

# Lumis International GmbH

Empowering Biopharma & MedTech Companies  
to Enter and Navigate EU, UK & Swiss Markets

# Lumis International, Your Trusted Partner

A Life Science Consulting firm specializing in **Legal Representation, Regulatory Affairs, and Clinical Consulting.**

We support small to mid-sized **Biopharma** and **Medical Device** companies in achieving **EU, UK, and Swiss** market access.

**Berlin**

Headquarter

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**UK & CH**  
Local offices

**2013**

Trusted Since

12 Years in Clinical &  
Regulatory Consulting

**100+**

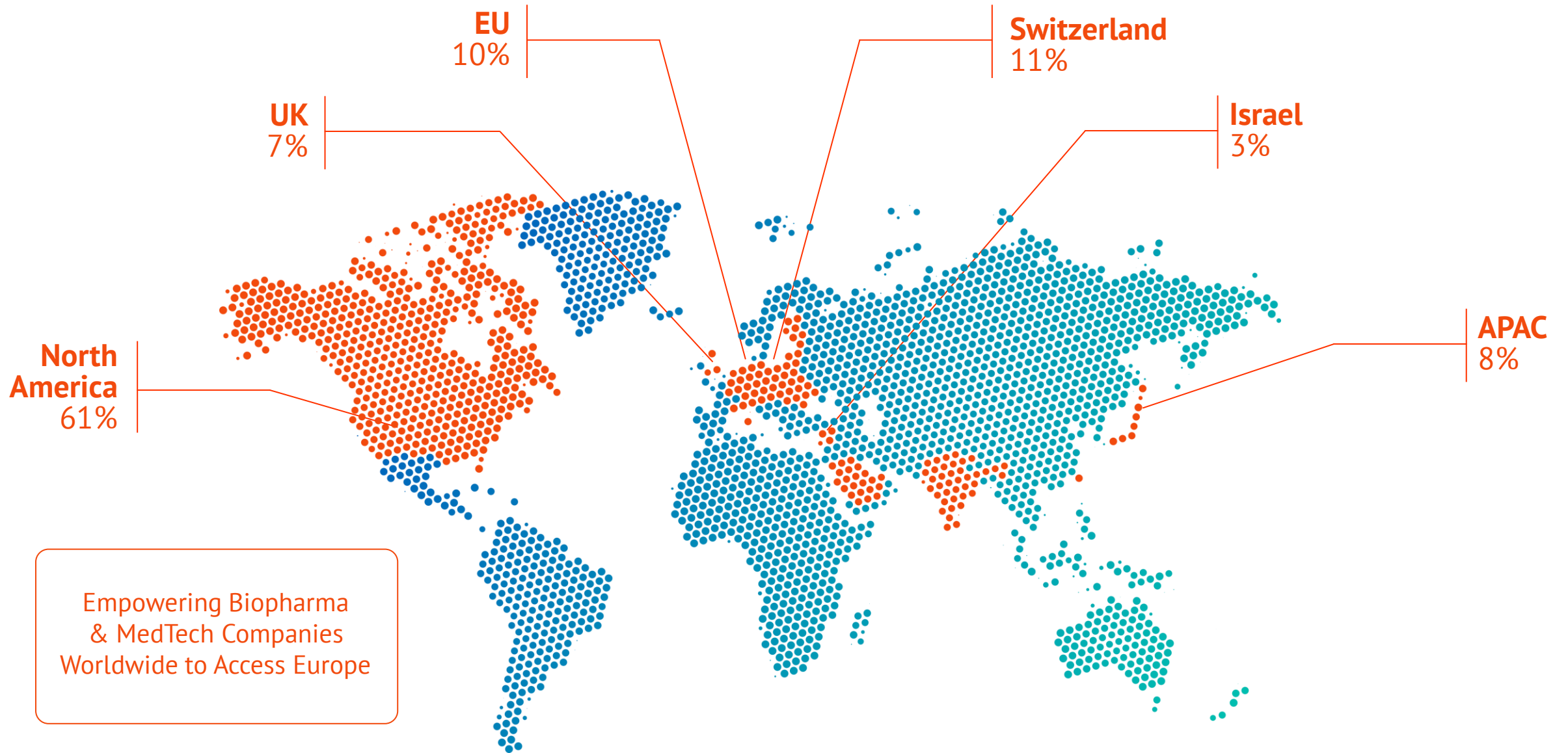
Supported

Biopharmaceutical  
& Medical device  
Companies

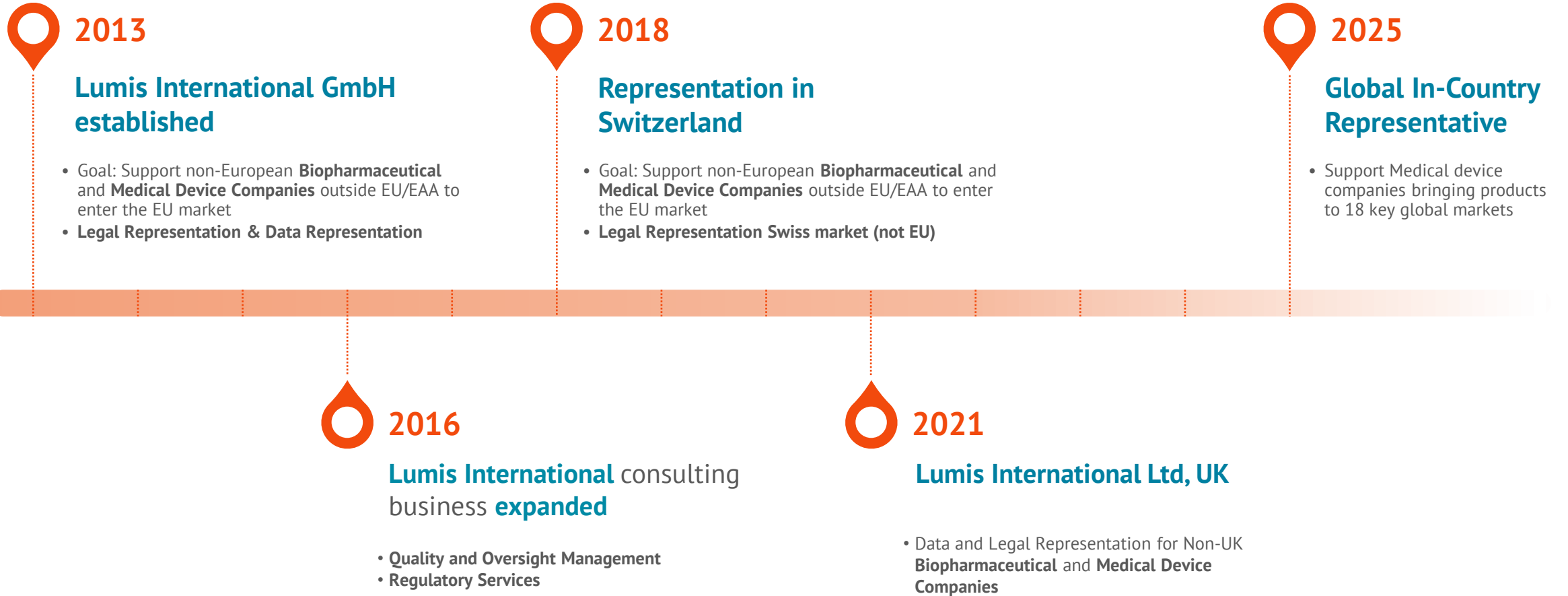
**250+**

Projects Completed

Legal Representation &  
Regulatory Consulting



Empowering Biopharma & MedTech Companies Worldwide to Access Europe



Tailored for Biopharma & MedTech

## Lumis Core Services



### Legal Representative Services

- Legal & Data Representative
- Authorized Representative



### Consulting Services

- Regulatory Consulting & Services
- Vendor & Quality Management



### Biopharma

Early Development & Clinical Support

- Regulatory & Market Access Strategy (SA, ODD, PRIME, PIP)
- Clinical Trial Support, regulatory & vendor management
- Legal & Data Representation

*Focus on development & clinical trial Phases*



### Medical Devices

Full Lifecycle Support

- Product Development & CE planning
- Clinical Investigations & Technical File & CE Marking
- Global In-Country Representative (18 markets), Market Entry & Post-Market Compliance

*Support from Pre-market to Post market*

# Legal Representation Services (LR) – EU, UK, Switzerland



# What Is Legal Representation?



• **Required** for non-EU/EEA sponsors to conduct clinical trials in Europe (e.g., EMA, national agencies), Switzerland and UK



