
LOOKING
forward
to serving
YOU

Company Milestones

Looking forward to serving you

2004

Creation of the company

Regulatory Affairs
Exploitant status
WDA
Distribution
Market Access

2008 2015

Eudracon Member

+350 MAs / Year

Batch releaser/Import License

GMP/GDP

2016

Launch of our 1st Early Access Product

KOLBAM

Partnership

Retrophin

Chemineau

2017 2018

New medicine launches

Partnerships

Clinigen

Kalceks

STD Pharmaceuticals

2019 2020

Partnerships

Altan

InfectoPharm

Tilray

Camurus

Pharma SGP

MaaT

Company Milestones

Looking forward to serving you

2021

Participation in French cannabis experimentation and MaaT013 EAP in France

Partnerships

- Sedana
- Agepha
- Pierrel

2023

Partnerships

- Tillomed
- Gensight
- Cipla
- Waymade

2024

Medipha Santé celebrates its 20th anniversary

Partnerships

- MSN Vivanta

Market access knowledge in special products

- Cold chain
- Narcotics
- Experimental drugs
- Orphan drug
- Hospital & retail

EUDRACON

GEMME générique, même médicament

TARIUS an IQVIA company

“Exploitant” and distribution

Looking forward to serving you

“Exploitant” is a company or organization responsible for the “exploitation”, i.e. commercialisation of the product in French market.

The “exploitation” activities include but are not limited to:

- Pharmacovigilance
- Information
- Batch follow-up
- Batch recall if required
- Advertising
- Wholesale and distribution of operated products
- Importation operations
- Product storage operations

Expertise & services

Looking forward to serving you

From Market Analysis, to MA Submission, all the way until launching your Product and invoicing the delivered clients, we are at your side for tailormade solutions!

Our achievements

Looking forward to serving you

Our network

Looking forward to serving you

EUDRACON

French representative of European consultant's network specialized in regulatory affairs.

GEMME

French Union of the generic companies.

TARIUS
an IQVIA company

Global regulatory intelligence and compliance for human drugs, biologics, medical devices, IVDs.

Medipha Santé core offerings

Looking forward to serving you

01

Regulatory affairs

02

Pharmaco-vigilance

03

Quality assurance

04

Exploitation

01

Regulatory affairs

Our expertise: the warranty to your RA

Looking forward to serving you

Marketing authorization & post-marketing authorization maintenance (variation, renewal, sunset clause…) & market access

RA advices, expertise and submissions according to regulation of target country

Evaluation, creation, redaction and regular update of dossier according to regulations' evolution

Meeting with national Competent Authorities – communication and update of dossier for RtQ

Our expertise: the warranty to your RA

Looking forward to serving you

Marketing authorization & post-marketing authorization maintenance (variation, renewal, sunset clause…) & market access

RA advices, expertise and submissions according to regulation of target country

ALL TYPES OF PROCEDURES

National procedure
DCP/MRP/RUP/CP
WHO
FDA
UEMOA
…

Evaluation, creation, redaction and regular update of dossier according to regulations' evolution

Meeting with national Competent Authorities – communication and update of dossier for RtQ

Our expertise: the warranty to your RA

Looking forward to serving you

Marketing authorization & post-marketing authorization maintenance (variation, renewal, sunset clause…) & market access

RA advices, expertise and submissions according to regulation of target country

ALL TYPES OF PROCEDURES

National procedure
DCP/MRP/RUP/CP
WHO
FDA
UEMOA
…

Evaluation, creation, redaction and regular update of dossier according to regulations' evolution

ALL TYPES OF DOSSIERS

Generic, hybrid, WEU, full dossiers
compassionate use (and other FR derogation access programs)
ASMF/DMF/CEP
IMPD/CTA
…

Meeting with national Competent Authorities – communication and update of dossier for RtQ

