



25 years



We are a leading consultancy and solutions provider of
regulatory and scientific services with offices in
Barcelona, Madrid, Pamplona, Munich and London



‘At Asphalion we contribute to improving people’s health by helping life sciences companies bring medicines and medical devices to patients in a smarter and more efficient way’

Núria Romero
Managing
Director

Mission

Our team’s mission is our passion: Working together with our clients in order to generate ideas and implement solutions that contribute to improving health in all our lives.

Vision

Our dream is to be a global reference and a driving force in the evolution of the healthcare sector, offering the best environment for the individual and collective growth of our team and clients.

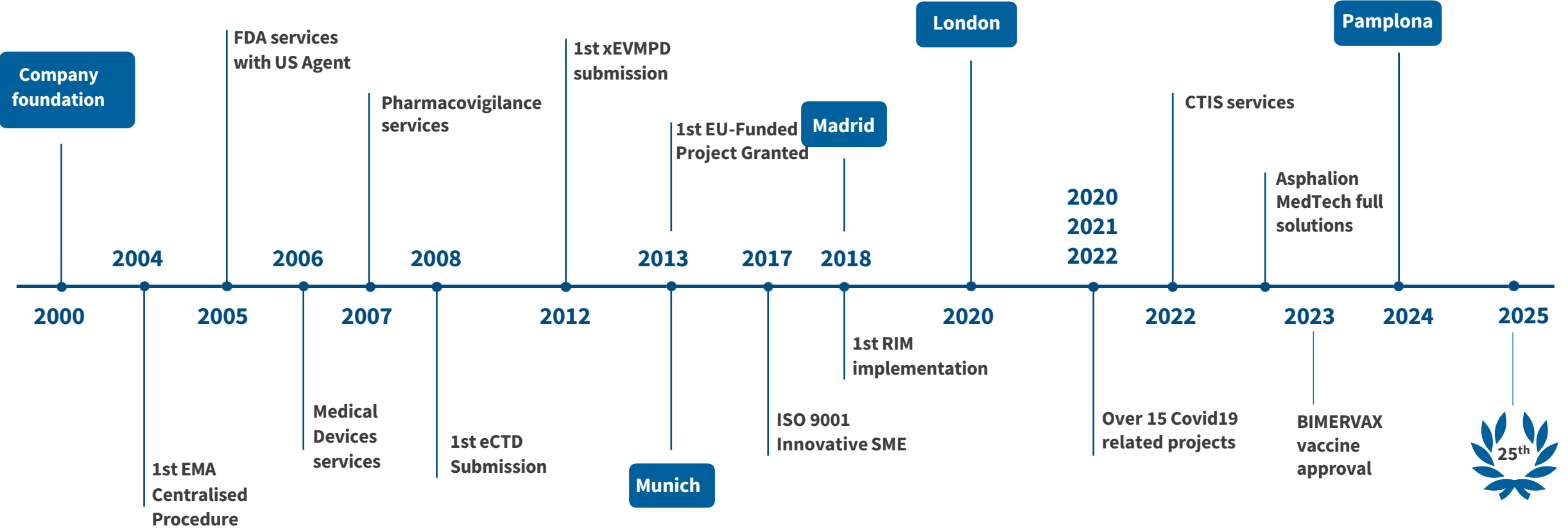
Values

Passion
Flexibility
Commitment
Quality
Companionship



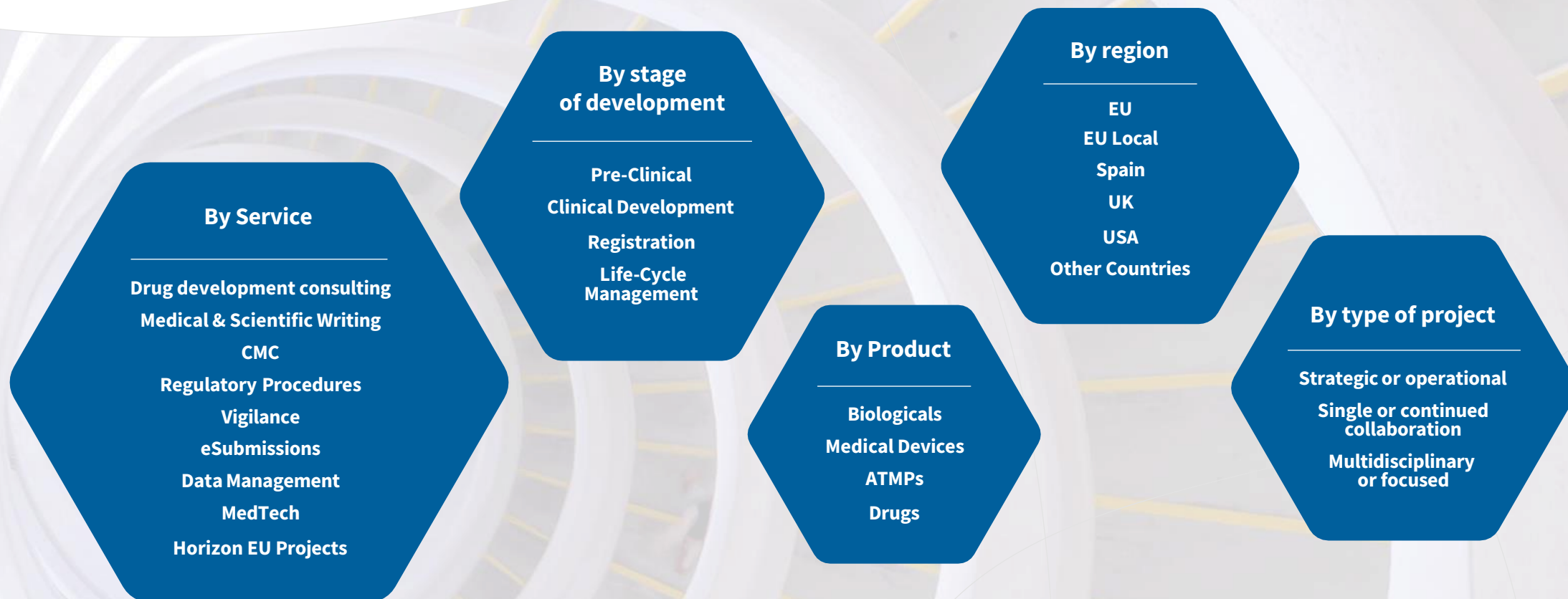
Our journey

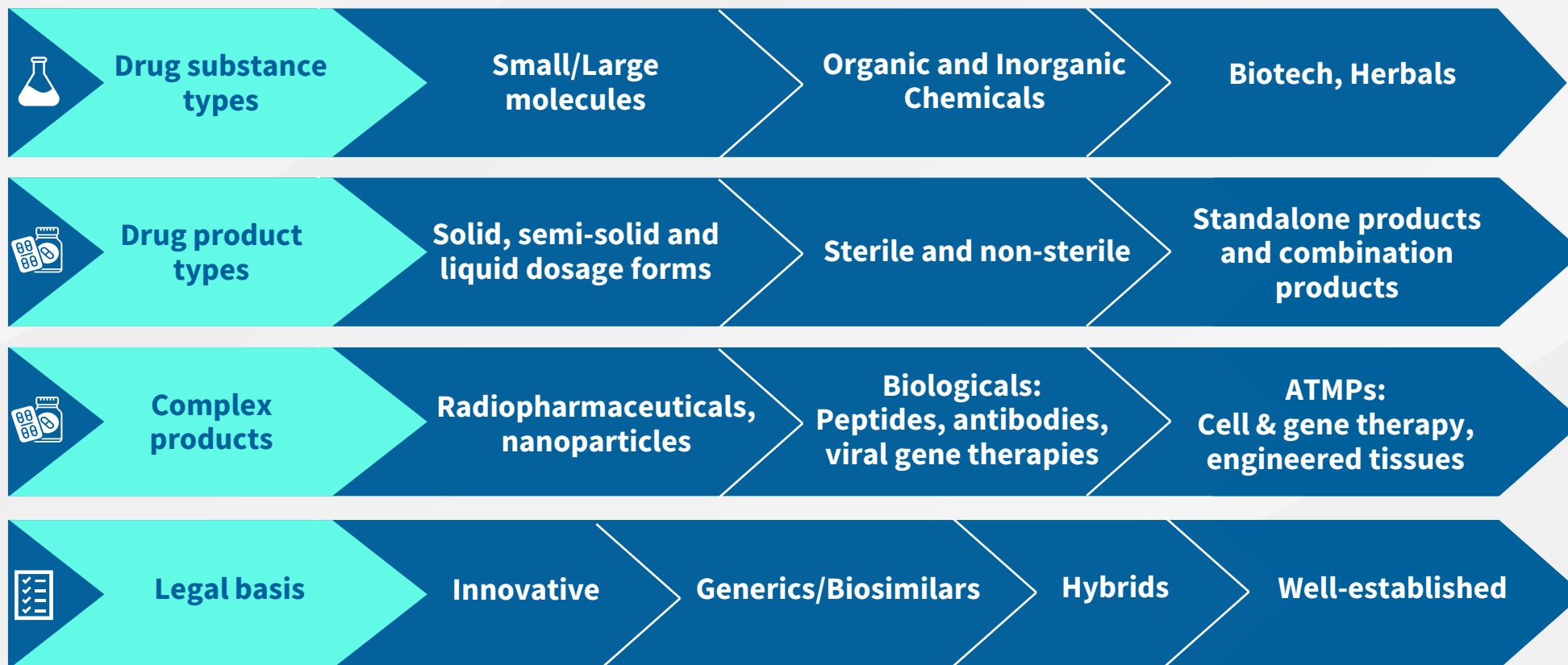
At the forefront delivering the best solutions,
continuously growing and expanding our services



