Contatta

www.linkedin.com/in/emanuela-disconzi-42a19233 (LinkedIn)

Competenze principali

CRO
Clinical Trials
ICH-GCP

Emanuela Disconzi

Principal Site Start-up & Regulatory presso Syneos Health
Marnate

Esperienza

Syneos Health
4 anni 6 mesi

Principal Site Start-up & Regulatory Specialist
aprile 2021 - Present (9 mesi)
Saronno, Lombardia, Italia

Senior Site Start-up & Regulatory Specialist
luglio 2017 - marzo 2021 (3 anni 9 mesi)
Saronno

Local Submissions: primary point of contact for the PM/SSUL (or designee) during start-up on allocated projects. Reviews essential document packages for site activation and may also be involved in essential document collection from site. Prepares and submits Central EC Applications, Local EC Applications, RA Applications, and other local regulatory authorities (like narcotic board) or hospital approval submissions as required. Prepares ongoing submissions, amendments, and periodic notifications required by central and local EC and RA, and other local regulatory authorities as needed within the country; includes safety notifications as required by local rules.
Country Start-Up Advisor: Acts as Subject Matter Advisor for in-country performance within the Site
Start-Up.
Local Site ID and Feasibility Support-
Local Investigator Contract and Budget Negotiator - Works with contracts specialist to agree on site specific country template contract and budget.
Line management responsibilities -Participate to activities related to department staff
operations, such as interviewing and selection, professional development, performance management,
and employee counseling and separations.
Mentorship for new hire

INC Research
Site Start Up & Regulatory Specialist II
agosto 2012 - giugno 2017 (4 anni 11 mesi)

Saronno

Local Submissions Specialist - Primary point of contact for the Project Manager/Site Start Up Lead
during start-up on allocated projects. Prepares all tyhe documents required in Italy for submission and submits Central EC Applications, Local EC Applications, RA Applications, using AIFA web portal. Support for the Sponsor for submission to other local regulatory authorities or hospital approval submissions as required (Narcotic board, data privacy Authority). Prepares ongoing submissions, amendments, and periodic notifications required by central and local EC and RA, and other local regulatory authorities as needed within the country; includes safety notifications as required by local rules.

Kendle International Inc
Clinical Regulatory specialist I
settembre 2010 - luglio 2012 (1 anno 11 mesi)

Kendle International s.r.l
Clinical Research Associate II
agosto 2007 - agosto 2010 (3 anni 1 mese)
Saronno

OPIS
Clinical Research Associate
agosto 2005 - luglio 2007 (2 anni)
Desio

Università degli Studi di Milano-Dipartimento Scienze Farmacologiche
Ricercatrice
aprile 2003 - agosto 2005 (2 anni 5 mesi)
Milano

Formazione

Università degli Studi di Milano
Laurea in biotecnologie farmaceutiche, biotecnologie · (1997 - 2002)