

Ylenia Runci

WORK EXPERIENCE

January 2020 – Present

Regulatory Affairs Senior Manager

Seqirus S.r.l.

RA Senior Manager, WHO & EU pandemic vaccines

Principal current accountabilities:

- Independently lead the development and implementation of the regional regulatory strategy for assigned products.
- Provide regional expertise to support global regulatory strategies for global development products, global CMC & compliance projects and global labelling projects.
- Ensure dossiers are compliant and meet content requirements for the region.
- Responsible for coordinating preparation, compilation and submission of high quality applications including marketing authorisation applications, variations, renewals, responses to questions and regulatory agency briefing documentation.
- Develop collaborative and respectful relationships with staff at National Human Medicines Regulatory Agencies within the region and represent the company at external regulatory agency meetings as relevant to the project or product portfolio.

Regulatory Affairs key activities experienced over the time:

- RA activities related to lifecycle management of pandemic and seasonal influenza vaccines for both Europe (CP and MRP) and RoW countries (National) such as variations including seasonal strain updates, renewals, marketing authorization transfers, clinical trials applications (CTA), PIP amendments, PSUR, DSUR, etc.
- Preparations of pandemic influenza vaccine regulatory submissions in Europe (CP) during 2009-2010 pandemic outbreak.
- Managing of WHO Pre-qualification submissions.

[Business or sector](#) Regulatory Affairs in Pharmaceutical Industry

September 2016 – December
2019

Regulatory Affairs Manager

Seqirus S.r.l.

[Business or sector](#) Regulatory Affairs in Pharmaceutical Industry

April 2015 – August 2016

Regulatory Affairs Senior Specialist

Novartis Vaccines Influenza S.r.l.

[Business or sector](#) Regulatory Affairs in Pharmaceutical Industry

September 2013 – April 2015

Regulatory Affairs Specialist

Novartis Vaccines and Diagnostics S.r.l.

[Business or sector](#) Regulatory Affairs in Pharmaceutical Industry

- 2008 – August 2013 **Regulatory Affairs Senior Associate**
Novartis Vaccines and Diagnostics S.r.l.
Via Fiorentina 1, 53100 Siena - Italy
Business or sector Regulatory Affairs in Pharmaceutical Industry
- 2006 – 2007 **Regulatory Affairs Associate**
Novartis Vaccines and Diagnostics S.r.l.
Business or sector Regulatory Affairs in Pharmaceutical Industry
- 2005 – 2006 **Post Doc researcher**
Chiron S.r.l.
- Main project: Evaluation of antigen candidates for the development of a vaccine against Group B streptococcus (GBS).
- Business or sector** Research in Pharmaceutical Industry
- 2001 – 2004 **PhD in Biotechnology**
Department of Molecular Biology, University of Siena, Italy
- Main project: Production of new dendrimeric peptides that neutralize anthrax lethal toxin in vivo.
- Business or sector** Academic research institution
- 1999 – 2001 **Contractor**
Institute of Anatomy and Pathological Histology, University of Siena, Italy
- Main project: Development of advanced diagnostic and therapeutic methodologies.
- Business or sector** Academic research institution

EDUCATION AND TRAINING

- 2006 **Specialization in Clinical Biochemistry** 70/70 magna cum laude
Institute of Clinical Biochemistry, University of Siena, Italy
- 2004 **PhD in Biotechnology**
Department of Molecular Biology, University of Siena, Italy
- 1999 **Qualification exam for Biologist profession** 150/150
- 1998 **Master's degree in Biological Sciences** 110/110 magna cum laude
University of Siena, Italy

PERSONAL SKILLS

Mother tongue(s) Italian

Other language(s)	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	C1	C1	C1	C1	C1
French	A2	A2	A1	A1	A1

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user
[Common European Framework of Reference for Languages](#)

Communication skills ▪ Good communication and effective listening skills.

Organisational / managerial skills ▪ Very good organizational and prioritization skills.
 ▪ Action-oriented, drives results, attention to details, problem-solving.
 ▪ Good leadership skills.

Computer skills ▪ Proficient with Microsoft Office programmes, Outlook and Internet Explorer.

ADDITIONAL INFORMATION

Memberships

National Order of Biologists

Training Courses

- “Managing@Seqirus”, Amsterdam, 22-23 January 2019 and 12-13 March 2019
- “Interpersonal Communication skills”, Siena, 11-12 June 2014
- “Analysis and Problem Solving”, Siena, 19-20 November 2013
- “Writing in the Regulated Environment When English Is Your second Language”, Siena, October 2010.
- “Special Training Course on US Regulatory Affairs”, Amsterdam, 23-26 October 2006.
- “Introduction to European Regulatory Affairs”, London, 01-03 November 2006.