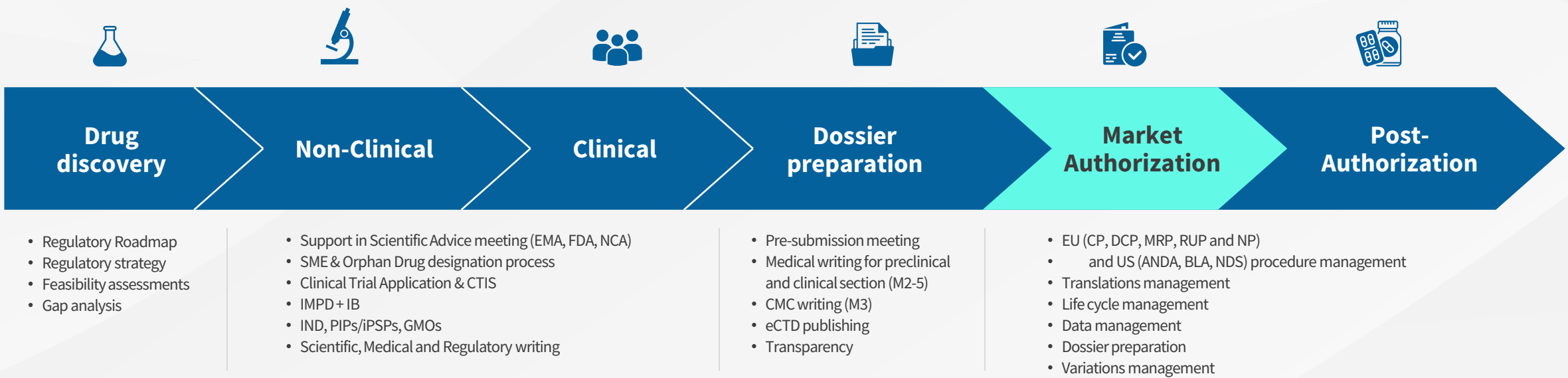
Our Solutions

Thanks to our wide scope of services we can offer you **tailored solutions** for all your regulatory and safety needs





Asphalion End to End support during product life-cycle



CMC and Medical Device

Gap Analysis | Feasibility Assessments | Strategic Consulting | Document writing during development | Document writing for registration and life-cycle

Experience

Continuous Improvement

Vision

Pharmacovigilance

Drug Safety for Clinical Trials | EU-QPPV, PSMF, RMP and PV agreements | Case management, safety reports

Regulatory Operations

xEVMPD:

- New MAs
- Variations
- Investigational products (IMP)

SPOR:

- SMS
- OMS Registrations
- QC Eudravigilance registrations

ISO IDMP compliance:

