Maxia STRATEGIES

# ACCELERATE INNOVATION
# CREATE POSSIBILITIES

## REGULATORY AFFAIRS
## PRODUCT DEVELOPMENT STRATEGIES
## LIFE CYCLE MANAGEMENT

BIOTECH PHARMA MEDICAL DEVICE

# ABOUT MAXIA STRATEGIES

## FUTURE-PROOF YOUR STRATEGY WITH THOROUGH INTERROGATION AND PURSUIT OF POSSIBILITIES

At Maxia Strategies we integrate your business demands with health authority expectations. As regulatory professionals we apply our knowledge and experience to transform innovative ideas into commercially successful products.

Regulatory considerations heavily impact business strategies. From start-up throughout development and marketing, a strong regulatory partner is critical to success.

Maxia Strategies' creative solutions and record of success accelerate the translation of your concepts into products.


### COLLABORATION AND PARTNERSHIP

Based in Europe, Maxia Strategies maintains a global perspective through its own affiliates and its extensive collaborative network.

Maxia Strategies continuously monitors global regulatory trends to balance the diverse requirements and ensure successful registration and product launch.

# ADDRESSING YOUR NEEDS BEFORE THEY ARISE

## BUILDING A SOLID FOUNDATION TOGETHER TO MASTER THE CHALLENGES OF DRUG DEVELOPMENT

### KICK-OFF

- Define development strategies and explore different approaches.
- Lay out timelines and resource requirements to support the business plan.
- Special terms for Start-ups.

### EXPLORATION

- Perform due diligence assessments and gap analyses for in/out-licensing.
- Develop creative solutions and assess probabilities of regulatory success.
- Advise on regulatory trends and potential for accelerated development.

### FOUNDATION

- Identify and manage risks through comprehensive regulatory assessments.
- Create key messages and collate supporting evidence.
- Establish efficient and flexible data and document management policies.

### EXECUTION

- Advise on suppliers to meet time and cost constraints.
- Provide project management support to synchronise activities and maintain momentum.
- Drive the process to ensure continuous value creation.

### AREA OF EXPERTISE

Neurology
Oncology
Virology
Antibiotics
Psychiatry
Inflammation
Small Molecules
Biologics
Medical Devices
Drug-Device combinations

| DISCOVERY/RESEARCH | EARLY DEVELOPMENT |
|---|---|
| Development Strategy | IND/CTA Submissions |
| Document Management Systems | Quality Management Systems |
| In-licensing Due Diligence | IB/IMPD Development |

# EXPANDING CAPABILITIES CREATING SYNERGIES

## COMBINING YOUR TEAM'S KNOWLEDGE WITH OUR EXPERTISE TO DRIVE FORWARD DEVELOPMENT

### STRATEGIC DEVELOPMENT

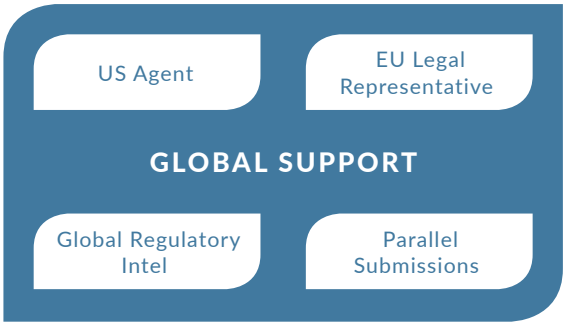
- Define optimal development strategies to balance risk.
- Exploit emerging trends to provide the best regulatory approach along the entire development pathway.
- Execute the strategies to support the product's quality, safety, and efficacy.
- Create decision matrices to facilitate analysis and ensure selection of optimal solutions.

### FUNCTIONAL EXPERTISE

- Identify risks early and frontload solutions.
- Establish Regulator buy-in to ensure first cycle success.
- Collaborate effectively with all stakeholders to maximise coordination and minimise surprises.

