PharmaSoft

Let Us Take Care!

- DRUG SAFETY
- REGULATORY EXCELLENCE
- SMART TECHNOLOGY
- STRONG PARTNERSHIPS
- DATA DRIVEN INSIGHTS

Case Study #7

Building End-to-End Regulatory Support Since Day One

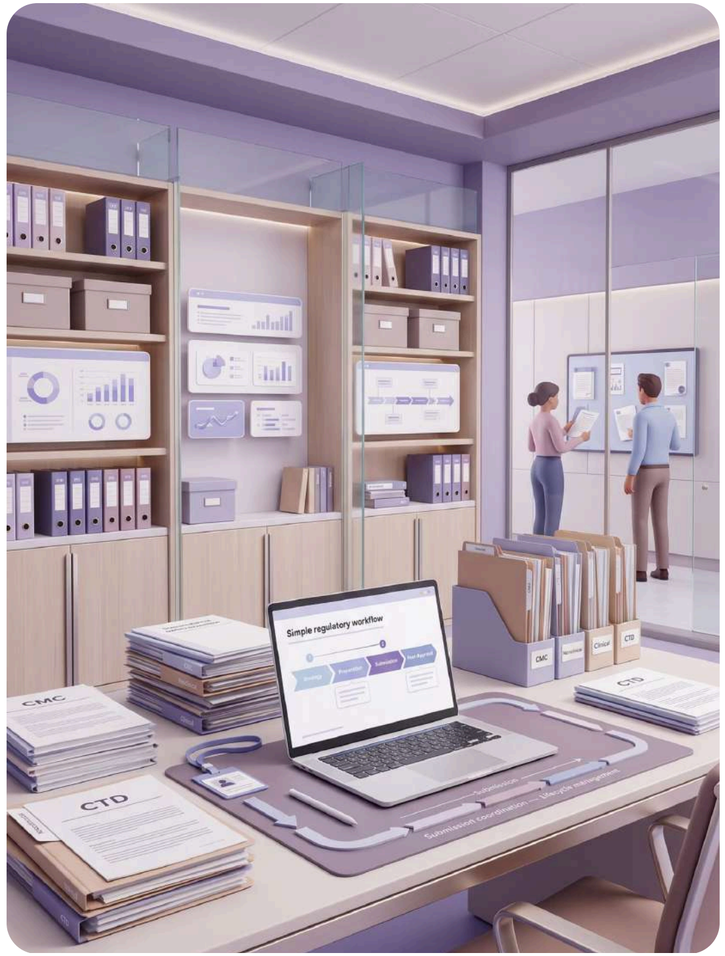
Smarter today, Safer tomorrow.

PharmaSoft

CASE STUDY REGULATORY AFFAIRS

Building End-to-End Regulatory Support Since Day One

From a single expert report to a full-service regulatory affairs model, PharmaSoft's journey in pharmaceutical regulatory support.