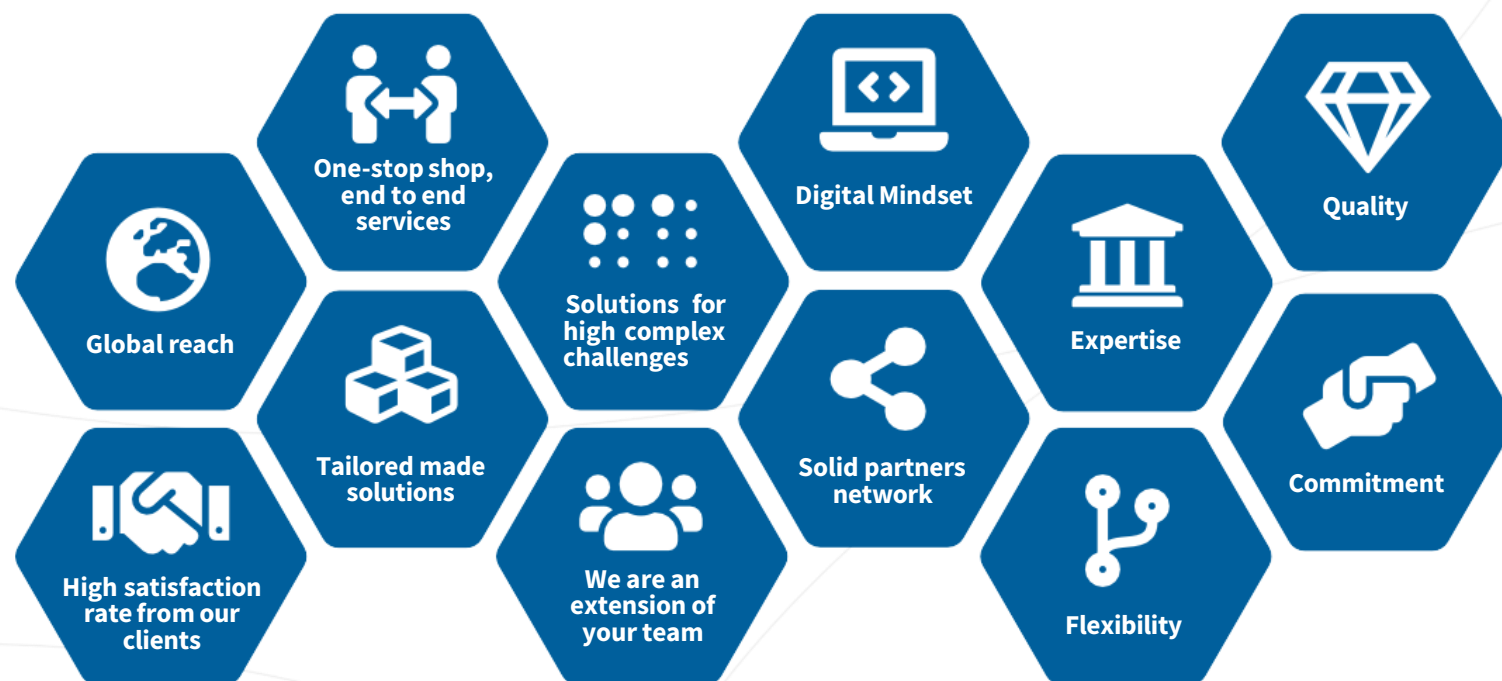
- Consulting and Strategy
- Data management
- IDMP readiness
- Regulatory intelligence

Implementation of:

- CTMS, RIMS, DMS, eCTDtools, etc.
- Overall Data Management: Preparation, Migration, Validation
- Active Regulatory Review

Why work with us

As a close, committed and **high added-value partner**, we contribute decisively to the success of your project



Testimonials

What clients say about
us...

I appreciate the fact of receiving **multidisciplinary** support in the regulatory and scientific field.

Regulatory Affairs Manager
European pharmaceutical company

Thank you very much for helping us complete the submission on time, taking into account that we always send you the documents at the last minute.

Your **flexibility and dedication** are always of great help in these critical moments.

Head of Regulatory Affairs
European biopharmaceutical company

It has been my privilege and pleasure to work with many executives and my experience with you has always been **excellent**.

Couldn't ask for more!

Technical Officer
Spanish pharmaceutical company

Impeccable the way you have handled this issue with so little time.

Spectacular **attitude and technique**.

Thank you!

CEO
European Medical Devices company

Contact

In case you are interested in our services,
please contact us for more information!

Barcelona

C/Tarragona, 151-157
08014 Barcelona, Spain
T +34 93 238 59 45
info@asphalion.com

Madrid

Golfo de Salónica, 27 6º A
28033 Madrid, Spain
T +34 917 90 20 00
madrid@asphalion.com

Munich

Leopoldstrasse, 244
80807 München, Germany T
+49 (0)89 208 039 280
munich@asphalion.com

London

19The Circle, Queen Elizabeth St.
London, SE1 2JE, UK
T +442033141698
london@asphalion.com

Pamplona

MISO Centro- C/ Julián Arteaga, 3
31002 Pamplona
T +34 848 488 900
pamplona@asphalion.com

Memberships & Partnerships



Certificates



ISO 9001:2015



ISO 13485:2016





info@asphalion.com
www.asphalion.com