CURRICULUM VITAE

CASUCCI MARCO
Frazione Molinazzo 1F – 23883 – Brivio (LC) - Italy
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Place of birth: Carrara (MS) - Italy
Nationality: Italian

PROFESSIONAL EXPERIENCE

July 2019 - present
Sr Director Regulatory Affairs – Italian Country Manager, Precision for Medicine (IT) Srl – Milan, Italy

- Leads and coaches the regulatory team (Managers, Associates)
- Line management role (manages workload, resources, assignations, utilization, development)
- Assignation of regulatory resources (wider team)
- PSPs and budget
- SOP writing
- Trainings delivery (regulatory people and wider organization)
- Oversees regulatory affairs activities and deliverables, as needed, for trials carried out by the company
- Reviews and provides technical advice for regulatory submissions (CA and ECs)
- Coordinates large global clinical trial submissions (as global regulatory lead) with global cross-functional teams
- SME for regulatory topics [EU CTR] and for the Italian regulatory environment
- Italian country manager
- Works for the compliance of the Italian affiliate (eg to AIFA Decree 15nov2011, Decree 81/2008..)

November 2018 – July 2019
Regulatory Affairs Manager, PPD Italy Srl – San Felice, Italy

- Coordinates large global clinical trial submissions with global cross-functional teams.
- Acts as subject matter expert in providing regulatory strategy advice and technical expertise.
- Provides regulatory consulting and strategic advice to internal and external clients to determine the most appropriate regulatory and product development strategy for client's products.
- Manages project budgeting/forecasting functions
- Reviews and provides technical advice for regulatory submissions in Italy.
- Oversees regulatory affairs activities, as needed, for all trials carried out in Italy

June 2017 – November 2018
Drug Regulatory Affairs – Senior Clinical Trial Manager, Idorsia Pharmaceuticals Ltd – Allschwil, Switzerland

- Global coordination and interaction with teams and third parties (CRO) to give regulatory input and guidance for clinical trials and their submission (Initial CTA, Import/Export Licenses, Amendments, EOT, CSR) to European and international Health Authorities (HAs).
  REGIONS: EU, EEU, China, Asia-Pacific, Canada & South America, Africa & Middle-East

- Prepares, submits and maintains CTAs to European HAs in accordance with the applicable regulatory requirements (both VHP procedure and National Applications).
- Interactions with HAs regarding CTAs.
- Contributes to update of existing and creation of new internal SOPs and processes.

October 2015 - June 2017

Drug Regulatory Affairs – Clinical Trial Manager, Actelion Pharmaceuticals Ltd – Allschwil, Switzerland (via Stamford Consultants AG – Dornach, Switzerland)

- Global coordination and interaction with teams and third parties (CRO) to give regulatory input and guidance for clinical trials and their submission (Initial CTA, Import/Export Licenses, Amendments, EOT, CSR) to European and international Health Authorities (HAs).
  REGIONS: EU, EEU, China, Asia-Pacific, Canada & South America, Africa & Middle-East
- Prepares, submits and maintains CTAs to European HAs in accordance with the applicable regulatory requirements (both VHP procedure and National Applications).
- Interactions with HAs regarding CTAs.
- Contributes to update of existing and creation of new internal SOPs and processes.

December 2009 –October 2015

Regulatory Affairs Consultant, PC-CTRS, PAREXEL International S. r. l. – Milan, Italy

- acts as Regulatory Leader (Regulatory Clinical Trial Manager), globally coordinating regulatory teams and relevant tasks for multicentre international studies
  - participation to Bid Defence Meetings and Kick-Off Meetings;
  - main Sponsor point of contact to define regulatory strategies and for any regulatory issues;
  - main responsible person for regulatory targets achievement;
  - coordination and guidance of assigned local teams (Regional Leaders and Local Regulatory Contacts);
  - management of the budget;
  - drafting and release of CORE EudraCT Annexes (Initial CTA, Amendments, EOT) as well as interaction with Sponsor to build up the CORE package for global submissions (from cover letter wording to check of needed documentation, including management of CMC data - IB-IMPD-Manufacturing Authorizations...);
  - drafting and release of IMP Master Labels;
  - interaction with Clinical Supply Dept. for proper management of the IMP (drafting of the study kit of the IMP, shipments, storage in central depot..);
  - coordination of local teams for translation and adaptation of Country IMP labels, IMP management, country submissions to local Regulatory/Competent Authorities;
  - experience in VHP procedure.

