JORGE MILTON LOMBARDO MD, MSc.

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MEDICAL DOCTOR / CLINICAL RESEARCH SPECIALIST

Clinical trial/research specialist: Extensive knowledge, experience, and expertise in Ethics, Legal Medicine, Clinical Research, Monitoring, Auditing, GCP Compliance, TMF&KPIs Metrics, and Diversity & Inclusion. Extensive and qualified therapeutic, healthcare, vendors (CROs) and pharmaceutical experience. Vast proficiency in Oncology & Internal Medicine.

A proven leader with an analytical mindset, strategy, and goal orientated. I am seeking a challenging opportunity to continually manage and lead large cross-functional projects where my advanced education and many years of experience and achievements can be fully utilized.

PROFESSIONAL EXPERIENCE

Senior US Regional Process Control Manager, **Monitoring Excellence, Global Clinical Operations, Novartis, NJ USA** **Aug 2021-**

- I support the overarching compliance oversight & process control of the Trial Monitoring Organization (TMO)/Global Clinical Operations (GCO) activities focused on ICH-GCP (Good Clinical Practices). I oversee and manage GCP Compliance, issue management, audits & inspections at per trial/country/site level. I handle audits, inspections, GCO quality issues, deviations & quality events management focusing on high quality, compliance & active risk management & collaborating with GDD & Quality Assurance.
- I provide strong support to SSO (Study & Site Operations)/GCO dedicated to clinical site management, strengthening Operational Excellence & enabling to generate of reliable scientific evidence. I deliver GCO self-assessment strategy-related checks and controls.
- I oversee & coordinate audits & Health Authority (HA) sites & sponsor inspections and guide & support SSO/GCO RCA and CAPAs.
- I conduct reviews of GCP audits and inspection findings to identify trends & systematic gaps in the monitoring processes. I ensure self-assessment strategy development & accountability for its delivery. I oversee mandatory training compliance for all SSO roles.
- I am SSO's point of contact for Process, GCP Compliance & quality oversight: I lead SSO with a focus on high quality, compliance, and active risk management, driving operational health and continuous improvement and implementing best-in-industry practices.
- I work to achieve quality objectives, ensuring operational excellence is met, and proactive planning exists for the maintenance & remediation of quality on ongoing clinical trials to secure timely regulatory approvals. I lead the innovation of new solutions (internal and external) for diversity, equity & inclusion in clinical trials. I ensure that process issues are identified, addressed, and resolved.
- I identify process gaps through the review of data available: clinical trial management systems, trial databases, metrics, Trial Master File (TMF), and Quality KPIs, as well as I support with Quality Assurance co-monitoring activities: Health Authority preparation visits.
- I support & oversee SSO/GCO activities: 1) I support the Feasibility and the Study & Site Operations group to proactively identify risks for the assigned studies within the SSO team and develop respective mitigation plans. 2) I support and maintain a strong knowledge of the study protocol to answer process questions from the SSO group: CRAs, CRAMs, FM Area Heads, CSMs & CSMGHs. 3) I oversee study training, compliance strategy, handover process & documentation. 4) I oversee study close–out activities that are performed correctly and documented in a timely manner. I ensure aligned communication with all the SSO stakeholders.
- I am accountable for support monitoring quality, and issue resolution to ensure quality trial oversee and appropriate issue escalation. I promote a compliance culture advocating adherence to the highest standards and ethical integrity.
- I oversee escalation points for issues in monitoring visit reports (MVRs) for SSO/GCO studies: to improve this activity and proactively seek information about systematic risks & innovative new opportunities across SSO/GCO.
- I evaluate trends identified in MVRs and oversee & ensure issues & gaps resolution correctly and in a timely manner.
- I developed the US TMO weekly Site Cockpit Tool with the possibility of seeing the SSO/GCO issues gaps and escalation activity.
- I Provide day-to-day support to studies in monitoring processes, systems & SOPs. I contribute to developing & implementing new tools (more than 20), techniques, processes, and operational excellence initiatives to improve SSO/GCO issue management.
- I lead and support vendor (CROs) activities with the Strategy & Operations (S&O) team: I deliver monthly Tools to the CROs.
- I develop monthly the US FMMO tracker for Strategy & Operations (S&O): this tracker is key for S&O reports.
- I translate the priorities of the compliance monitoring program into the full suite of analytics required to provide comprehensive monitoring, real-time diagnostics, advanced predictive modeling, metrics, KPIs and proactive risk management.
- I lead monthly KPIs analysis & TMF activities to review trends for SSO/GCO and CROs and I promote remedy & proactive action.
- I support & contribute to the SSO US Book of Work development and insights and act as a key partner to functional S&O activities.
- I created the 2023 Global Inspection Readiness tracker & PCP tracker: these tools will be used worldwide across the organization.
- I co-lead the STAR system, Document Lifecycle and Curriculum Management Tool, and assign the correct curricula to 17 GCO roles.
- PEG groups: I contribute to multidisciplinary task forces to support continuous improvement initiatives (SOPs, Insp. Readiness)

