Electronic Signature Page

Document title: TRR-CV-RA-Lorenza_Olivieri-FINAL-18APR2023

Sign-off status: FINAL

Digitally signed by:

Certified by PSI CRO AG

NAME, POSITION	ROLE	DATE TIME STAMP
Olivieri, Lorenza Head Regulatory Affairs, Country/Region *lorenza.olivieri@psi-cro.com*	reviewer	18-APR-2023 10:59 (GMT +03:00)

This signoff page has been automatically generated to capture the digital signatures of authorized signatories. Each record has been time-stamped and verified as authentic by certified software, providing evidence that the signed document has not been altered or tampered with post-signature.

Lorenza Olivieri

Head Regulatory Affairs, Country/Region

Professional Experience

Jan2021–present — **PSI**

Head Regulatory Affairs, Country/Region

Milan, Italy

Scope of responsibilities:

management of the RA staff in the Country/Region; establishing operational objectives and performance goals; allocation of regulatory affairs resources; resolution of resourcing conflicts; department staff hiring and dismissal; performance appraisal of Regulatory Affairs employees'; oversight of Regulatory Affairs employees' career development; development and implementation of training programs for the department staff; interaction with other company departments; development and implementation of quality systems and quality controls within the department; development of quality systems documents within the functional area; collaboration with Quality Management for the development and implementation of internal audit plans; participation in and facilitation of systems audits and regulatory inspections; supervision of procurement of essential study documents and site-specific documents required for regulatory and ethics submissions; preparation and review of regulatory and ethics committee submission dossiers; tracking of regulatory project documentation flow; tracking changes/amendments to legislative acts pertaining to clinical trials, and timely notification of all parties concerned; safety reporting; acting as a primary contact for contact for regulatory aspects of feasibility evaluation; participation in client/bid-defense meetings

Sep2013–Dec2020 — **Worldwide Clinical Trials**

Sep2015–Dec2020 — **Line Manager, Global Regulatory Affairs, Clinical Study Start- up and Regulatory**

Milan, Italy

Scope of responsibilities:

'Gate keeper' of the Company Regulatory Intelligence; contributing to development and implementation of projects to improve Company processes (SOP review council, Process Improvement Committee, etc.); managing a team of up to 15 Regulatory Leads worldwide (Europe, Asia, North and South America); support to Business Development on different regulatory topics and tasks (e.g., proposal review, protocol risk assessments, etc.) and help in the preparation of bid defense meetings; trainer within the regulatory team on different Intelligence matters;

Sep2013–Sep2015 — **Senior Global Regulatory Manager and Start- up Manager**

Milan, Italy

Scope of responsibilities:

as regulatory manager: coordination & management of a team of Regulatory Affairs Specialists across Europe; as start-up manager for global projects: coordinating a team of Regulatory Specialists, Contract Specialists and Compliance Specialists worldwide to make sure start-up timelines of projects are met as planned; being the main contact point for client and project management team for all start up activities; liaising with the Regulatory Affairs Director to plan, organize, compile progress and submit regulatory submissions on a timely basis; management/supervision of

regulatory & ethics committee submissions and maintaining approvals throughout European, Asia Pacific and Latin America regions for multinational clinical studies; participation in business development activities preparing regulatory sections of proposals and feasibility reports, regulatory costing and budgets and attending bid defense meetings to meet business needs; providing expert regulatory advice and contributing to regulatory project work; providing training, coaching and mentoring to junior members of staff;

Mar–Sep2013 **INC Research**

Senior Global Regulatory Lead

Milan, Italy

Scope of responsibilities:

preparing the core clinical trial application dossier and complying with forecasted submission/approval timelines; producing and reviewing core documentation for clinical trial application to see if in compliance with GCP and local regulations (such as protocol, IB, patient information sheet, labels etc.); Regulatory Lead for Start-up multi-regional studies and for maintenance studies; responsible to ensure that projects stay within contracted or client-approved scope within the regulatory components of the project and timelines; review of the essential documents for IP release;

