DYNEX TECHNOLOGIES	**Document type:** **Job Description**	**Document Number:** **JD103**
Job Title: Regulatory Manager	**Revision** **A**	**Authored Date:** **2018-7-3**

Department: Quality Assurance (QA)

FLSA Status: ☒ **Exempt** ☐ **Non-Exempt**

Job Summary: To deputize for the QA/RA Director(s) in their absence. To act as a responsible Person as required by regulation.

To have direct responsibility for technical files (STED), international registration and to keep the company abreast of new regulations that are applicable. To assist with 510(k) and clinical trials.

Quality Assurance responsibilities are risk management, auditing and new product development design control although other duties may be assigned as required.

Essential Functions:

Sole: Construct and maintain Standard Technical files as evidence of compliance to European and US regulations and other authorities as required.

Sole: To produce reports and training literature on new regulations.

Sole: To oversee the RoHS technical file construction and to verify their compliance.

Sole: To produce post market surveillance reports and trending.

Joint: To ensure risk management files are compliant to ISO14971 and are current.

Joint: To give strategic direction for 510(k) and clinical trials.

joint: As required, to be a contact person for European authorities and FDA.

Joint: To take on and manage discrete quality or regulatory projects.

Joint: To be involved in and to manage planned site inspections and Audits.

Joint: To be the Regulatory subject matter expert for design control projects.

Joint: To conduct secondary and third party audits.

Joint: To act as one of company's Qualified Person (responsibilities are defined by regulation).

Joint: to be a Subject Matter Expert for vigilance and reportable events.

Joint: To write procedures in support of Quality, Regulatory and Clinical processes.

Joint: To train Dynex personnel on quality and regulatory topics.

Sole: to act as the Quality Representative for all Dynex European sites.

Joint: to assist with shipping compliance issues.

Supervisory Responsibilities: direct report of Regulatory Associate(s). Responsible for project managing discrete projects.

Success Factors: To be able to work independently and to manage project teams. To stay up to date with the current regulatory changes. To be able to communicate effectively through both written media and verbally. Strong mediation and negotiation skills. It would be beneficial to have formal qualification in auditing and project management.

Minimum Qualifications / Education: Specific knowledge of International standards and regulations inclusive of ISO, FDA, and EC/98/79 IVDD. A minimum of 5 years working with IVD devices with a scientific or engineering degree.

Computer Skills: Computer literacy in Windows, Word, Excel, powerpoint and Vision.

Work Environment: Office.

Physical Requirements: Must be able to meet National Institute for Occupational Safety & Health (NIOSH) Standards.

EMPLOYEE ACKNOWLEDGEMENT

I, _____, acknowledge review of this job description.
(Employee's Name - PRINT Name)

_____ **Date:** _____
Employee's Signature **YYYY-MM-DD**

_____ **Date:** _____
Supervisor's Signature **YYYY-MM-DD**