



Ioannis Papadopoulos

Regulatory Affairs Manager | Global Clinical Submissions | EU CTR / CTIS | EU MDR (2017/745) Certified | ISO 13485 (QMS, In Progress)

Open to Relocation | Open to EU Remote Roles

Bratislava, Slovakia | +421 949 674 756 | +420 607 651 324
mgr.ioannis.papadopoulos@gmail.com | linkedin.com/in/ipapadopoulos1/

- Senior Regulatory Affairs professional with 10+ years of experience in clinical development, regulatory operations, and study start-up across global CRO and sponsor environments.
- Bridging Regulatory Affairs across pharmaceutical and medical device environments.
- Strong expertise in EU CTR 536/2014, CTIS, CTA submissions, MAA-related activities, and clinical trial lifecycle management.
- Certified in EU Medical Device Regulation (EU MDR 2017/745), currently expanding expertise in ISO 13485 and Quality Management Systems to strengthen capabilities across MedTech regulatory and compliance frameworks.
- Proven ability to deliver study start-up (SSU/RSU) activities, site activation timelines, RFIs, substantial modifications, and regulatory maintenance across EMEA, APAC, and global programs.
- Experienced in clinical investigations (medical devices and pharmaceuticals), including interventional and non-interventional studies across multiple therapeutic areas.
- Strong cross-functional collaborator driving alignment across Regulatory, Clinical, and Quality functions.
- EU citizen; open to EU relocation and remote roles.
- Currently completing ISO 13485 (Quality Management Systems for Medical Devices) – expected Apr 2026

Core Competencies & Skills

- EU MDR (2017/745) & Medical Device Regulatory Affairs
- Quality Management Systems / Design Control & Risk Management (ISO 13485 – In Progress)
- Global Regulatory Submissions (ICH, EMA, FDA, PMDA, ANVISA)
- Regulatory Strategy Development & Lifecycle Management
- EU CTR 536/2014 & CTIS Implementation
- Clinical Trial Applications (CTA) & Regulatory Maintenance
- Regulatory Start-Up (SSU/RSU) Strategy & Execution
- Health Authority & Ethics Committee Liaison
- Risk Assessment & Regulatory Compliance
- Change Control & Lifecycle Management
- Cross-Functional Regulatory Project Leadership
- Multi-Country Clinical Operations Support
- Medical Device & Pharmaceutical Regulatory Affairs
- Swissmedic & DACH Region Submissions (DE/AT/CH)
- Good Clinical Practice (GCP)
- Audit Readiness & Inspection Support

Work Experience

August 2023 – December 2025

Senior Site Activation Lead - (Sr. Regulatory startup lead for global interventional and non-interventional studies)

ICON PLC, (Regional EMEA Role, based in Bratislava)

Professional Recognition:

SPARK Award – Partnership Excellence, AstraZeneca (2025)

Formal recognition for professionalism, dedication, and outstanding collaboration on AstraZeneca-sponsored clinical studies.

- Supported compliance and documentation practices aligned with regulatory and quality standards, contributing to inspection readiness and process standardization across global studies
- Directed regulatory strategy and site activation for interventional, non-interventional, and medical device studies across US, Brazil, South Korea, and multiple EU countries.
- Accelerated site start-up timelines by 30% through optimized CTIS workflows and proactive RA engagement.
- Led cross-functional collaboration to ensure compliant submissions and adherence to regulatory deadlines.
- Presented SSU strategies at client meetings and managed multi-country amendment submissions.
- Reduced time to site activation by 15%.
- Led regulatory and start-up activities across 13 countries for a single global study while concurrently managing 4 clinical studies. Delivered regulatory packages under tight 6-week timelines that otherwise would mean a financial penalty for the company.
- Key achievements: Delivered submission packages under 6-week deadlines across 13 countries | Reduced site activation times by 30% through CTIS optimization.

November 2021 – July 2023	<p>Site Activation Manager (Regulatory startup lead for global interventional and non-interventional studies) Syneos Health (Regional EMEA Role, based in Bratislava)</p> <ul style="list-style-type: none"> • Coordinated country team deliverables, monitored LEC/CEC/RA submissions, and updated sponsor on study status. • Led regulatory document preparation and submissions across multiple EU regions including Belgium and Germany. • Oversaw full SSU lifecycle from site identification to contract finalization and EC/RA communication. • Maintained budget alignment and scope control to ensure profitability and timely project execution. • Successfully delivered regulatory and site start-up milestones across 12 countries for a large-scale global study. • Supported submissions to Swissmedic for Switzerland. • Zero audit findings.
May 2021 – October 2021	<p>Site Activation Manager (Interventional, Non-interventional and Medical Devices studies) (promoted from Regulatory Startup Specialist 2) IQVIA RDS, (Regional EMEA Role, based in Bratislava)</p> <ul style="list-style-type: none"> • Oversaw startup activities and planning for sponsor-specific submissions (Janssen). • Coordinated country team deliverables, monitored LEC/CEC/RA submissions, and updated sponsor on study status.
January 2020 – May 2021	<p>Regulatory Startup Specialist 2 (Interventional, Non-interventional and Medical Devices studies) (promoted from Regulatory Startup Specialist 1) IQVIA RDS, (Regional EMEA Role, based in Bratislava)</p> <ul style="list-style-type: none"> • Handled startup submissions and regulatory authority interactions in Austria, Germany, and Greece. • Negotiated budgets and contracts, and acted as ICF process lead. • Delivered regulatory submission packages for Austria and Greece while serving as the primary point of contact for sites and contract negotiation processes.
October 2015 – December 2019	<p>Clinical Process Associate (promoted from Clinical Process Coordinator) IQVIA RDS, (Regional EMEA Role, based in Bratislava)</p> <ul style="list-style-type: none"> • Streamlined ICF adaptation across North America and Europe, supporting timely approvals in 10+ countries while acting as global regulatory SPOC. • Supported Swissmedic processes via ICF adaptations and regulatory alignment for Switzerland.

Early Career Experience

- **Supply Chain Operations Administrator** | IBM Slovakia
- **Pharmacist experience** | Greece

Education & Training

Sept. 2008 – June 2013	Pharmacist (Magister of Pharmacy degree) Comenius University, Bratislava (Slovakia)
Sept. 1998 – Oct. 2004	Graduate in Aesthetics-Cosmetology Technological Educational Institute, Thessaloniki (Greece)
Sept. 1996 – June 1998	Dental technician (Bachelor's) Pasteur Institute, Thessaloniki (Greece)

Certifications / Professional Development:

- **EU Medical Device Regulation (EU MDR 2017/745) – Regulatory Affairs Training Medical Device HQ** - (Completed, 2026)
- **ICH GCP E6(R2) for Operational Personnel** (27 June 2024)
- **In Vitro Diagnostic (IVD) medical devices and IVD Regulations [ISO 20916:2019]** (18 July 2024)
- **EU CTR & CTIS Advanced Training** (Completed)
- **Currently completing ISO 13485 (Quality Management Systems for Medical Devices)** – expected Apr 2026

Languages:

- Greek – Native
- English – C1 (Oxford University Certification)
- German – A2 (basic understanding, studying for B1)

Regulatory Systems & Tools:

- Regulatory systems
- CTIS
- Veeva Vault
- eTMF
- CTMS
- SharePoint
- Microsoft Teams / Office

Soft Skills:

- Strong organizational and planning abilities
- High resilience under pressure
- Excellent communication and stakeholder coordination
- Workflow automation and optimization mindset
- Team coordination and leadership in cross-functional, global setups