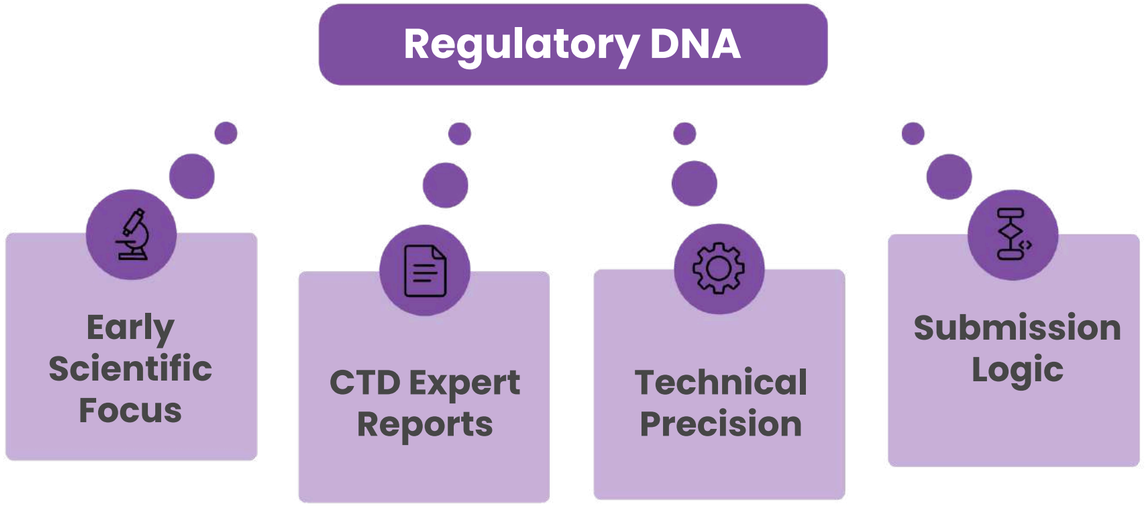


Foundation

Where It All Began

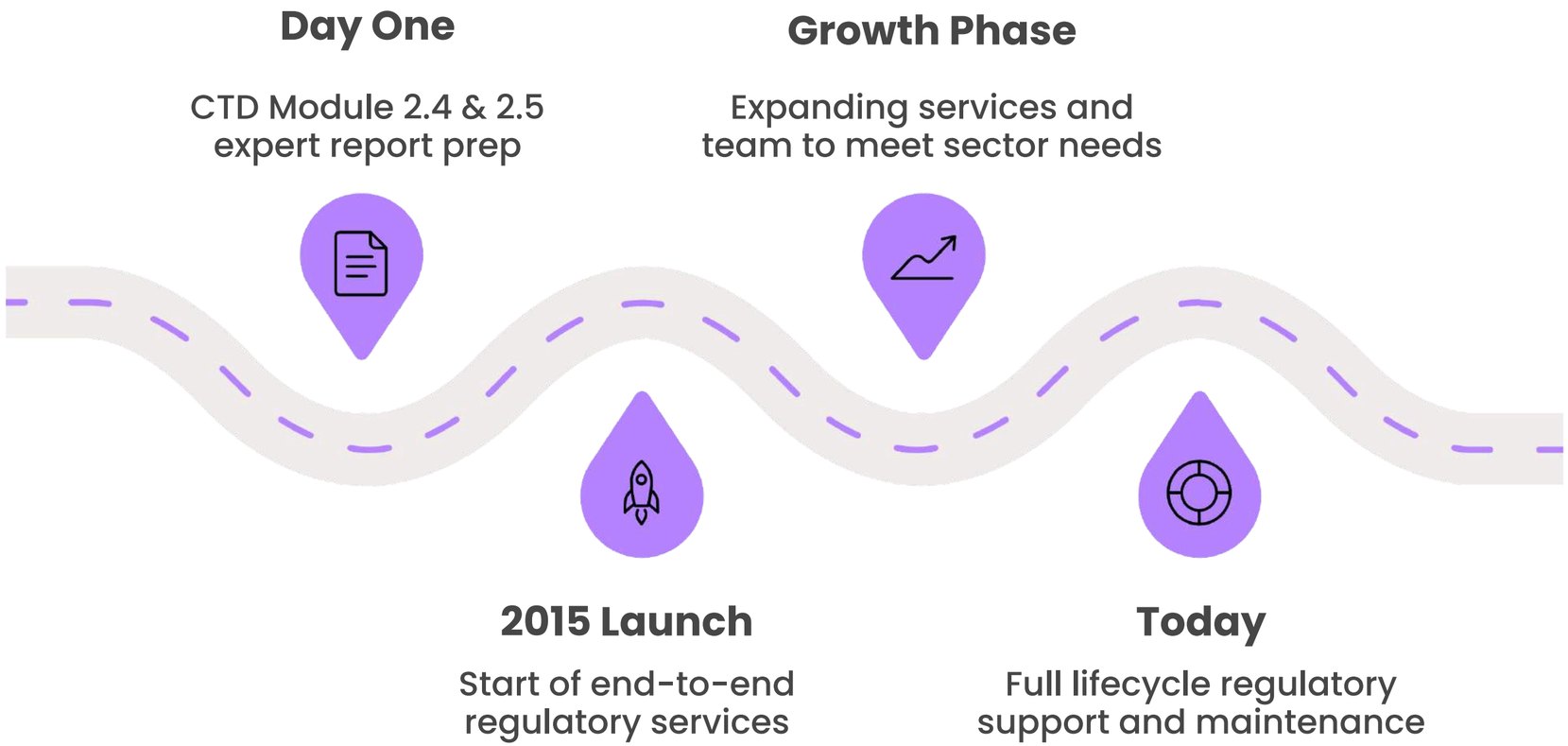
The **first invoice ever issued by PharmaSoft** was for the preparation of **CTD Module 2.4 and 2.5 Clinical and Non-Clinical Expert Reports,** a detail that speaks to the company's regulatory DNA from the very start.

