



PharmaSoft

Let Us Take Care!



DRUG
SAFETY



REGULATORY
EXCELLENCE



SMART
TECHNOLOGY



STRONG
PARTNERSHIPS



DATA DRIVEN
INSIGHTS

Case Study #2

*From Project Support
to Full PV Department
Partnership*



*Smarter today,
Safer tomorrow.*



CASE STUDY

2016 – PRESENT

From Project Support to Full PV Department Partnership

How a focused engagement grew into a long-term PV partnership built on continuity, trust, and technical depth.





From CTD Preparation to Full Pharmacovigilance Department Partnership

A long-term collaboration that evolved from regulatory support into full pharmacovigilance department responsibility built on trust, continuity, and technical depth.

2016

Partership Started

2019

PharmaSoft Became PV Department

10+ Years

Continued Support

Molecules

130+

Products

200+

Employees

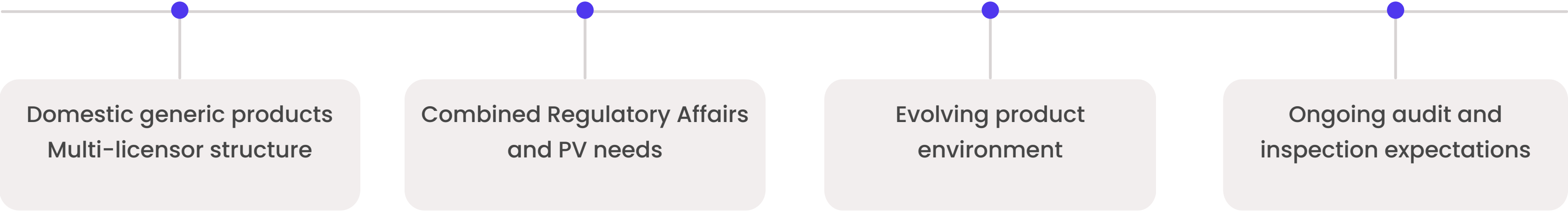
5000+

A Multi-Licensors Business with Complex PV Demands

Who They Are

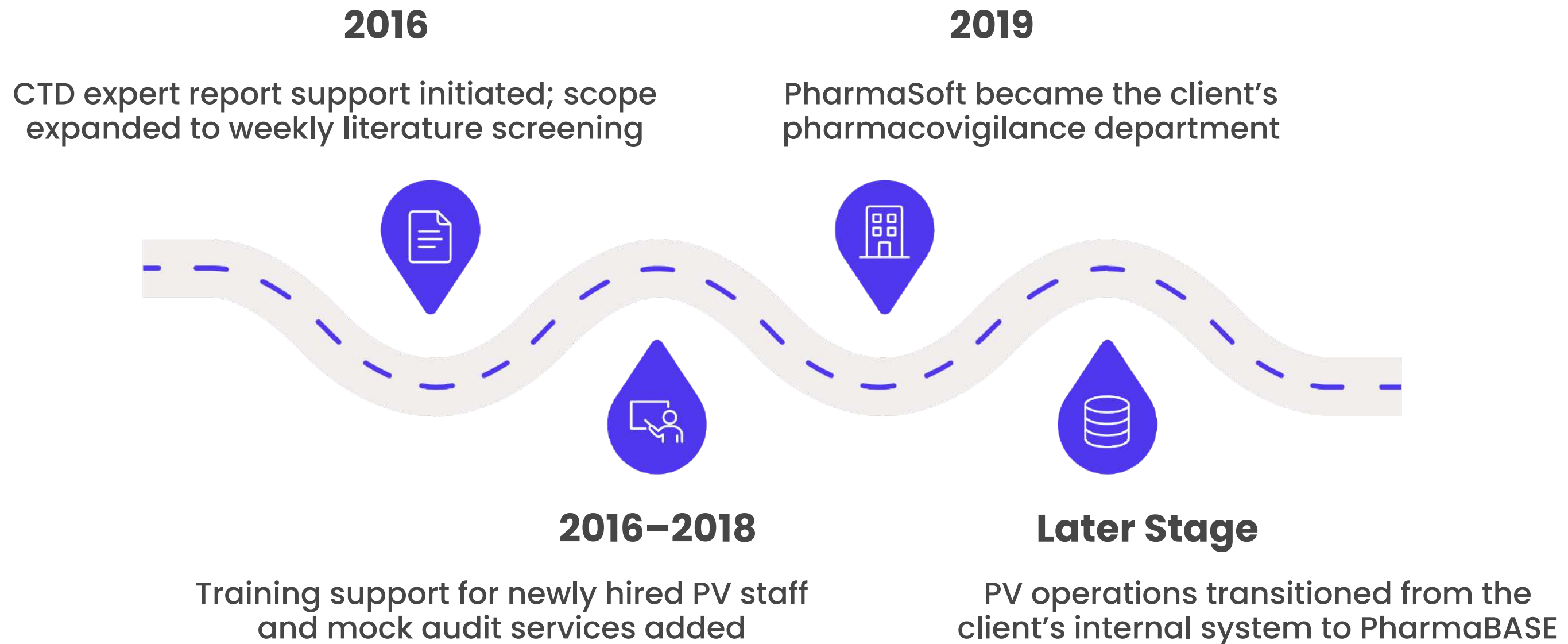
A pharmaceutical company manufacturing domestic generic products, while also operating with multiple licensors in a complex and evolving product environment.

