Heather L. Harvey, MS, RAC

9 Newbury St, Woburn MA 01801 – 617-959-4856 –
h.louise.harvey@gmail.com

Objective

Seeking Regulatory Affairs position in the medical device field where I may best utilize my knowledge and experience while developing new skills.

Experience

Regulatory Affairs Specialist

InVivo Therapeutics, Cambridge, MA

August 2016 – Present

- Responsible for the compilation and submittal of regulatory submissions in the United States in support of the company's IDE and HDE applications including the company's Annual Report
- Responsible for the compilation and submittal in support of two Investigational Testing Applications in Canada.
- Responsible for the completion and submittal of Clinical Trial Applications in the United Kingdom.
- Supported the development and submittal of company's HDE Modular Submission
- Supports Vice President of Regulatory Affairs in daily Regulatory Activities.
- Developed plan for electronic capture of Document Change Orders utilizing SharePoint
- Participant in Project Team Meetings.

Regulatory Affairs Specialist I

Instrumentation Laboratory, Bedford, MA

January 2016 – July 2016

- Authoring and filing of incident reports to Health Canada and FDA (through eMDR System in U.S).
- Responsible for implementation and success of field actions.
- Author of Recall Strategies to be submitted to FDA.
- Provides support for product registrations in the EU, China, and other major markets.
- Provides support for 510(k) submissions.
- Maintains product registration database
- Active participant in ISO Audits
- Active participant in risk analysis activities.
- Special 510(k) cleared 3/16/2016 (K160445).

Regulatory Affairs Coordinator

Instrumentation Laboratory, Bedford, MA

March 2013 – January 2016

- Author and filing of incident reports to Health Canada and FDA
- Provided support through field action process.
- Maintained product information spreadsheet
- Provided support for product registrations in the EU, China, and other major markets.
- Provided direct support to Regulatory Affairs Director.
- Maintained Certificate to Foreign Government Files and Submissions.
- Administrative duties as needed.

Additional Experience

Adjunct Professor

Northeastern University College of Professional Studies

January 2017 – Present

Course: Intro to Drug and Medical Device Regulations

- Develop course lectures and activities to provide students with an understanding of the basic principles of US Medical Device Regulations.

Education

Master of Science, Regulatory Affairs
Northeastern University, Boston, MA
Graduated: July 2016

Bachelor of Arts, Professional Writing
Fitchburg State University
Graduated: December 2012

Skills & Achievements

US RAC Certification Obtained Spring 2017

Member of the Fitchburg State University English Honors Society

Proficient in Sharepoint, ShareFile, SAP, FileMaker Pro, and Visio.

Notary Public.

References

References Available Upon Request

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