

PERSONAL INFORMATION

Nicola Orlandi

WORK EXPERIENCE

April 2016 – today

Head of Data Privacy Pharma

Novartis International AG

- In my role I am partnering with divisional business to enable growth, productivity and innovation, implementing privacy controls and considering data privacy requirements as well as business needs.
- Major accountabilities: to build scientific and business expertise in area of division in order to fully understand data privacy related business needs, to assess business strategy and projects as well as project proposals with regard to arising data privacy challenges and provide associated legal counselling.
- Main area of involvement: Digital Medicine, Real World Evidence/Big Data, Data transparency; Data Anonymization and pseudonymization and participation in external projects (IMI Webradr, IMI DO-IT) representing Novartis.

July 2014 – March 2016

Global Pharma Privacy Officer

Novartis Pharma AG

- Define Group strategic Data Privacy approach participating in the Group Data Privacy Team;
- Develop strategy for divisional privacy procedures framework based on Group Privacy policies including creation of procedures, processes, toolkits, training and awareness programs privacy requirements specific to the division (for example a new toll for assessing new system and databases from a privacy point of view; Guideline on anonymization);
- Monitor emerging data privacy legislation, trends, and legal analysis impacting the Division's business priorities;
- Train and oversee a global network of privacy representatives responsible for implementing the divisional privacy program within their countries;
- Managing and coordinating Countries within the Pharma Division in the implementation of the global data privacy program and Binding Corporate Rules;
- Supporting and advice business in the implementation of new project (for ex. Big Data/RWE Initiatives and related governance model, Digital Medicine, Global Outsourcing projects, EFPIA initiative for the disclosure of payments to HCP; EMA initiative for the transparency of clinical trials data) or in improving existing business activities and processes related to the processing of personal data (delocalization of HR data, definition of a global Master Processing Agreement);
- Support cross-divisional privacy projects;
- Oversees privacy risks and remediation and act as the local data protection officer for the Swiss Pharma entities;
- Leading privacy impact assessment teams for assessments of privacy relevant systems and processes within Pharma Switzerland including global systems and advising and counselling the business and IGM on privacy matters, DPA inspections, security breach incidents, data subject access requests and/or complaints;
- Monitor divisional compliance of privacy program through country assessments and report findings and related risks to Pharma Executive Committee and Global Head Data Privacy;
- Oversee the Company Level Controls for Privacy within the Pharma Division
- Lead Privacy Impact Assessments for Global projects monitoring impacts to patient, consumer and employee privacy resulting from Pharma projects and systems.

February 2011- June 2014

Head of Legal and Compliance. Data Privacy Officer for Sandoz S.p.A. and Sandoz Industrial Products S.p.A. and Country Data Privacy Officer for Italy

Sandoz S.p.A (Origgio)

- Area of interests: Advice and support on pharmaceutical matters, labour law, Intellectual Property, including litigations; advice and support on compliance matters including Novartis policies and procedures and European and local law implementation (231/2001 Decree on Company responsibility; HSE; Data Privacy Legislation). Compliance activities were mainly focused in assessing new projects and initiatives in line with global and local policies and laws, in monitoring risks through dedicated tools; training people in the organization and, in the area of Company responsibility, in leading the local Surveillance Committee according to 231/2001 decree and supporting external advisors in monitoring and auditing activities.

- In Data Privacy: Implementation of global policies and guidelines as well as of local laws and regulation (including implementation of Novartis Binding Corporate Rules); advice to business in case of local and/or global projects and activities; drafting of notices, privacy clauses; management of data processing and data transfer requirements; monitoring activities and support to local certification of the HCP databases according to the local law working with a certification agency.
- Reporting structure: 3 associates (Compliance Manager; Legal Specialist; Legal support)

2002 to 2011 Group Company Legal Department Officer

Novartis Farma S.p.A (Origgio)

- Responsible for legal affairs of various companies and product lines (Sandoz S.p.A.; Sandoz Industrial Products S.p.A.; Ciba Vision S.r.l.).
- Area of interests: Contract law, litigations, company law, labour law, Intellectual Property, implementation of 231/2001 Decree on Company responsibility, Data Privacy Legislation.

2000 to 2002 Appointed to Divisional Legal Office

Novartis Consumer Health S.p.A.

- Particular areas of interest include: Contract Law, Company Law, Civil Law; Nutritional and Pharmaceutical Legislation.

2000 Brief Internship with Group Company HQ

Novartis Italia SpA

- Training and assistance in all areas of company law.

EDUCATION AND TRAINING

2003 Official Entitlement in Italy to practise Law**1994 Graduate of Faculty of Law.**

University of Pisa

1993 Erasmus project

International University of Lisbon, Law Faculty