Operating Context





Seven Years of Growing Responsibility



Each phase of expansion was driven by genuine operational need, making the growth of the partnership a natural reflection of trust and performance.



An Internal PV Structure That Was Difficult to Sustain

Frequent PV Specialist Turnover

Repeated onboarding needs and the ongoing loss of internal know-how created a fragile operational foundation.

Operational Disruption

Continuity was affected each time personnel changed, leaving critical PV processes vulnerable.

Increasing Complexity

A multi-licensor environment required a more stable, audit-ready PV structure than internal resources could reliably provide.

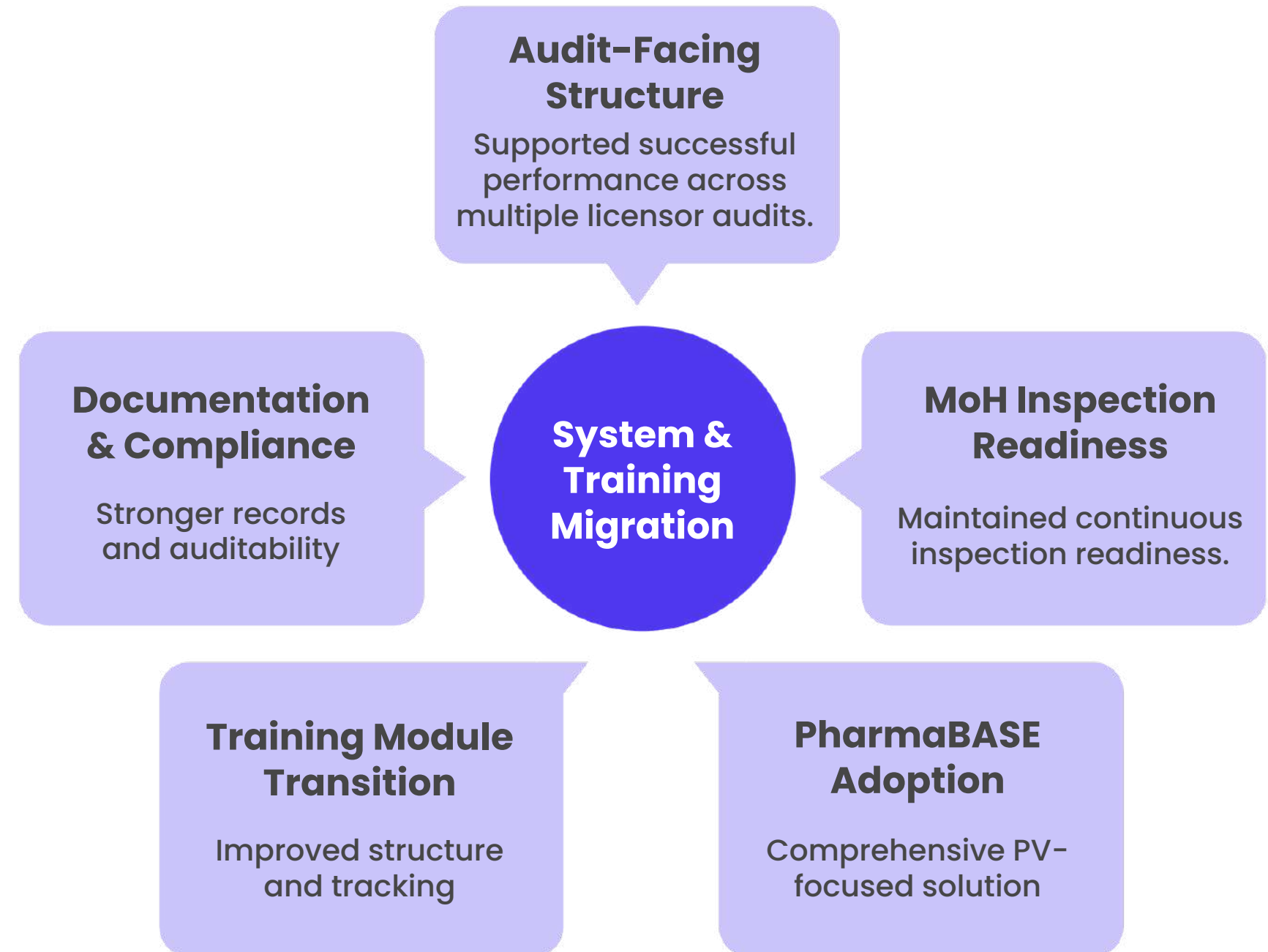


Expansion, Continuity, and System Migration

How the Partnership Deepened

Support began with CTD Module 2.4 and 2.5 expert reports, then expanded to weekly literature screening, PV staff training, and mock audits. By 2019, PharmaSoft had taken on full PV department responsibility.

