specialists who spend most of their time on method and formatting rather than on reasoning. Each of these platforms runs on the same validated foundation, which is what makes every new platform more efficient than the one before it.

The second priority is proximity to the regulators our clients answer to. Their obligations sit with the FDA, EMA, MHRA and TGA, and clients want people who understand those regimes in the same time zone as the affiliate carrying them. We are building client-facing leadership in Europe, with leads based in Prague and in Switzerland, and delivery from Bengaluru, Romania, Hyderabad and Mysuru.

The third is depth of domain talent, which for us means people who have worked inside pharma rather than people who have worked on pharma projects. It is the slowest thing to build and the first thing a client notices.

Pivot Path serves more than 70 pharma companies across five continents. Could you share details about some of your key clients in India and globally, and the nature of your engagements with them?

At Indian CDMO, the business doubled year on year. We advised on and automated 50+ IT processes, absorbing 2x growth without them having to add headcount. After acquiring a plant in Europe, a global client faced a strict seller deadline. We were able to carve out and transition their entire IT, SAP and quality infrastructure setup in just 60 days, ensuring continued operations and no downtime.

In Singapore, we digitised a client's entire validation system and went live in two and a half months, achieving error-free compliance. Buoyed by this success, we are doing the same for a large Indian generics brand, as we speak.

A deep multi-modal engagement we can talk about, was with an Indian bio-similar manufacturer. We entered the project with a 200-day launch window, and were able to build the enterprise IT setup, executed system validation and 200 personnels to staff it.

Most clients engage with us on more than one of the three things we do. Consulting is a decision or a remediation: an inspection response, a validation strategy. Operations are running a function to a service level: pharmacovigilance case processing, validation execution, IT across a manufacturing network. Technology is implementing the enterprise applications a company runs on or deploying our own platforms. All three are contracted separately, which matters, because a client can start with one and add the others without renegotiating the relationship.

How has the pharmaceutical technology landscape evolved over the years, and what are the key trends shaping the industry today?

For two decades, pharma technology was built around inspections. The industry became very good at proving what it had done and very poor at using the same information to make better decisions. Three things changed in recent years:

The first is access. A capability that once required a dedicated research team is now accessible to every organisation. Whether you could build it stopped being the constraint.

The second is that AI crossed from pilots into production. Every pharma AI project used to stall as a proof of concept, because nobody could explain to an inspector how an output had been produced. That is now solvable: retrieval that cites its sources rather than guessing, outputs that are versioned, traceable and re-runnable, and a knowledge graph underneath holding the context an answer depends on.

The third, and the least discussed, is that the regulators have matured. GAMP 5 addresses AI and machine learning directly, the EU AI Act sets out expectations and inspectors increasingly arrive with questions rather than objections. You can now validate an AI system instead of avoiding one.

India is witnessing a surge in pharmaceutical GCCs. What factors are driving this growth? What are the biggest digital transformation priorities for pharma GCCs today?

We are a product of this trend, which gives me a more direct view than most. Pivot Path is the demerged entity of Arcolab, built as the global capability centre for a pharmaceutical group with a 35-year history, and now an independent company. The arc from cost centre to capability centre to a business with its own products is the arc this question is about, and we have walked it.

Only one of the three drivers is cost. Talent depth is first: three decades as the pharmacy of the world has left India with people who have run regulated operations rather than read about them. Second, the mandate moved. A centre that began with transaction processing now runs pharmacovigilance for a global portfolio, owns validation across a site network and builds software. Third, cloud, data and AI talent now sit in the same cities as pharma talent, which was not true ten years ago.

Proving to the parent that work done here can carry regulatory accountability, not merely execute against it. And holding quality while headcount doubles, in a market where the best people now have better options than they did five years ago.

Looking ahead, which emerging technologies have the greatest impact on the pharmaceutical industry over the next five to ten years?

Digital twins with predictive analytics in manufacturing because that is where the industry still leaves the most value on the floor. Pharma manufacturing is data-rich and decision-poor. Batch records, process parameters and equipment telemetry all exist in volume, and almost all of it is used retrospectively to demonstrate a batch was acceptable, rather than to steer it while it is still running.

The second is immersive technology, where we work with a partner, 8Chili. VR is for training; we convert SOPs and machine operations into digital twins, so an operator is trained and certified on a line before going near it. AR is for execution. The SOP instruction arrives in the operator's field of view at the moment of the task; the operator performs it, and evidence is captured as it happens rather than written up afterwards, with the checker verifying through the same channel. That is human-in-the-loop in the most literal sense, and in an industry where deviations often trace back to human factors, it is a compliance investment rather than an HR one.

Autonomous manufacturing sits further out for regulated products, correctly so. What arrives first is autonomy inside bounded loops, with a qualified person holding the release decision.