• **Acts** as the legal point of contact between the sponsor and regulatory authorities



• **Ensures** compliance with EU/UK/Swiss regulatory requirements



# When Is Legal Representation Needed



- **Clinical Trials (CTR 536/2014)** – Mandatory for non-EU sponsors conducting Clinical trials in the EU
- **Clinical Investigation (EU MDR 2017/745)** – Mandatory for Non-EU sponsors conducting Clinical Investigations in the EU
- **Scientific Advice** - Required to facilitate regulatory dialogue with EU competent authorities or EMA, where legal presence is necessary
- **SME Application** - Legal representative required when applying for Small and Medium-sized Enterprise (SME) status with the EMA.
- **Pediatric Investigational Plans (PIPs) (EC 1901/2006)** – Legal presence needed for PIP submissions To EMA
- **Orphan Drug Designation (ODD) Submissions (EC 141/2000)** – Supporting regulatory filings ODD in the EU
- **Post-Trial Reporting & Compliance** – Ensuring sponsors meet EU regulatory obligations after trial completion (Safety report, final study reports)

# Lumis as your legal representative (LR)



## Our Role in Your Clinical Trial

- **Lumis assumes legal responsibility** for the trial under EU CTR 536/2014. (UK & Swiss CTR)
- **Regulatory Liaison** – Acts as the primary contact with Competent Authorities (e.g., EMA, national agencies) and Ethics Committees.
- **Dedicated Project Manager** – Assigned to oversee regulatory compliance, CTIS monitoring (EU) every two days as per EMA guidelines.

## Access & Integration

- **Required access to CTIS** (Clinical Trials Information System)/IRAS/BASEC to manage applications and communications.
- **Integration and collaboration** with the sponsor's protocols, regulatory documents, and safety reports.

## Service Timeline

- **Start:** Responsibilities begins with Clinical Trial Application (CTA) submission.
- **End:** Concludes upon submission of the final Clinical Study Report (CSR).

Tailored for Biopharma & MedTech

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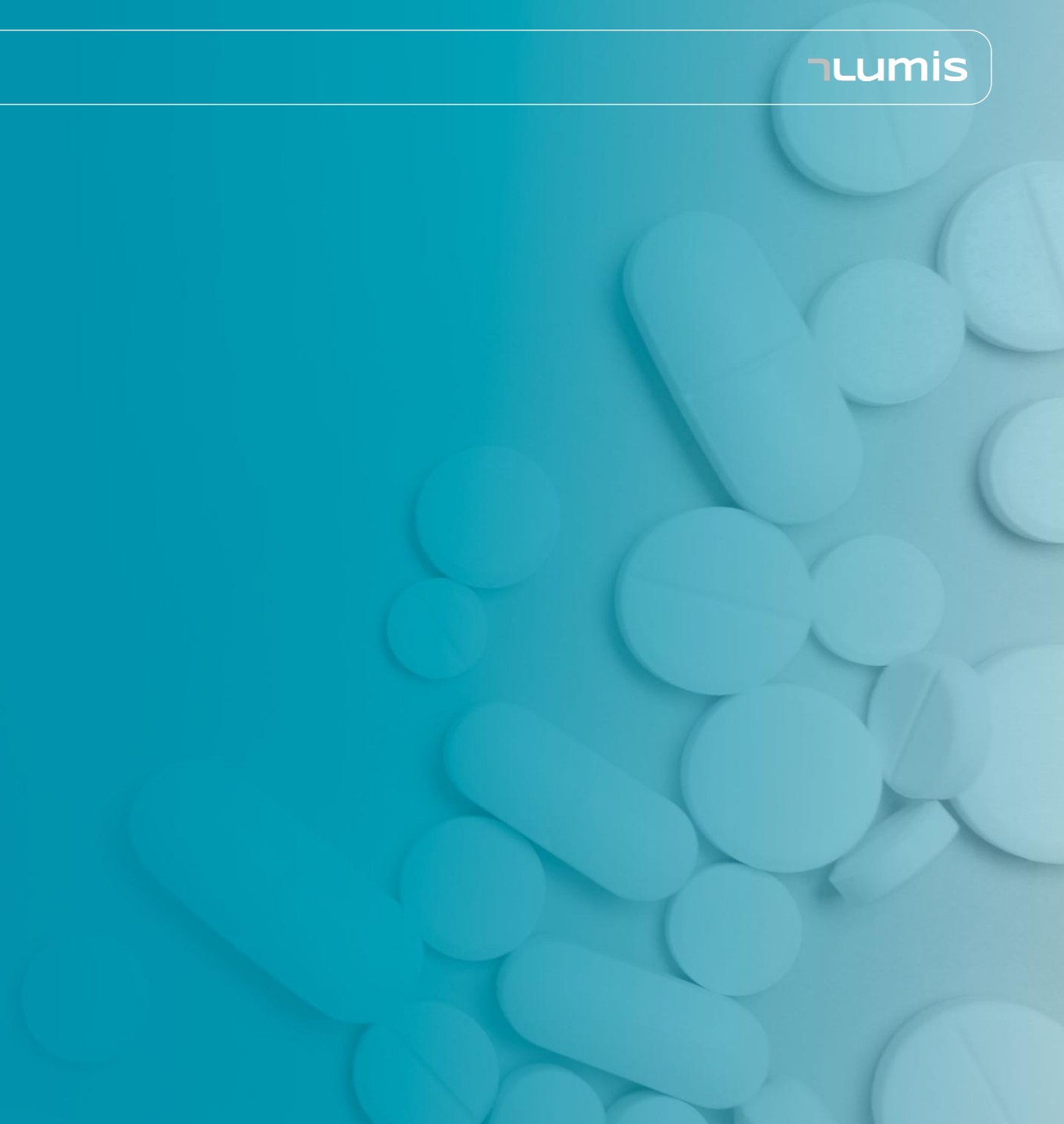
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# Biopharma Services