US Regional Process Control Manager, **Monitoring Excellence, Global Clinical Operations, Novartis, NJ USA** **Jan 2020-Aug 2021**

- I liaised and strategically partnered with multiple stakeholders (Global/Region/Country) to identify quality gaps, set plans, and act to address and ensure proactive risk management & training development in collaboration with GCO Excellence Training resources.
- I was responsible for quality issue management (QIM) and quality event management within the quality reporting timelines by facilitating root cause analysis, CAPA development from development to closure, CAPA effectiveness checks and quality issue trending by supporting country business owners and collaborating with Country QA/US NCQ.
- I supported audit & inspection preparation & HA inspections. I supported SSO RCA & CAPAs. I identified gaps in the monitoring processes to improve SSO activities.

US Country Process Control Manager, **Monitoring Excellence, Global Clinical Operations, Novartis, NJ USA** **Dec 2018-Jan 2020**

- I was accountable for developing a quality mindset in US TMO to support the vision of Quality by Design and remediate process issues through the implementation of training by partnering with the Country Training Manager and corrective/preventive actions (CAPAs) as required. I assure TMO teams were always inspection ready. I oversaw & coordinated audits & support RCA & CAPAs.
- I engaged closely with TMO/SSO to ensure clinical trial & protocol adherence and risk-based monitoring plans.
- I supported SSO teams in inspection readiness, ongoing inspections, and inspection follow-up by performing visits at clinical sites.

Global Process Control Manager, **Monitoring Excellence, Global Clinical Operations, Novartis, NJ USA** **Jun 2017- Jun 2018**

- I was a first-line responder for process and quality issues, providing and facilitating trial monitoring specific advice and solutions.
- I was responsible for the activities undertaken within the quality assurance system to verify that the requirements for the quality of trial-related activities had been fulfilled. I delivered GCO self-assessment strategy-related checks & controls.
- I drove continuous process improvement to increase quality, speed, and productivity in trial execution, focusing on monitoring and field monitor oversight. I tracked the progress of KPIs that impact quality, Quality Plan, and overall compliance with application monitoring processes, regulations, and training requirements. I worked with business & QA stakeholders to ensure GCO wide systemic Quality Issues & Quality Events were identified, assessed, managed & resolved effectively. I managed GCO audits & inspections landscape and coordinated system/process audits & global inspections supporting authorizations including inspection readiness. I implemented issue identification and RCA to troubleshoot systemic issues & help to resolve them through new or enhanced processes and training. I ensured RCA & CAPAs commitments were adequate, submitted, and completed promptly.

Legal/Forensic Medical Head & Medical Auditor, **La Equitativa Del Plata SA, Buenos Aires Argentina** **Jan 1998 - Oct 2016**

Institutional Review Board, Chairman, **CINME, Centro de Investigaciones Métabolicas, Bs. As. Argentina** **Jan 2008- Dec 2009**

Medical Research, Investigator, **Instituto De Investigaciones Metabólicas, IDIM, Bs. As. Argentina** **1999-2008**

Gynecology and Obstetrician, Physician & Surgeon, **CEMIC, Buenos Aires (Hospital, healthcare). Bs. As. Argentina** **1995-2005**

Professor **of Histology, Embryology and Cellular Biology at Buenos Aires University, Medicine. Argentina** **1989-1998**