  MAIN AREAS: vaccines, oncology, dermatology, rheumatoid arthritis, analgesics.
  MAIN REGIONS: EU, Russia, Belarus,Serbia, Turkey, Ukraine, North America, South America, India, Australia, Asia Pacific.
  - Ability to make decisions involving conflicts of interest
  - Coordination and planning of budgets, people and time management
  - Problem solving at a strategic level
  - Careful planning to achieve accurate and timely results

- acts as Italian Regulatory Advisor for any consultancy or activity related to Italian regulatory environment:
  - local laws and regulations (phase I-II-III-IV clinical trials, non-interventional studies, compassionate use, no profit studies, import-export drugs e.g. narcotics / dietary supplements, management of expired IMPs.);
  - translation and regulatory compliance of IMP Italian labels;
  - management of the Osservatorio database and relevant applications to AIFA;

- Italian maintenance of product licenses (e.g. variation preparation and submission)

Italian Privacy Officer ("Data Protection and Privacy Coordinator"), PAREXEL International S. r. l. – Milan, Italy,

- Acts as the Italian contact person for data protection & privacy related questions. Company issues – e.g. management of employees' data protection, drafting of company privacy documents (DPS), appointment of data processors, management of system administrators.
  Clinical Issues – e.g. check of the ICFs (Informed Consent Forms) compliance with the privacy law, privacy consultancy related to clinical trials management (e.g. genetics studies, bio-banks, special authorizations ex art 110 of DLgs 196/2003)
- Monitors local data protection & privacy related legal requirements and inform other privacy officers about changes
- Coordinates and delivers local privacy trainings

February 2008 – December 2009
Clinical Trial Specialist, PAREXEL International s.r.l. – Milan, Italy,

- preparation and submission of documents to ECs (e.g. request of authorization, standard documents needed for submission of protocol and protocol amendments).
- negotiation and finalization of contracts with the sites.

August 2003-February 2008
Contract Manager & Privacy Officer of the CRO (Contract Research Organisation) **studio vizzotto HIGH RESEARCH S.r.l.** (formerly Studio Vizzotto sas) – Via Fara, 30 – 20124 Milano

- drafting and negotiation of national and international clinical trial contracts between:
  (1) Sponsors and Institutions
  (2) Sponsors/other CROs and studio vizzotto HIGH RESEARCH srl
- legal, regulatory and ethical-administrative consultancy in the pharmaceutical area
- privacy consultancy (DLgs 196/2003) at a Company level (management of employees' data protection, drafting of company privacy documents (DPS), appointment of data processors) and at a Clinical trial level (check of the ICFs compliance with the privacy law, privacy consultancy related to clinical trials management)
- resolution of clinical trial insurance policies issues
- resolution of European VAT issues

EDUCATION

05 October 2015
Degree in Law at the **University Bicocca**, Milan

March 2007-November 2007
March 2008-November 2008
Master in DRA ("Regulatory Affairs") at the **University of Pavia**

October 2002
Master's Degree in Economics at the **University Luigi Bocconi**, Milan

1997
Senior High School - Science Education "B. Pascal", Milan.

LANGUAGE SKILLS

ITALIAN
Mother tongue

ENGLISH
Business Fluent - in written and spoken

FRENCH
Upper-Intermediate - in written and spoken
2000 - "*Certificat pratique de français commercial et économique" at "Chambre de Commerce et Industrie de Paris*"

GERMAN
Beginner (level A.2) - in written and spoken

COMPUTER LITERACY

In depth knowledge of:
- Windows
- Internet Explorer
- Office (Excel, Word, Power Point, Outlook, Publisher)

ORGANISATION SKILLS

Ability to work within a team environment.
Ability to work under pressure to tight deadlines.
Accuracy and attentiveness to details.
Ability to function in a high-paced, dynamic environment.
Showing initiative.

DRIVING LICENCE

"B"

MILITARY SERVICE

Fulfilled.

I give my consent to process my above indicated personal data for selection and communication aims.