PERSONAL INFORMATION

Alessandra Sola

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Sex F | Date of birth 21-Jan-1977 | Nationality Italian

JOB APPLIED FOR
POSITION
PREFERRED JOB
STUDIES APPLIED FOR

Site Start Up & Regulatory Activities

WORK EXPERIENCE

Aug-2012 - Present

Site Start Up & Regulatory Specialist / Start Up Lead

INC Research Italia, Saronno (VA), Italy

- Activity of Regulatory Specialist and Start Up lead in international studies.
- Activity of Country Start-Up Advisor
- Management of studies phase I-IV, observational studies and studies with medical device.
- Management of studies with genetic data and studies with narcotic drug.
- Preparation and submission of EC/CA Applications
- Submission of amendments, periodic notifications, safety notifications, etc.
- Review of essential documents packages for site activation
- Customization of Informed Consent, Contract Templates and study documents as per country requirements
- Support in the creation of internal training materials on local legislation requirements and Good Clinical Practices (GCP)

Aug-2016 - Present

Referent of Internship program at University of Pavia

University of Pavia & INC Research, Saronno (VA), Italy

- Maintaining relations between the Company and the University of Pavia
- Hold lectures at the University during the student study course
- Select students for in-company internships
- Mentoring activities with the internships

Mar-2007 - Jul-2012

Lead Clinical Research Associate

INC Research, Saronno (VA), Italy (ex- Kendle International)

- Management of activities associated to Phase II-IV clinical research studies.
- Management of applications to the Ethical Committees and Regulatory authorities
- Maintenance of current regulatory documentation according to Regulatory Guidelines
- Clinical and technical support for Clinical Research Associates

Sep-2006 - Feb-2007

Clinical Project Manager

Hyperphar Research, Milan, Italy

- Management of national and international phase IV clinical studies and observational studies, in different therapeutic areas.
- Management of applications to the Ethical Committees and Regulatory authorities
- Preparation of start-up clinical Investigators Meetings of the study
- Development and finalization of clinical trial agreements

Jan-2005 - Aug-2006

Clinical Research Associate

MDS Pharma Services, Assago (MI), Italy

- Project activities associated with monitoring functions of Phase II-IV clinical research studies.
- Site visits from pre-study visit to close-out visit.
- Submission of documents to Ethics Committees; preparation of applications and associated information for Ethics Committees; preparation of critical documents required for study implementation.

Sep-2002 - Dec-2004

Pharmacological Researcher

Department of Pharmacological Sciences, Milan, Italy

- *In-vitro* and *in-vivo* studies investigating processes involved in cardiopulmonary diseases (asthma, BCPO, bypass grafting)

EDUCATION AND TRAINING

Aug 2012 - present

Attendance of training organized by different organization

"Nutriceuticals" (SIMeF) – 2019
"Pharmocogenetic Study" (SSFA) – 2018
"e-Consent" (SSFA) - 2018
"IMP in clinical Trials" – 2017
"Nutriceuticals" (SSFA) - 2016
"Clinical Trial in Italy" (SSFA) - 2015
"European Regulation 536/2014" (Regione Lombardia) - 2015
"Informed Consent Form" (AICRO) - 2014
"Privacy Law in Clinical Trial" (AICRO) - 2014
"Future of Clinical Trial in Italy" (SSFA) - 2013

Jan-2004 - Jun-2004

Pharmacovigilance Post-degree Specialization Course

SEFAP, Milano, Italy

- The course had the objective of providing appropriate tools to address pharmacovigilance problems and to identify the most appropriate approaches to develop this activity. It also provided solid and thorough basis of biostatistics, pharmacology and pharmacoepidemiology

Sep-1996 - Jul-2002

Degree in Chemistry and Pharmacological Techniques

Università degli Studi, Milano, Italy

- Graduated on July 17, 2002 discussing a thesis titled "Oxidative stress in coronary artery bypass grafting: two techniques compared" held at the Department of Pharmacological Sciences in collaboration with the Cardiology Centre Monzino. Score: 107/110

PERSONAL SKILLS

Mother tongue(s): Italian

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	C1	C1	C1	C1	C1

Levels: A1/2: Basic user - B1/2: Independent user - C1/2 Proficient user
Common European Framework of Reference for Languages

Communication skills	▪ Maintain timely and effective communication among study team members and EC/CA staff.
Organisational / managerial skills	▪ Ability to successfully support internal and external customers. ▪ Ability to develop, organize, and manage multiple tasks. ▪ Ability to work independently and good attitude for teamwork. ▪ Routinely anticipates/identifies potential issues and implements corrective actions independently.
Job-related skills	Knowledge of the most important Italian ministerial/legislative decrees and the international regulations
Computer skills	▪ Competent with most Microsoft Office programmes (Excel, Word, PowerPoint), Outlook and Internet Explorer
Other skills	▪ Enjoy running and trekking ▪ Enjoy reading
Driving licence	Driving licence type B

ADDITIONAL INFORMATION

Honours and awards Memberships	▪ Membership: SIMeF (Società Italiana di Medicina Farmaceutica) ▪ Qualification to practice as a Pharmacist (July 2003)
Personal Data	I authorize the treatment of my personal data pursuant to European Regulation 536/2014 and to Italian Legislative Decree 30 June 2003, n. 196 as modified by Legislative Decree 10 August 2018, n. 101