### OPERATIONAL EXCELLENCE

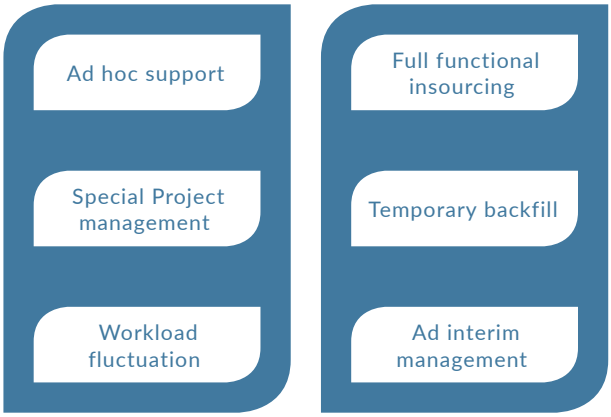
- Integrated document preparation across all functions.
- Seamless and synchronized regulatory support, in parallel with data creation, to reduce regulatory-related delays.
- High quality dossier management to accelerate submission timelines.




| FULL DEVELOPMENT | REGISTRATION / APPROVAL |
|---|---|
| PIP/PSP Development | Dossier Coordination |
| Scientific Advice | Review Management |
| Out-licensing Support | Label Negotiations |

# STRENGTHENING YOUR REGULATORY TEAM

## HIGH QUALITY REGULATORY SERVICES TO FOSTER CROSS-FUNCTIONAL COLLABORATION AND SUSTAIN OPERATIONAL EXCELLENCE




### YOUR OUTSOURCED REGULATORY AFFAIRS DEPARTMENT
### YOUR IN-HOUSE REGULATORY LEAD

- Obtain and maintain Marketing Authorisations.
- Manage all product and project related activities.
- Ensure effective cross-functional integration.

### REGULATORY MAINTENANCE

- Commitment management
- OTC switch
- Portfolio streamlining

### HEALTH AUTHORITY INTERACTION

- Swissmedic
- EMA
- FDA
- EU National authorities
- PMDA

| COMMERCIALISATION | LIFECYCLE MANAGEMENT |
|---|---|
| Pricing and Reimbursement | Line Extensions / New Indications |
| Promotional Material | Variations |
| Launch | Pharmacovigilance |

# WHY MAXIA STRATEGIES

- Creative
- Collaborative
- Knowledgeable
- Operational Excellence
- Trustworthy
- Flexible
- Experienced

GRIPs – Using our proprietary Global Regulatory Innovation Procedures, we ensure all operational aspects are performed as efficiently as possible, and designed from the beginning to support global utilisation.

## PEOPLE AT MAXIA STRATEGIES

**«Rules exist for reasons, but the Reasons are more important than the Rules.»**

As regulations and technology become increasingly complex, it is more important than ever to maintain balance between both and never lose sight of the ultimate goal of bringing safe and effective medicines to patients in need.

*Founder and MD Karl Burgin, PhD*

**«Our solutions are tailor-made, based on out-of-the-box thinking supported by know-how and great Maxia team spirit.»**

Understanding the ‹Why› behind a legislation is important. Working with customers, it is just as important to understand their individual needs first before working on solutions which align with the Regulations. This is my challenge and my promise.

*Senior Consultant Eva Bleul, DVM*

**«I believe team spirit is the core to a successful business.»**

By each person contributing their expertise, success is ensured.

*Operations Director Deborah Burgin*

**«From bench to bedside, from molecule to medicine, the lifecycle of drug development requires regulatory decision making at every step.»**

With knowledge and personality, we ensure the success of our client's products from early development to marketing authorisation and beyond.

*Consultant Marian Rösinger, PhD*

**«Coming together is the beginning. Keeping together is progress. Working together is success.»**

When we begin together with the same vision and mutual commitment, we create the path that leads us to share success.

*Office Manager Naer Rodatz, MBA*

# STORIES OF MAXIA STRATEGIES:

### GERMAN START-UP

**«[We] engaged Maxia Strategies to support the creation of the development strategy for our lead compound in preparation for a Series A funding round. Preparations are now underway for an accelerated development program. This repurposing exercise has created exciting opportunities for developing creative solutions to bring new life to an older product.»**

Creative and focused – Aligning older data with current expectations requires creativity and a keen attention to detail, applying real-world data in new and interesting ways.

### AUSTRALIAN START-UP

**«Maxia Strategies has been instrumental in implementing our clinical development program and managing our regulatory and quality management infrastructure. As an almost exclusively virtual organisation, we have benefitted greatly from Maxia Strategies' global perspective and flexible efficiency.»**

Flexible and Efficient – Maxia Strategies supported the expansion of the clinical program from Australia into Europe and US, ensuring regulatory and quality compliance, with minimal overhead, cost and bureaucracy.

