Contatta

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www.linkedin.com/in/giada-di-leo-a8679470 (LinkedIn)

Competenze principali

Regulatory Affairs
Sperimentazioni cliniche
Regulatory submissions

Languages

Italiano (Native or Bilingual)
Inglese (Professional Working)

Certifications

European Computer Driving Licence (ECDL)

Giada Di Leo

Regulatory Affairs and Pharmacovigilance Manager
Modena

Esperienza

JSB Solutions

1 anno 9 mesi

Regulatory Affairs and Pharmacovigilance Manager
settembre 2020 - Present (1 anno 3 mesi)

Senior Regulatory Affairs Coordinator
marzo 2020 - settembre 2020 (7 mesi)
Italia

Holostem Terapie Avanzate S.r.l.

3 anni

Regulatory Affairs and Clinical Trial Coordinator
gennaio 2018 - marzo 2020 (2 anni 3 mesi)
Modena, Italia

Proactively manage project level operations, including but not limited to, aspects including management of trial timeline, budget, resources with consideration of quality standards and risk mitigation. Provide efficient and effective updates on trial progress to the Medical Director as requested. Study start-up processes, including but not limited to, conduct the trial kick-off meeting, the quality control of trial master file (TMF), vendor and CROs selection, site selection and finalization of site and vendor. Clinical Trial Agreements (CTAs) and budgets; ensure effective project plans are in place and operational for each trial. Proactively coordinate with the Clinical Trial Team to establish the priorities in accordance with applicable project plans, company standard operational procedures (SOPs), GCP guidelines and regulatory requirements. Develop and preparation, in collaboration with medical expert, of clinical study protocol; develop specific protocol training for Site Initiation Visits and Investigator Meetings, for the company site facing roles and vendor / CRO staff. Assist the medical expert in the preparation/ writing of the clinical content of regulatory submissions/documents (e.g. New Drug Application, Marketing Authorization Application, Investigational New Drug dossier, Investigators Brochure (IB), Annual Report). Regulatory submission for Competent Authority and Ethic Committee according to local and scientific requirements; managing Initial Clinical Trial Application form

on different website and amendments to different regulatory documentation. Regulatory compliance, Compassionate-use program and ethics committee applications.

Start up Specialist and Clinical Trial Assistant
aprile 2017 - dicembre 2017 (9 mesi)
Modena, Italia

Regulatory submission for Competent Authority and Ethic Committee according local and scientific requirements. Managing Initial Clinical trial Application form on different website and Amendments to different regulatory documentation. Preparation of regulatory dossier for authorization to the Competent Authority for trials. Life cycle management for Clinical trial and CMC documentation;
applications for orphan designation and Advanced Therapy Medicinal Product. Compassionate-use program and ethics committee applications.

JSB Solutions
3 anni 2 mesi

Regulatory Affairs and Study Start up Specialist
settembre 2016 - marzo 2017 (7 mesi)
Modena, Italia

Regulatory submission for Competent Authority and Ethic Committee according tolocal and scientific requirement - Managing Initial Clinical trial Application form on different website and Amendments to different regulatory documentation - Preparation of regulatory dossier for authorization to the Competent Authority for trials - Regulatory submission - Marketing Authorizations according to the CTD structure - Evaluation and/or review of dossiers for already registered products - Life cycle management for licensed products - Variations, extensions and renewal CMC documentation - Applications for orphan designation and Advanced Therapy Medicinal Product
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Compassionate-use program and ethics committee applications.

Regulatory Affairs Consultant
febbraio 2014 - agosto 2016 (2 anni 7 mesi)

Regulatory submission - Marketing Authorizations according to the CTD structure;
Evaluation and/or review of dossiers for already registered products, Life cycle management for licensed products, Variations, extensions and renewal, CMC documentation;
Applications for orphan designation; Advanced Therapy Medicinal Product;

Compassionate-use programmes, ethics committee applications; Cosmetic Products Notification.

Cosmofarma S.r.l.
Regulatory Affairs junior
gennaio 2013 - gennaio 2014 (1 anno 1 mese)
Pistoia

-Revision of the Cosmetics Directive
-Preparation of documentation of notification to the Italian Ministry of Health needed to get the permissions to the production and marketing of cosmetic products and notification to the CPNP, the online notification system created for the implementation of Regulation (EC) No 1223/20091 of the European Parliament and of the Council on cosmetic products.
-Implementation / verification of GMP requirements.
-GMP and Regulatory Support.

Formazione

ALMA LABORIS Business School
Master in Management & pharmaceutical marketing · (2013 - 2013)

ALMA LABORIS Business School
Regulatory Affairs Specialist, Corso di Alta Specializzazione in Affari Regolatori · (2013 - 2013)

Università di Pisa / University of Pisa
Master's degree in Chemistry and Pharmaceutical Technology · (2012)

Università di Roma Tor Vergata
Course: Understanding the EU Regulation – Accelerate the pathway to approval for Orphan Drugs, Farmacia