EDUCATION

1 Post Grade Course: **Specialist in Legal Medicine**, UCA, Pontificia Universidad Católica Argentina, 2005 2007

2 Post Grade Course: Residency, **Gynecology and Obstetrician Specialist**, 1995-1998

- ✓ Department of Gynecology and Obstetrics, CEMIC, **Universidad de Buenos Aires**, UBA, Argentina
- ✓ Department of Gynecology and Obstetrics, **Baylor College of Medicine**, **Baylor University**, Houston, Texas

3 **Medical Doctor**, **School of Medicine**, University of Buenos Aires, UBA, Argentina, 1987-1994

4 Associate´s Degree, **Bachelor in Biological Science**, Colegio Nacional de Buenos Aires, Buenos Aires University, UBA 1987

SKILLS & ACHIEVEMENTS

- ✓ **Intercultural, cross-functional, change management & international experience & expertise:** *I worked for more than 25 years in LATAM & Global, Regional & Country positions in the US: this has allowed me to improve my communication with co-workers & understand different mindsets & ways of working.* ***As PCM****, I can communicate across all levels of the organization, including TMO (SSO) leadership. I developed excellent negotiation, conflict & resolution skills and have decision-making strengths throughout my career.*
- ✓ **Good self-awareness, conflict & coaching skills:** **As PCM**, *I updated the Curricula (SOP) in Novartis for my position, doing the same for other 12 roles, being proficient in change management, challenging the status quo and working with global matrix teams*
- ✓ **Critical thinker & Detail Oriented:** ***As a medical auditor*** *and* ***PCM****, I am used to finding issues, gaps, and weaknesses in procedures from the beginning to the end of the process to solve them rightly; I Identify different paths to improve process adherence.*
- ✓ **Risk Management:** ***As Investigator****, I coordinated & managed several clinical trials simultaneously, from inception to completion, leading physicians, and associates to* work in a matrix environment and meet deadlines. **As a medical auditor and PCM**, *I am used to performing & checking strict compliance with healthcare compliance policies. As* ***PCM****, I oversee TMF activities & improved TMO metrics: I developed the US TMO CREDI TMF Tool, and I am working with TM & DOC GOV MGMT team to have more & better TMF metrics.*
- ✓ ***Audits and inspections experience:*** ***As PCM****, I helped increase compliance with SOP, GCP and decreased audit & inspection findings.*
- ✓ **Strategic thinking and analytical skills; risk management and risk-based decision-making knowledge and mindset:** ***As PCM****, I develop and improve tools, WBs, PPP, & monthly reports to the vendors & strong project management and operational abilities ensuring excellence of execution. Strategic partnering and support S&O by providing monthly trackers (FMMO WBs) and reports (CROs Tools).*
- ✓ **Team player & leader:** ***As an IRB Chairman****, I coordinated a diverse group of people with different backgrounds incorporating everyone's voice & speak-up culture.* ***As PCM****, I used to liaise between countries, regions, & other line functions, proactively recognizing and adapting to the different thinking, learning styles & cultural profiles in compliance with healthcare policies, regulations, and laws.*
- ✓ **Proactively identify regulatory issues/risks and design/execute mitigation plans:** **As a medical auditor** and ***PCM****, recommend proactive actions to avoid repeated findings. I co-create & improve NVS's SOP showing knowledge of GCP and ICH regulations.*
- ✓ **Proficiency in Microsoft Office & SharePoint administration** ***as PCM*** *I created new processes to improve SSO projects: I developed + 20 innovative tools: improving how TMO shares this information with SSO/GCO organization and the vendors (CROs).*
- ✓ ***Strong mindset and fostering a culture of experimentation and high performance****:* ***as PCM*** *I interact monthly with vendors sharing their metrics and KPIs to improve and boost our trials & drug development process and activities. I created an innovative platform solution aligned with available technology (TMOmeter, Qlik Sense, Origin & Site Cockpit) for transparent communication of key risks/issues, risk trends, mitigation plans and resolution status to the appropriate stakeholders/vendors and measure its execution.*

Language: Bilingual-Fluent in English and Spanish **Work permit:** USA, Europe (EU) and South America