### SWISS BIOTECH

**«Maxia Strategies has played a pivotal role in our success. They designed the regulatory development strategy for [our lead compound], obtained orphan designation in both EU and US and coordinated EMA scientific advice and FDA Type C feedback. Subsequently, Maxia Strategies provided regulatory support during due diligence activities for [our expanding portfolio] and designed the Regulatory infrastructure needed to stand-up our own regulatory department.»**

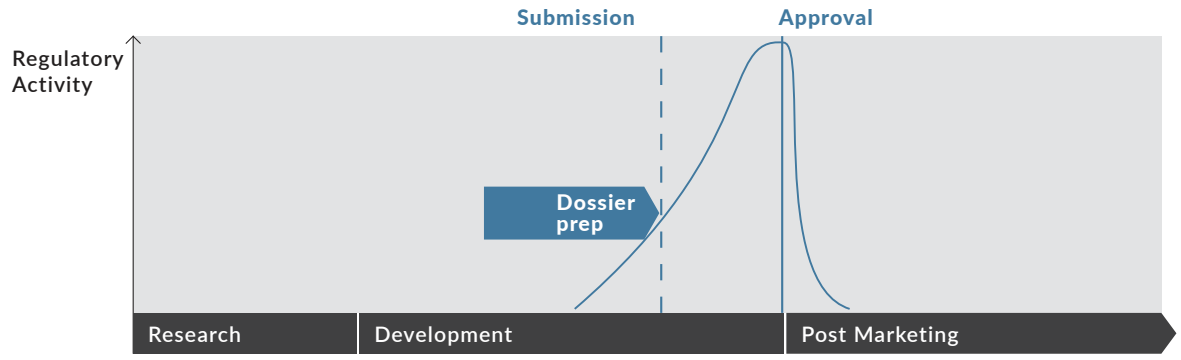
Stable and Dependable – long term partnerships provide the opportunity for flexible yet continuous support. Maxia Strategies provides optimal support and adjusts to meet our client's evolving needs, when and where they need it.

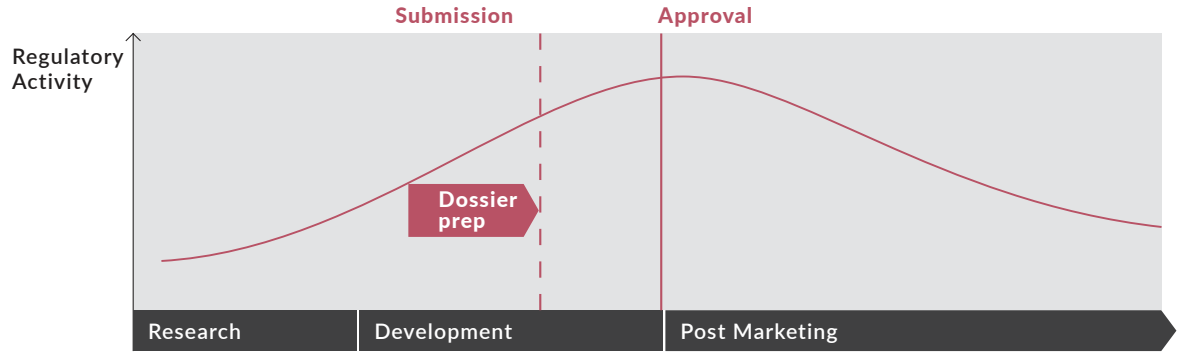
### GERMAN MEDICAL DEVICE MANUFACTURER

**«Ich möchte mich an dieser Stelle auch nochmal ganz herzlich für die wieder sehr gute, produktive, hilfreiche, schnelle und unkomplizierte Zusammenarbeit bedanken. Es wird ganz bestimmt nicht das letzte Mal sein, dass wir/ich Sie kontaktiere.»**

Ad hoc consulting for a returning customer – Supported the establishment and update of QM documents for a Medical Device with focus on clinical evaluation.

# THE BENEFIT OF EARLY REGULATORY ACTIVITY




# MOVING FORWARD

10 YEARS OF EXCELLENCE

Integrity — Dependability — Teamwork

- Reflecting on our 10 year journey
- Celebrating past achievements
- Planning for the future

# SCHEDULE A MEETING WITH OUR EXPERTS TODAY
# JOIN OUR COLLABORATION NETWORK

4052 Basel, Switzerland
Gellertstrasse 4
Tel: +41 61 511 45 63

Email: office@maxiastrategies.com
Web: www.maxiastrategies.com

Dublin 4, Ireland
13 Upper Baggot Street, 2d Floor
Tel: +353 (1) 254 99 09

4101 Bandera Hwy
Kerrville, TX 78028, USA
Tel: +1 (830) 522 4300

Maxia STRATEGIES