Feb2010–Mar2013 **Worldwide Clinical Trials**

Senior Global Regulatory Affairs Specialist

Milan, Italy

Scope of responsibilities:

collaboration with business development for the preparation of business proposals for potential clients; contributing towards preparation of technical reports which may involve chemical, pharmaceutical, toxicological, pharmacological, and clinical aspects of specified regulatory submissions; coordinating & managing regulatory & ethics committee submission and maintaining approvals throughout Europe (in both Western and Eastern EU countries) and outside EU (Asia, North America and South America); planning, organizing, compiling progress and regulatory submissions of Clinical Trial Applications (for medicinal products and medical devices, different Therapeutic Areas) on a timely basis; providing advice on appropriate regulatory submission strategy; providing advice on regulatory strategy for clinical development plans; responsible for the maintenance of the Osservatorio Database for the Italian projects;

Nov2002–Jan2010 **Bioxell S.p.A.**

Oct2007–Jan2010 **Clinical and Regulatory Project Manager**

Milan, Italy

Scope of responsibilities:

budget responsibility of the main project of the Company; clinical and preclinical development planning, regulatory strategy, review and preparation of documentation such as IMPD and Investigators' Brochure according to ICH guidelines, requests of scientific advice from EMEA and FDA; collaboration with Business Department in identifying new projects to develop and for in-licensing activities (clinical evaluation of new products); collaboration with Preclinical Development in the preparation of preclinical development plans for new compounds to move into Clinical Development; contacts with key opinion leaders; cooperation with Chief Medical Officer in setting up of national and international phase I and II clinical trials (writing protocol, drawing CRFs and other study supporting documentation, selection of clinical centers, preparation of IMs, etc.); coordination of Regulatory

Expert consultants and management of Regulatory Aspects within the company; coordination of the activities managed by the CROs; member of TOPRA (The Organization for Professionals in Regulatory Affairs); preparation of briefing packs and INDs, preparation and attendance of preIND meetings; responsible for a development team within the Clinical Department;

Nov2002–Sep2007 **Clinical Project Manager**
Milan, Italy
Scope of responsibilities:
collaboration with Business Department in identifying new projects to develop and for in-licensing activities (clinical evaluation of new products); collaboration with Preclinical Development in the preparation of preclinical development plans for new compounds to move into Clinical Development; contacts with key opinion leaders; cooperation with Chief Medical Officer in setting up of national and international phase I and II clinical trials (writing protocol, drawing CRFs and other study supporting documentation, selection of clinical centers, preparation of IMs, etc.); coordination of the activities managed by the CROs;

Apr2001–Nov2002 **Pharmacia Italia**
Junior Medical Advisor
Milan, Italy
Scope of responsibilities:
contacts with key opinion leaders; cooperation in setting up of phase IIIb and IV clinical trials; cooperation in training courses to sales representatives on the therapeutic area product; planning and setting up of medical-marketing activities (consensus conference – observational studies/national surveys); working with the appointed Product Manager to grant scientific support to marketing activities;

Oct1998–Mar2001 **University of Bologna and Chiron Vaccines of Siena**
Intern
Bologna, Italy
Scope of responsibilities:
scholarship in Gastroenterology, topic “Helicobacter pylori and related pathologies”;

Education

1991–1997 **BSc (Molecular Biology)**
University of Bologna, Bologna, Italy

Professional Development

Additional Trainings

Mar2023 Online Refresher: Good Clinical Practice (GCP E6 R2) For Clinical Trials – Refresher, v. 3.0b
Barnett Educational Services

Apr2021 Online Training: Good Clinical Practice (GCP) for Medical Devices: ICH E6 GCP (R2) and ISO 14155: 2020
Barnett Educational Services
Milan, Italy

Oct2010	Course: Introduction to Regulatory Affairs for Medical Devices TOPRA, London, UK
Oct2008	Course: Advance Strategy in Regulatory Affairs TOPRA, London, UK
Nov2006	Course: Statistics Elements for Physicians ENVESTIA, Bergamo, Italy
Oct2006	Course: Conducting Clinical Trials in Europe TOPRA, London, UK
Jul2006	Course: European Regulatory Affairs Summer School TOPRA, Cambridge, UK
Feb2006	Course: Introduction to European Regulatory Affairs ENVESTIA, London, UK
Oct2003	Course: Clinical Trial Design AIFA, Milan, Italy
1997	Training: Applied Biology Laboratory of Analytical Chemistry, University of Bologna, Bologna, Italy

PSI training records are available upon request.

Additional Skills

MS Word, MS Outlook, MS Excel, MS PowerPoint, MS Lync / Skype
Italian, mother tongue
English, advanced