

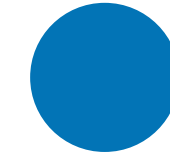


Looking forward to serving you!



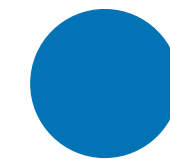
About Us

Medipha is a service provider for pharmaceutical companies founded in 2004.



Versatile and tailor -made services

We support our partners throughout the entire product lifecycle: from registration to commercialization, with a comprehensive portfolio of expertise.



Member of Athena pharmaceutiques group

Since June 2025, Medipha Santé has been part of the Athena Pharmaceutiques Group, strengthening our international footprint and expanding our operational capabilities

Our Services

For over 20 years, Medipha Santé has been a recognized partner, offering expertise in Regulatory Affairs, Pharmacovigilance, Quality Assurance, and Exploitation.



Regulatory Affairs

Medipha provides end-to-end regulatory support, including:

- Marketing Authorization submissions and updates
- Regulatory Affairs strategy
- eCTD publishing and management of electronic submissions
- Review of promotional materials.
- Dossier audits
- FR/EN translations and national phase support
- Access to a strong international regulatory network.



Pharmacovigilance

Our PV department ensures robust safety monitoring and full regulatory compliance through:

- EU-QPPV services
- Local PV support across multiple markets.
- Systematic literature monitoring for early detection of safety signals
- ICSR management, from collection to regulatory submission
- Preparation of PSURs and RMPs
- PV training sessions tailored for teams and partners.
- PV audits

Our Services



Quality Assurance

We strengthen Quality Systems and ensure market compliance through:

- Batch release and certification performed under strict regulatory oversight.
- Continuous improvement of Quality Systems
- Internal and external audits
- Quality risk management to proactively identify and mitigate potential issues.



Commercialization & Business Development

Our BD team supports commercial growth and market entry strategies through:

- Market penetration strategies
- Launch planning and execution to ensure efficient market introduction.
- Product referencing activities with key stakeholders and partners.
- Coordination of importation and distribution to secure product availability.

The “Exploitant” Service

Since 2016, Medipha Santé has acted as an exploitant in France, marketing medicines on behalf of European Marketing Authorization Holders and ensuring their availability for patients. As exploitant, we take responsibility for all local activities required for the safe and compliant commercialization of medicinal products.

Our responsibilities include:

- Pharmacovigilance (local PV system, safety reporting)
- Local regulatory activities and compliance
- Tender management for hospital and institutional markets
- Medical information for healthcare professionals and patients
- Batch follow-up and product recalls
- Product storage and distribution in accordance with GDP
- Invoicing and administrative management
- Audits of partners, systems, and processes

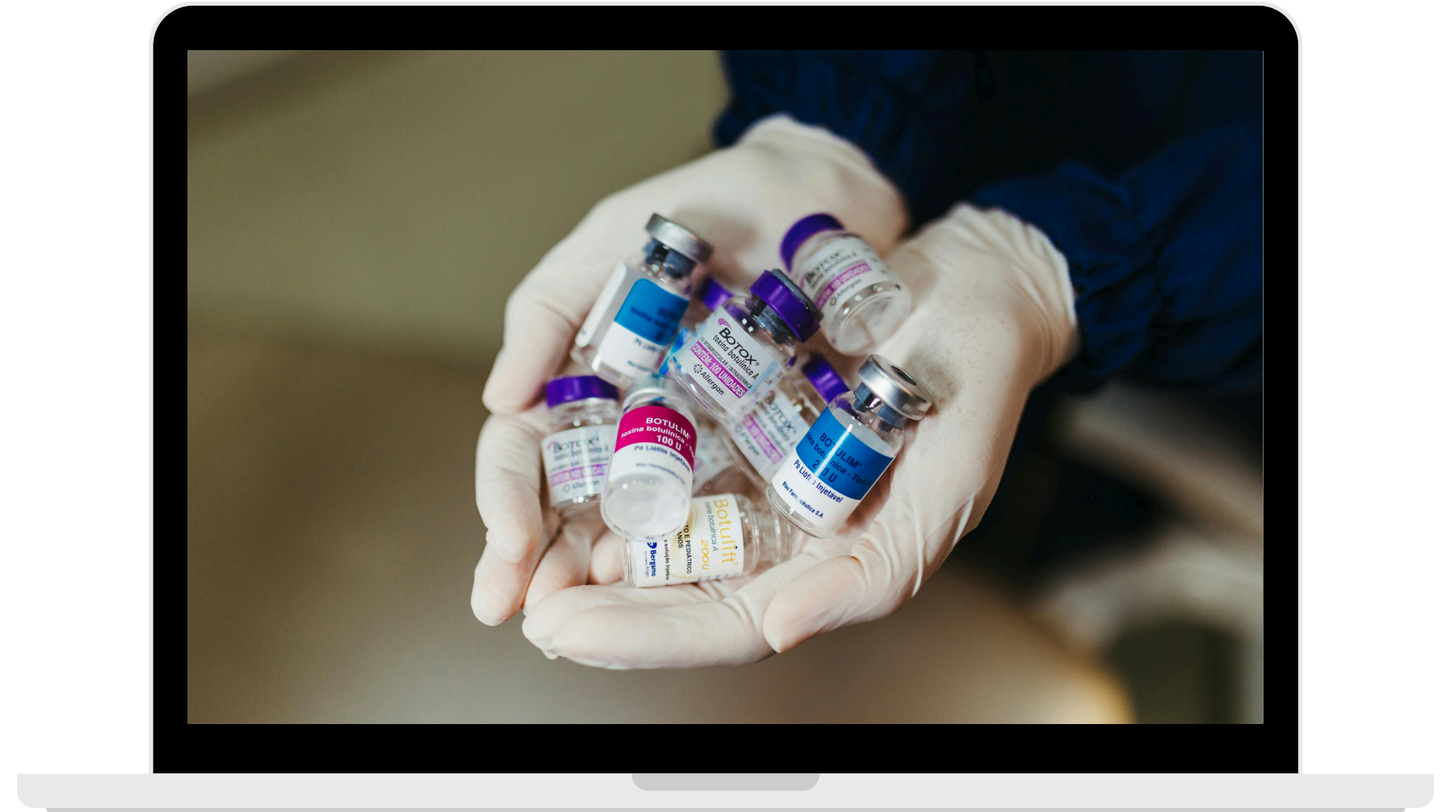
Our Portfolio

As exploitant, Medipha Santé manages and markets a broad portfolio of medicinal products across both the retail and hospital markets. Our experience covers a wide variety of product types and regulatory specificities:

- + Products under compassionate use (AAC, CPC)
- + Cold-chain products
- + Narcotic and controlled substances
- + Innovative medicines and generic

Compliance & certifications

- ✓ Regularly inspected by the ANSM
- ✓ Frequently audited by clients and partners
- ✓ Holder of GDP and GMP certificates
- ✓ HAS-certified for the promotion of medicinal products



Medipha Team



CEO
Alexandre Williams



CCO
Luc Lamirault



GM & CPO & EUQPPV
Kévin Bondiguel



CFO
Valérie Bennis



RA DIRECTOR
Maxime Chauveau



**QUALITY ASSURANCE
DIRECTOR**
Clémence Brault



R&D DIRECTOR
Claire Reymann



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Thank You!



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