

Maxim Kots, MD
Clinical Development and Medical Affairs consultant

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PROFESSIONAL SUMMARY:

Pharma professional with two decades of well-rounded experience in medical function. Leveraging strong scientific and business skills and knowledge in building and leading teams and processes at the different levels of the companies. A medical doctor by training and an entrepreneur by passion.

Equally strong scientific and business skills. In deep experience in the scientific and operational aspects of the complete drug life cycle. Practically confirmed execution of early-, mid-, and late- stages of product clinical development, launch, and lifecycle management. Wide network of contacts with pharma experts, vendors, and opinion leaders.

AREAS OF EXPERTISE:

- Business areas: Rx products | Vaccines | Medical devices | Cosmeceutical
- Therapeutical areas: Respiratory | Allergic diseases | Diabetes | Gastroenterology | Thrombosis | Inflammation | Antimicrobial therapy | Surgery | Pediatrics | Rare disease | Anti-age therapy

CLINICAL DEVELOPMENT EXPERIENCE:

Aligned therapeutical area strategy across different company functions and levels.

Built target product profile and clinical development strategy.

Served as global clinical development expert across company committees.

Represented the company in different external committees (EFPIA, IMI, ERS, GOLD, GINA, etc.).

Performed all development stages of the trials from Phase I First-in-Human, through Phase III Registration, to RWE.

Created clinical trials starting from hypothesis generation, through trial synopsis, full protocol, data analysis and to final clinical study report.

Served as a clinical expert in the interactions with regulators (EMA, FDA, China, Japan, Australia, etc.).

Managed CRO and external vendors.

Supervised the team of Clinical Program Leaders and Clinical Research Physicians.

Budget management and people management/development/retention.

MEDICAL AFFAIRS EXPERIENCE:

Led the Therapeutical area Global medical affairs division.

Established a therapeutic area medical affairs division and launched a new company portfolio.

Focused on governance, and ensured medical affairs input and value across all company levels.

Co-created company strategy with business functions.

Representing the company in different external committees (GINA, GOLD, ERS, etc.).

Responsible for ethics and compliance either at global regional and affiliate levels.

KOLs management. Patient-oriented programs.

Managed CRO and external vendors.

Supervised the team of Medical advisors, Medical scientific liaisons, Global medical leads, and Medical directors.

Budget management and people management/development/retention

ENTREPRENEUR AND CONSULTANT EXPERIENCE:

2016 – current: Entrepreneur and consultant for biotech and medtech companies.

2023 – 2024: European Respiratory Society executive consultant. Strategic guidance.

2021 – 2022: Anti-age therapy – synthetic collagen medical device class III.

2020 – 2022: anti-COVID therapies and diagnostics business development projects.

2020 – 2021: New chemical entities business development projects: Parkinson's disease, Antidepressant therapy, anti-Flu therapy.

2016 – 2018: Development of the multidose multi-cartridge inhaler device.

2013 – 2016: Russian-speaking doctors scientific society executive consultant. Society settlement and strategic guidance.

2010 – 2016: Russian Respiratory Society executive consultant. Strategic guidance.

WORK EXPERIENCE:

2015 – 2023: Global Clinical Development and Global Medical Affairs departments, Chiesi Farmaceutici S.p.A.

2008 – 2015: Medical Affairs department, Novartis Pharma

2006 – 2008: Clinical research associate, CRO company

2005 – 2006: Surgeon, Hospital

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EDUCATION & TRAINING:

2023 – 2024: Fundamentals of Corporate Finance; HSE University; coursera platform

2020 – 2021: The Science and Business of Biotechnology; MITx; edx platform

2020: Private Equity and Venture Capital; Bocconi University; coursera platform

2010 – 2013: Specialist in pharmaceutical medicine (SPM); European Center of Pharmaceutical Medicine; Basel (Switzerland)

1999 – 2005: Medical doctor; Russian State Medical University; Moscow (Russia)