# Early Development & Clinical Support

## Early Development & Regulatory Strategy



- Orphan Drug Designation (ODD)
- Paediatric Investigation Plan (PIP)
- Innovative Designations (e.g. PRIME, ILAP)
- SME Status Application Support
- Scientific Advice (national or EMA)
- Regulatory Pathway & Market Access Strategy
- Clinical Trial Planning & Strategy

## Clinical Trial Support & Compliance



- Clinical Trial Applications (CTA/CTIS)
- Quality Management & Compliance
- Vendor & Oversight Management

## Legal Representative Services



- Legal Representation (LR)
- Data Representation (DR)

# Early Development & Regulatory Strategy



- **Orphan Drug Designation (ODD)** – Support for rare disease drug developers in obtaining ODD status for regulatory & financial benefits.
- **SME Status Application** – Assistance for small/medium-sized enterprises in securing fee reductions & tailored regulatory guidance.
- **Scientific Advice** – Engaging with EMA/local authorities to shape clinical & regulatory strategies.
- **Regulatory Pathway & Market Access Strategy** – Identifying the most efficient regulatory route.
- **Paediatric Investigation Plan (PIP/PSP)** – Multi-disciplinary team devising regulatory-compliant paediatric development plans.

# Clinical Trial Support & Compliance



- **CTA/CTIS Submissions** – Managing clinical trial applications under EU CTR 536/2014, UK, and Swiss regulations.

- **Quality Management & Compliance**

Vendor and site audits

GCP-compliant QMS for clinical trials

SOP development & process optimization

Document review & inspection readiness

- **Vendor & Oversight Management**

Clinical trial and project oversight and governance

Risk management and monitoring strategies

Site compliance monitoring

Regulatory reporting support

# Legal Representation Services



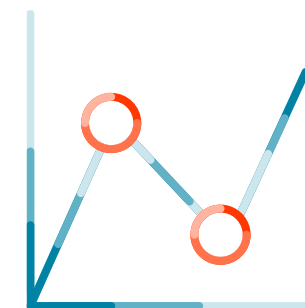
- **Legal Representation (LR)**

Acting as the legal entity for non-EU sponsors under EU Clinical Trial Regulation (CTR 536/2014).



- **Data Representation (DR)**

Ensuring GDPR compliance for EU data protection requirements.



