Corporate Presentation

Non-Confidential

Brussels, December 2024

Overview

1. **What we do**:
   Accelerating your regulatory journey
2. **Our differentiators**
3. **Contact us**

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What we do: Accelerating your journey with the best regulatory pathway

Accelerating your journey with the best regulatory pathway

Our wide range of service offerings

4 Other services

1 Regulatory strategy

3 Product expertise

2 Writing regulatory documents and submissions

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RLM proposes guidance on:

- **CMC requirements** regarding the manufacturing, characterization, control and stability of the drug substance and drug product
- **Preclinical** (proof of concept, pharmacokinetics, toxicology) and **clinical study protocols** required for the approval of different clinical phases

RLM acts as an applicant for:

- **Submissions** to the **EU (EMA and/or National level)** and/or the **US (FDA)**

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Our service offerings in **Europe** (EMA and/or National level)

- Briefing documents for Scientific Advice (SA), Protocol assistance, Innovation Task Force (ITF) briefing meeting,...
- Investigational Medicinal Product Dossiers (IMPD) and Investigator's Brochures (IB)
- Clinical Trial Applications (CTA) in CTIS
- Orphan Drug Designations (ODD)
- Pediatric Investigation Plans (PIP)
- PRIME designation dossiers
- Advanced Therapy Medicinal Product (ATMP) classification and certification
- Preparation of viral safety dossiers

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Our service offerings in **USA** (FDA)

- Meeting request and briefing book for INTERACT, Type A, B, C, and D meetings
- IND (modules 1-5)
- Investigator’s Brochures (IB)
- Orphan Drug Designations (ODD) and Rare Pediatric Diseases Designations (RPDD)
- Pediatric Study Plan (PSP)
- Breakthrough Therapy (BT) designation program

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Key expertise in RA guidance for development of chemical, biological, and advanced therapy medicinal products:

- Vaccines
- mRNA products
- Small molecules
- Synthetic peptides
- Monoclonal antibodies (mAbs)
- Live Biotherapeutic Products (LBP) incl. GMOs
- ATMPs: cell therapies, gene therapies and tissue engineering products
- Medical device-drug combination
- Fusion protein

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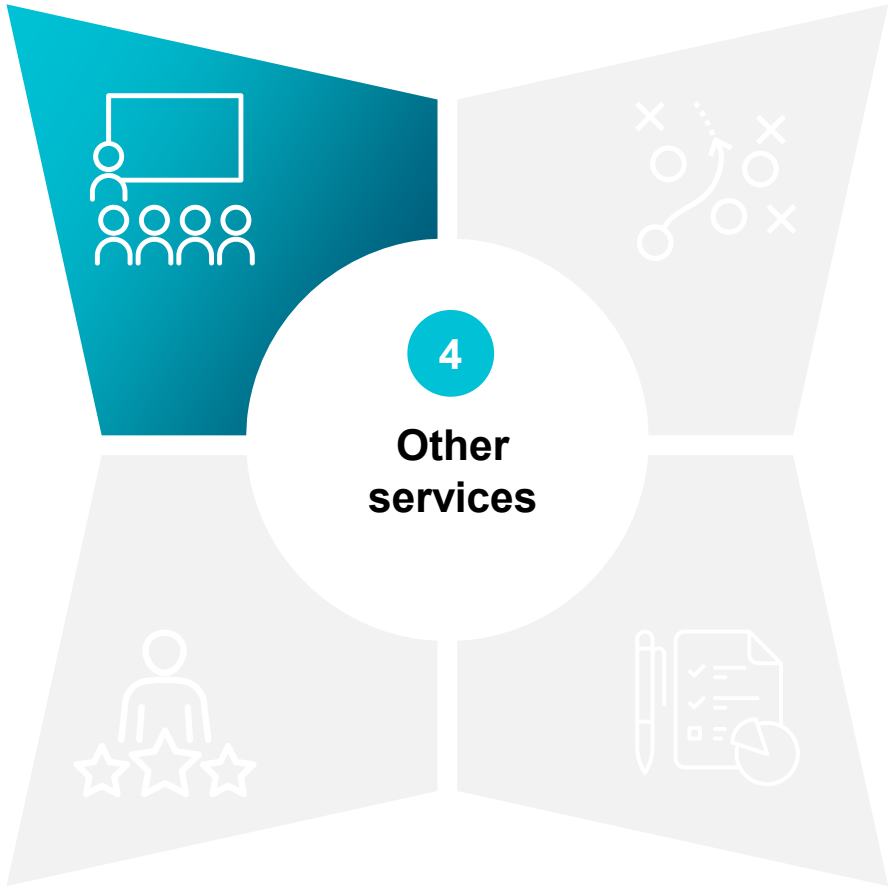
RLM Consulting can also provide other services internally and via partners:

- GxP: SOPs, audits, Qualified Person (QP)
- CRO/CDMO: selection and qualification
- Clinical Operations Project Management
- Medical devices
- Animal health
- Regulatory training
- Due diligence: investment assessment (audits, licensing, partnering, mergers, etc.)



2 Our differentiators

Our differentiators

Our assets

HIGHLY SKILLED

We are a team of **highly skilled scientists (Masters & PhDs) with complimentary degrees:** Biology (Microbiology, Cellular, Molecular,…), Biomedical, Chemistry, Pharmacy, Clinical Research, Infectious Diseases, MBA…

WRITING

We **write your dossiers** so you can focus on your product development knowing that we have your regulatory aspects covered.

INNOVATIVE SOLUTIONS

We strive to find **innovative solutions to your challenges so whenever** possible we will be creative in our recommendations and strategic guidance to you.

LONG-TERM RELATIONSHIP

We build long-term relationship with you. We have a small internal turnover, which allows us to have **one project manager per client** that stays together during the entire process.

3 CONTACT US

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