Our expertise: the warranty to your RA

Looking forward to serving you

Marketing authorization & post-marketing authorization maintenance (variation, renewal, sunset clause…) & market access

RA advices, expertise and submissions according to regulation of target country

ALL TYPES OF PROCEDURES

National procedure
DCP/MRP/RUP/CP
WHO
FDA
UEMOA
…

Evaluation, creation, redaction and regular update of dossier according to regulations' evolution

ALL TYPES OF DOSSIERS

Generic, hybrid, WEU, full dossiers
compassionate use (and other FR derogation access programs)
ASMF/DMF/CEP
IMPD/CTA
…

Meeting with national Competent Authorities – communication and update of dossier for RtQ

ALL TYPES OF SUBMISSIONS

Publishing eCTD/NeeS
All types of applications / all regions & countries: EU eCTD/US/GCC/CA/JP/HR, Baselines, initial application, amendment, RtQ, variations
…

Regulatory Affairs Services

Looking forward to serving you

Marketing Authorization applications (CP, DCP, MRP, FDA, WHO, National) human and veterinary use

Post-marketing authorization maintenance (variations IA, IB, II, art. 61(3), renewals, sunset clause...)

Publishing / Management eCTD, NeeS (all types of application / all regions & countries)

Compilation, Redaction of dossier (AMM Module M2, M3, CEP, ASMF, IMPD, etc.)

Regulatory strategy council

ICH compliance (Q3D Nitrosamines investigation report, Q1A shortage management plan...)

Pricing and reimbursement leading to Market Access

Translation (FR/EN, full dossier, national Phase, technical documentation)

Audit of dossier (M2 to M5)

Readability tests managment, mock-up production

Active substance (CEP, ASMF/DMF) submission and follow up

Review of promotional materials

Medical device

Clinical Trial Application management

Trainings (eCTD, NeeS...)

Outside EU (expertise i.e. African regulations, export, CPP...)

02

Pharmaco-vigilance

Medipha santé

Pharmacovigilance

Looking forward to serving you

Pre-Marketing Activities / Post-Marketing Activities / Early-Access Programs

- Global PV services provider
- Local PV services provider
- Ad hoc PV services provider

Pharmacovigilance

Looking forward to serving you

Pre-Marketing Activities / Post-Marketing Activities / Early-Access Programs

Global PV services provider

EU-QPPV
ICSR
PSUR/PBRER
RMP
Signal detection
International literature review
Auditing
Training

Local PV services provider

Ad hoc PV services provider

Pharmacovigilance

Looking forward to serving you

Pre-Marketing Activities / Post-Marketing Activities / Early-Access Programs

Global PV services provider

EU-QPPV
ICSR (electronic database)
PSUR/PBRER
RMP
Signal detection
International literature review
Auditing
Training

Local PV services provider

Compliance with French GVPs
LPVRP
Local literature monitoring
Local signal detection
Coordination with EU-QPPV
Local electronic database

Ad hoc PV services provider

Pharmacovigilance

Looking forward to serving you

Pre-Marketing Activities / Post-Marketing Activities / Early-Access Programs

Global PV services provider

EU-QPPV
ICSR (electronic database)
PSUR/PBRER
RMP
Signal detection
International literature review
XevmpD
PSMF

Local PV services provider

Compliance with French GVPs
LPVRP
Local literature monitoring
Local signal detection
Coordination with EU-QPPV
Local electronic database
Local PSMF

Ad hoc PV services provider

Auditing
Training
Quality documents management (SOPs, Instructions, Forms...)
Monitoring of the local legislation

Pharmacovigilance

Looking forward to serving you

- EU-QPPV / LPVRP & Deputy provision ⇔ PV assistance 24/7
- EudraVigilance registration and users' profile management
- xEVMPD maintenance
- PSMF writing and maintenance
- ICSR management (validated electronic PV database) including MedDRA coding, imputability, submission to EudraVigilance
- PSUR/PBRER management
- Survey management
- RMP management
- Signal detection activities management
- International and local literature review
- Quality documents management (SOPs, Instructions, Forms...)
- PV agreements management
- Reconciliations processes management
- Monitoring of the legislation management
- Auditing
- Training

03

Quality assurance

Quality Assurance

Quality Assurance Activities

Quality system:
documentation, quality topics...