Rather than treating regulatory affairs as a documentation task, PharmaSoft positioned it as a structured scientific function requiring technical precision, submission logic, and strategic alignment with lifecycle needs.



Evolution

A Decade of Expanding Capability



Since 2015, PharmaSoft has continuously evolved its regulatory model, expanding from specialist documentation into an integrated, lifecycle-spanning function.

Support Scope

Regulatory Services Across the Full Product Lifecycle

Dossier & Submission

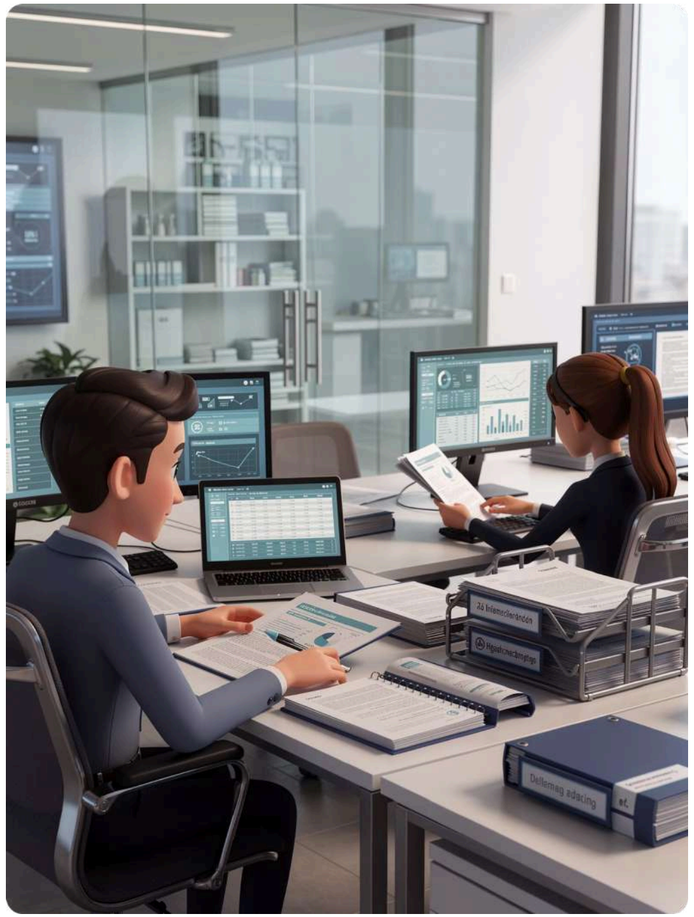
- Marketing authorisation application support
- End-to-end CTD dossier compilation
- Submission coordination
- CTD Modules 2.4 & 2.5 expert reports

Lifecycle Management

- Variation applications
- Renewal applications
- Post-approval maintenance
- Deficiency response support

Local & Operational

- New registration licensing support
- Artwork & packaging text review
- Regulatory document preparation
- Local regulatory coordination



Our Approach

What Makes the Difference

Regulatory success is not only about compiling documents. It demands **submission logic, technical consistency**, and **continuity** across the product lifecycle.

Scientific Rigour

Reports built on technical accuracy and clinical understanding

Integrated Model

Pre-submission to post-approval, managed under one function

Hands-On Support

Practical, responsive engagement valued by clients across markets

Sector Contribution

Investing in the Next Generation of Regulatory Talent

PharmaSoft extends its regulatory expertise beyond client services, actively contributing to **sector development** through structured **regulatory affairs training programmes**.

By developing new talent for the pharmaceutical industry, PharmaSoft transforms regulatory support into a platform for knowledge transfer, professional growth, and long-term industry impact.

Regulatory affairs at PharmaSoft is not only a service line, it is an active investment in the future of the sector.

Key Takeaway

From First Invoice to Full Lifecycle A Capability Built to Last

Since 2015

End-to-end regulatory affairs services delivered to pharmaceutical clients

Full Spectrum

Dossier preparation, submission, lifecycle management, and sector training

One Model

Scientific rigour and practical support integrated under a single growing function

PharmaSoft

Complex processes need the right partner.

Let Us Take Care!

Pharmacovigilance | Regulatory Affairs | Digital Solutions

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