Despite repeated internal personnel changes at the client, PharmaSoft provided the continuity needed to keep core PV operations stable.





From Operational Gaps to a Resilient PV Structure

Before

Turnover-sensitive, internally managed, and difficult to sustain. Operational continuity was vulnerable with every personnel change.

After

Continuity-driven, better documented, and more operationally consistent. Systems and training became better aligned with PV-specific workflows.

Long-Term Effect

A stronger PV structure aligned with audit expectations and the ongoing complexity of a multi-licensor environment.





A Partnership Built to Evolve



Trust That Expanded the Scope

The relationship grew from project-based support into broader responsibility over time, a clear reflection of confidence in delivery quality.



Support That Matched Business Growth

As operational needs became more complex, the service model expanded accordingly, supporting a more mature pharmacovigilance structure.



Specialised Industry Understanding

Working with a partner rooted in pharmaceutical operations brought practical, sector-specific thinking to every stage of the engagement.



Flexibility Without Loss of Control

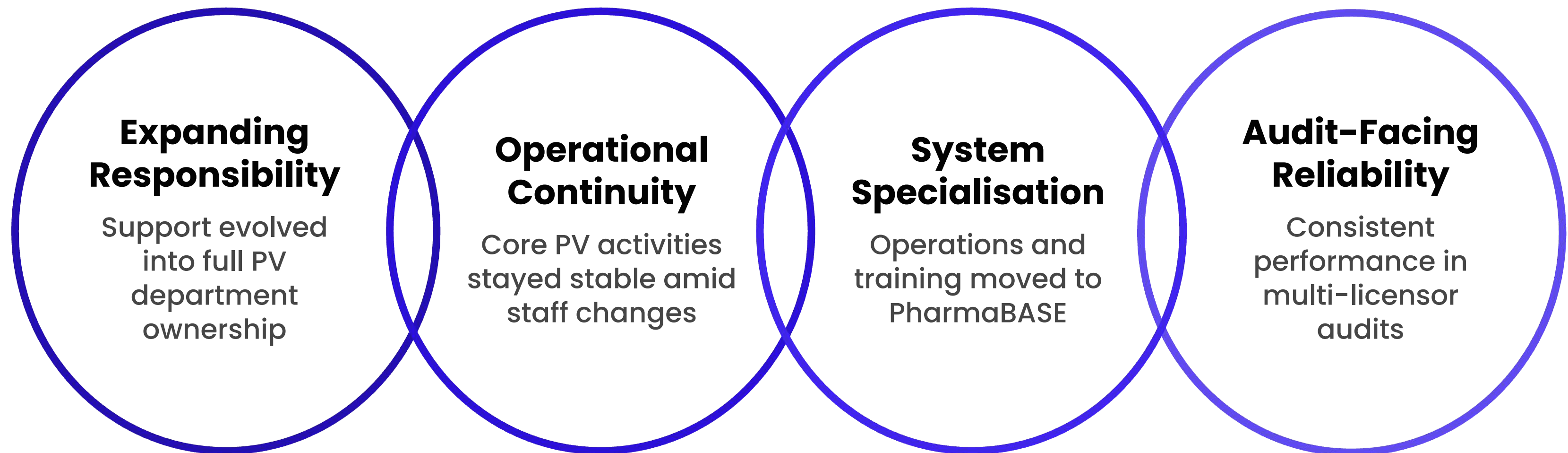
Different support models were implemented over time without compromising visibility, structure, or overall operational oversight.



The Progression Told the Story

Some partnerships begin with a single service and stay there. Others expand because the client continues to place greater responsibility in the same hands. In this case, the growth of the partnership itself became the clearest proof of value.

This case shows how a well-executed regulatory engagement can evolve into a long-term operational partnership.





A Focused Engagement That Became a 10-Year Partnership

What began in 2016 as a focused engagement evolved into a long-term pharmacovigilance partnership. Since 2019, PharmaSoft has served as the client's PV department, supporting continuity, system migration, training management, and audit readiness in a complex multi-licensor environment.

Continuity

Less disruption despite internal personnel changes

Specialisation

Better alignment between systems and PV workflows

Consistency

A reliable model for ongoing audit and operational demands





**Complex processes
need the right partner.**

Let Us Take Care!



Pharmacovigilance



Regulatory Affairs



Digital Solutions



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