# Medical Device Regulatory Services

# Full Life-Cycle Support



## 1. Product Development & Pre-Market Regulatory Planning

- Gap analysis (CE mark) – tech files and QMS.
- Classification & Market Access Strategy
- Pre-submission support.
- Regulatory Consulting Services
- Notified Body Selection
- Quality Management System development



## 2. Clinical Investigations, Technical File Development & CE-marketing

- Clinical Investigations
- Quality Management & Compliance
- Vendor & Oversight Management
- Technical File Preparation & Submission
- Audit preparation support



## 3. Legal Representation Services

- Legal Representation (LR)
- Data Representation (DR)



## 4. Market Entry & Post-Market Compliance

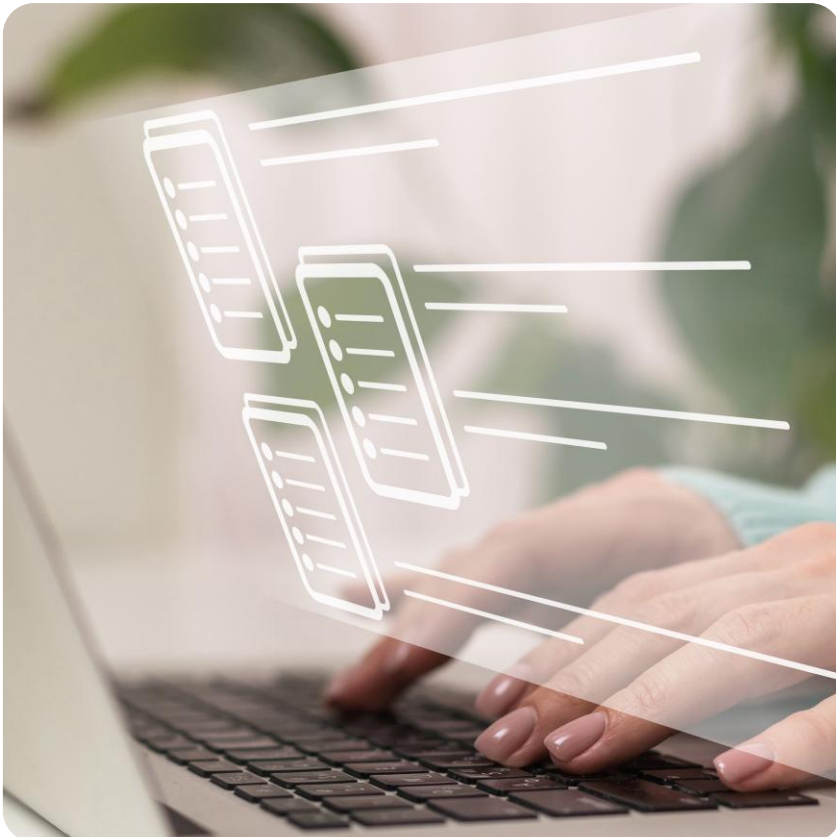
- Global In-Country Representative (18 markets, 5 continents)
- Post-Market Surveillance (PMS) & Vigilance
- Post-Market Clinical / Performance Follow-Up (PMCF/PMPF) services

# 1. Product Development & Pre-Market Regulatory Planning



- **Gap Analysis** – Assess technical file(s) & QMS for MDR/IVDR compliance gaps & outline a path to CE marking.
- **Classification & Market Access** – Determine regulatory pathway & correct classification.
- **Notified Body Engagement** – Identify & liaise with a suitable NB, including pre-submission meetings.
- **Regulatory Consulting** – Guidance on compliance, labeling, risk management & technical files.
- **Pre-Submission Strategy** – Engage with Notified Bodies & Competent Authorities for regulatory clarity.
- **QMS Development** – Prepare QMS for EN ISO 13485 compliance, including SOPs & audits.

## 2. Clinical Trial & CE Mark Support



### Clinical Investigations & Studies

- Supporting pre-market clinical investigations for MDR/IVDR compliance. This can include operational support and regulatory support

### Quality Management & Compliance

- Clinical trial vendor and site audits
- Implementing GCP-compliant QMS for clinical trials
- SOP development & process optimization
- Document review & inspection readiness