Batch Management:
batch release/certification...

Quality service:
agreement, audit...

Quality Assurance

Looking forward to serving you

Quality Assurance Activities

Quality system:
documentation, quality topics...

Quality Document Management (SOP, Qualification/validation...)

Quality Topics Management (Complaints, Change Controls , Deviations CAPAs, Training, Product Quality Review, Risk analysis, Audits...)

Quality System Improvement (Quality Indicator, Quality meeting)

Development of the Quality System to comply with the French/EU Pharmaceutical regulation (Authorities communication...)

Batch Management:
batch release/certification...

Quality service:
agreement, audit...

Quality Assurance

Looking forward to serving you

Quality Assurance Activities

Quality system:
documentation, quality topics...

- Quality Document Management (SOP, Qualification/validation...)
- Quality Topics Management (Complaints, Change Controls , Deviations CAPAs, Training, Product Quality Review, Risk analysis, Audits...)
- Quality System Improvement (Quality Indicator, Quality meeting)
- Development of the Quality System to comply with the French/EU Pharmaceutical regulation (Authorities communication...)

Batch Management:
batch release/certification...

- Batch Review, Batch Release, Batch Certification, Batch Traceability
- Batch Recall Management
- Importation Activities
- Products of Major Therapeutic Interest Management (SMP)
- Artwork Management

Quality service:
agreement, audit...

Quality Assurance

Looking forward to serving you

Quality Assurance Activities

Quality system:
documentation, quality topics...

Quality Document Management (SOP, Qualification/validation...)

Quality Topics Management (Complaints, Change Controls , Deviations CAPAs, Training, Product Quality Review, Risk analysis, Audits...)

Quality System Improvement (Quality Indicator, Quality meeting)

Development of the Quality System to comply with the French/EU Pharmaceutical regulation (Authorities communication...)

Batch Management:
batch release/certification...

Batch Review, Batch Release, Batch Certification, Batch Traceability

Batch Recall Management

Importation Activities

Products of Major Therapeutic Interest Management (SMP)

Artwork Management

Quality service:
agreement, audit...

Agreements Management with partners (subcontractors, suppliers, manufacturers, distributors...)

Contact with partners on a Quality Assurance point of view

Development of Quality Assurance services deliveries activities for Medipha Santé

Management of external audit

Quality Assurance

Looking forward to serving you

Quality Documentation Management

Training Management

Quality Topics Management
- Complaints Management
- Change Controls Management
- Deviations Management
- CAPAs, Management

Quality System Improvement
(Quality Indicator, Quality meeting)

Development of the quality system to comply with the French/EU Pharmaceutical regulation
(Authorities communication)

Quality Risk Management

Product Quality Review Management

Batch Release / Batch Certification

Batch Recall Management

Importation Activities

Products of Major Therapeutic Interest Management

Artwork Management

Internal / External Audit Management

Development of Quality Assurance Services

Quality Assurance Agreement Management

04

Exploitation

Commercialization

Looking forward to serving you

Pre-launch studies, launch plans, referencing, distribution, invoicing

Market Access: pre-launch market analysis, competitive review, pricing, presentations...

Distribution: batch release, storage, shipping, invoicing

Referencing: public tender responses / Private hospitals negotiation & referencing...

Commercialization

Looking forward to serving you

Pre-launch studies, launch plans, referencing, distribution, invoicing

Market Access: pre-launch market analysis, competitive review, pricing, presentations...

