Evnia

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MARTINA POLLASTRINI

Clinical Evaluation Writer
MEDDEV / MDR

PROFESSIONAL PROFILE

- Writer and editor of Clinical Evaluation Plan and Report for medical devices in accordance with Medical Device Directive 93/42/EEC and amendment 2007/47/EEC (MDD), Medical Device Regulation 2017/745 (MDR), MEDDEV 2.7.1 Rev 4 'Guidelines on Medical Devices. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under 93/42/EEC and 90/385/EEC' (2016) and GHTF Guideline SG5/N2R8:2007 'Clinical Evaluation'.
- Team leader of several projects on preparation and revision of regulatory documents for medical devices with different field of applications.
  - Main point of contact for key international customers for the execution of complex and high value multi-site projects across multiple business lines.
  - Ensuring clear definition of project objectives, roles and responsibilities and communication lines;
  - Coordination of the activities to ensure a consistent/standardized approach across different projects of the same protfolio;
  - Completion of assigned projects towards objectives within agreed timelines and guaranteeing high quality standards;

LANGUAGES:

- **English** (full proficiency)
- **Italian** (mother-tongue)

EDUCATION:

- **Ph.D. in Medicinal Chemistry**, University of Siena, Siena Biotech S. p. A, Italy. January 2007.
- **Second level Master in Drug Design and Synthesis**, University of Siena, Italy. December 2003.
- **Graduation degree in Chemistry and Pharmaceutical Technologies** (Medicinal Chemistry), University of Pisa, Italy, June 2002.

TRAINING / CERTIFICATIONS:

- Qualification to the practice of Pharmacists, December 2002.

EXPERIENCE:

- October 2018 - current: **Team Leader, Senior Medical Writer**. Evnia

  Main responsibilities:
  - Support Writers in Clinical Evaluation Protocols/Report
  - Final review of Clinical Evaluation Protocols/ Report to verify validity of content and use of language.
  - Provide project updates as required.
  - Liaise with client relevant stakeholders when necessary /required for the completion of the project as required.
  - Support documentation writers to Clinical evaluation Plan/Report completion within timelines.
  - Provide any amendments necessary by client.
  - Appraisal of clinical Evaluation Reports GAP Assessment (review of Clinical Evaluation Report against requirements of the European Medical Device Regulation (MDR) EU 2017/745)
  - Complete Clinical Evaluation Plan and Clinical Evaluation Report in accordance with: Medical Device Directive 93/42/EEC and amendment 2007/47/EEC (MDD), Medical Device Regulation 2017/745 (MDR), MEDDEV 2.7.1 Rev 4 'Guidelines on Medical Devices. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under 93/42/EEC and 90/385/EEC' (2016) and GHTF Guideline SG5/N2R8:2007 'Clinical Evaluation'
  - Provide correct proof documentation.
  - Search relevant regulatory & scientific databases for CER/CEPs and include the results in the relevant documentation.

- August 2017 - current: **Senior Medical Writer**. Evnia

  Main responsibilities:
  - Complete Clinical Evaluation Plan and Clinical Evaluation Report in accordance with: Medical Device Directive 93/42/EEC and amendment 2007/47/EEC (MDD), Medical Device Regulation 2017/745 (MDR), MEDDEV 2.7.1 Rev 4 'Guidelines on Medical Devices. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under 93/42/EEC and 90/385/EEC' (2016) and GHTF Guideline SG5/N2R8:2007 'Clinical Evaluation'
  - Provide correct proof documentation.
  - Search relevant regulatory & scientific databases for CER/CEPs and include the results in the relevant documentation.

- June 2015 - August 2017: Scientific Information Consultant and Project & Grant Manager, Indipendent Consultant.

  Main responsibilities:
  - Scientific information: preparation of white papers, peer reviewed articles, general scientific communications based on commissioner requirements.
  - Compound management activities: analysis of a compound collection, definition of compound set of interest and arrangement of all the activities for the transfer of the compound collection the screening site.
  - Grant manager of public co-funded research projects (Italian and European projects). Responsible for the preparation scientific reports; collection of all the documents required for the preparation of the financial statement (e.g. Orders, Invoices, Payments, Time sheets, payslip, etc…); Reconciliation of costs sustained and resources allocated to the project; transfer of documents to the funding entity via web based portal.

- July 2008 - June 2015: Scientist Compound Managment and analysis, Siena Biotech S.p.A, Siena, Italy

  Main responsibilities:
  - Quality control of internal and acquired compounds.
  - Internal Certificate of analysis preparation and release.
  - Analytical support to the Department of Medicinal Chemistry.
  - New compound registration in the Siena Biotech database.
  - From June 2014 responsible for the entire compound management platform.
  - From January 2013 Test Item manager for the management of external compounds belonging to other companies tested in house.

- January 2004 - July 2008: Junior Scientist Medicinal Chemistry, Siena Biotech S.p.A, Siena, Italy

  Main responsibilities:
  - Medicinal chemist. Medicinal Chemistry team representative in a Lead Optimization stage SNC drug discovery project.
  - For two years Laboratory superintendent.

- June 2002 - January 2003: Research Fellow Medicinal Chemistry, Univesrity of Pisa, Italy.

  Main responsibilities:
  - Medicinal chemist.