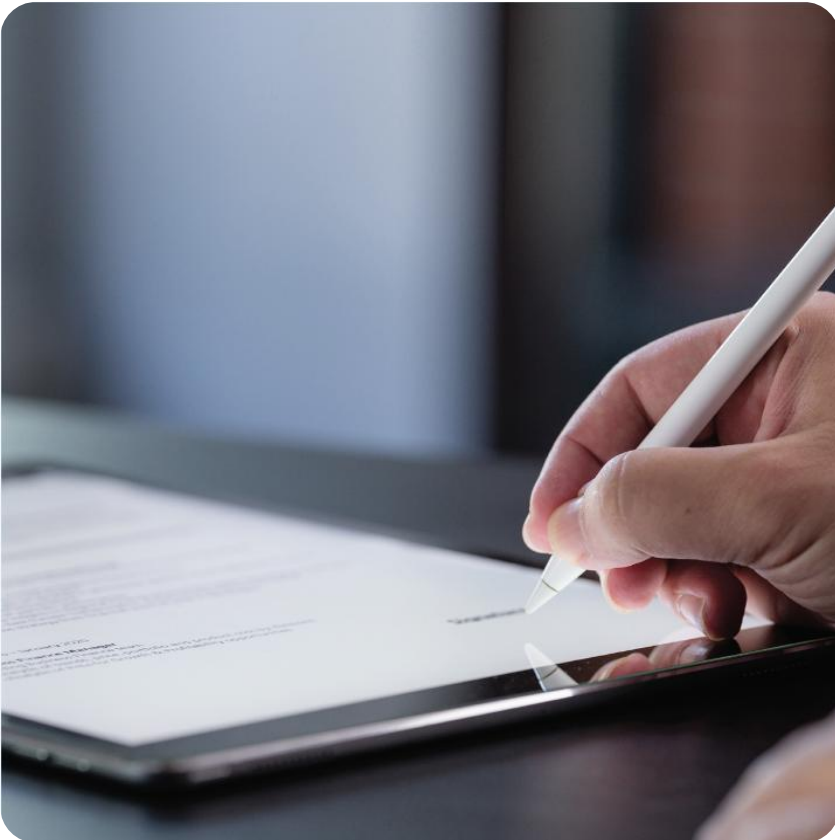
### Vendor & Oversight Management

- Trial oversight and project governance
- Risk management and monitoring strategies
- Site compliance monitoring
- Regulatory reporting supporting

### Technical File Preparation & Submission

- GAP Analysis & strategy
- QMS (e.g. ISO 13485)
- MDR/IVDR technical file preparation (e.g. CERs/PERs, risk management, master file preparation)

### 3. Legal Representation Services



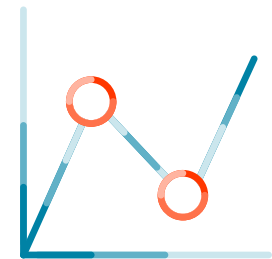
- **Legal Representation (LR)**

Acting as the legal entity for non-EU/EEA sponsors under EU Clinical Trial Regulation (CTR 536/2014).



- **Data Representation (DR)**

Ensuring GDPR compliance for EU data protection requirements according to Article 27 of the GDPR.



## 4. Market Entry & Post-Market Compliance



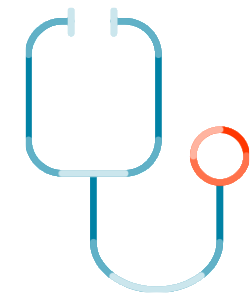
### • Global In-Country Representative

Designated representative for non-local manufacturers, ensuring compliance, authority communication, and post-market oversight across **18 key markets spanning five continents**.



### • Post-Market Surveillance (PMS/PMCF) & Vigilance

Supporting global regulatory compliance through proactive PMS planning, safety reporting, and post-market follow-up (PMCF/PMPF) in line with regional requirements (EU MDR/IVDR and beyond).



## Flexible. Strategic. Trusted



### Regulatory & Clinical Excellence

- Over **20 years** of experience navigating **EU, UK, and Swiss** regulatory frameworks.
- **Multi-disciplinary team** of regulatory strategists, quality experts, and clinical professionals.

### End-to-End Market Access & Compliance

- Supporting companies **from early development to post-market compliance**.
- Expertise in **clinical trial support, regulatory submissions, and legal representation**.

### Agile & Client-Centric Approach

- **Boutique firm with a hands-on, flexible approach** tailored to client needs.
- **Lean infrastructure = competitive pricing** without compromising quality.

### Proven Track Record

- **100+ companies supported** since 2013.
- Trusted by **biopharma & medical device firms** for **regulatory and clinical consulting**.

# Thank You.

lumis



**Heike Schön**

CEO

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