MARKET ACCESS

Pre-launch market analysis, competitive review, price and sales strategy definition, launch plans with wholesalers, market penetration strategy definition

Distribution: batch release, storage, shipping, invoicing

Referencing: public tender responses / Private hospitals negotiation & referencing...

Commercialization

Looking forward to serving you

Pre-launch studies, launch plans, referencing, distribution, invoicing

Market Access: pre-launch market analysis, competitive review, pricing, presentations...

Distribution: batch release, storage, shipping, invoicing

Referencing: public tender responses / Private hospitals negotiation & referencing...

MARKET ACCESS

Pre-launch market analysis, competitive review, price and sales strategy definition, launch plans with wholesalers, market penetration strategy definition

DISTRIBUTION

Importation operations, batch release, supply & TA with pre-wholesaler, storage, order management and shipping, invoicing, GDP knowledge, batch recall if required

Commercialization

Looking forward to serving you

Pre-launch studies, launch plans, referencing, distribution, invoicing

Market Access: pre-launch market analysis, competitive review, pricing, presentations...

MARKET ACCESS

Pre-launch market analysis, competitive review, price and sales strategy definition, launch plans with wholesalers, market penetration strategy definition

Distribution: batch release, storage, shipping, invoicing

DISTRIBUTION

Importation operations, batch release, supply & TA with pre-wholesaler, storage, order management and shipping, invoicing, GDP knowledge, batch recall if required

Referencing: public tender responses / Private hospitals negotiation & referencing...

REFERENCING

Mapping of public tenders & private sector, public tender responses, private referencing negociations, buyer KOL management & development

MA Hosting, market access and product launch

Looking forward to serving you

- Evaluation and assessment of your needs
- In-licensing & out-licensing of the product portfolio, optimization of authorized activities
- Market access strategies
- Seeking business and partnership opportunities, e.g., helping manufacturers find distributors and vice-versa
- Specialized professional advice, for example on registration and MA (Marketing Authorization) dossiers
- Support for the development of your activities or product portfolios
- Search for potential license holders for customers' own products
- Project management
- Drafting of various contracts (for the provision of services, licensing and delivery, mandates...)
- Contract negotiation
- Drafting offers
- Search of active substance sources
- Prices and Sales strategy
- Market Access
- Launch, Preparation and Co-ordination
- Promotion
- Supply and TA with pre-wholesaler
- GDP knowledge

Product list

Looking forward to serving you

Pantoprazole

Milrinone

Foscarnet

Caspofungine

Pentamidine

Meropenem

HOSPITAL

Levosimendan

Piperacilline/Tazobactam

Sugammadex

Acide Carglumique

Esomeprazole

Lacosamide

Bicnu

Busulfan

Clofarabine

Melphalan

Treprostinil

Cidofovir

Azacitidine

Product list

Looking forward to serving you

RETAIL

Paracetamol

Fibrovein

Sevelamer Chlorhydrate

Bexarotene

RETAIL

Aciclovir

Ciloxadex

Trientine

Zindacline

SPECIAL PRODUCTS

Maat13

Buvidal

Lumevoq

Orabloc

Ubistesin

Agency and broker activities

Looking forward to serving you

- In-licensing & out-licensing of product portfolio, leveraging authorized business.
- Locate products for in-licensing according to client’s specified requirements.
- Identify potential licensees for clients' own products.
- Wide & attractive product list.

About us

Looking forward to serving you

Medipha Santé, **“exploitant”** and importer, was set-up in 2004 and as a French pharmaceutical company, offers you a wide range of health-related services (medicinal products for human use and medical devices).

For 20 years, Medipha Santé has served more than sixty customers worldwide and has submitted around 400 MA dossiers per year to the European competent authorities (ANSM, EMA...) and markets, for third persons, around thirty proprietary medicinal products in France (pharmacies and hospitals).

Due to our experience, status and structure, we are able to provide you with swift and confidential expertise and assistance!


LOOKING
forward
to serving
YOU
Medipha
santé