

## **Director of Research and Development**

*r*<sup>2</sup> Diagnostics, a sister company to Enzyme Research Laboratories, provides general purpose and specialty assays to the clinical coagulation laboratory. ERL is known worldwide for purified coagulation factors and research reagents. *r*<sup>2</sup> was organized to incorporate ERL's high purity proteins and reagents into clinical diagnostic kits.

*r*<sup>2</sup> Diagnostics seeks a Director of Research and Development (R&D). We are looking for an energetic individual with an entrepreneurial attitude and a desire to play an integral role in the growth of the company.

### **Responsibilities:**

The Director of R&D is primarily responsible for new product development and technical support to manufacturing and to customers, consistent with the size and growth of the company, and in conjunction with the company Quality Policy and Objectives. Key activities include:

- Determine unmet needs of commercial potential for the clinical coagulation laboratory.
- Determine product and process essential requirements to meet these unmet needs.
- Plan, execute, and analyze experimental plans leading to manufacturing formulations and processes for products meeting or exceeding these essential requirements.
- Coordinate and lead multiple projects in new product development while meeting the requirements of the U.S. FDA and of ISO 13485 for IVDs.
- Provide technical support to operations and to customers for all existing and future products.
- Collate and maintain required files and documents which support regulatory submissions.
- If necessary, prepare and lead PMA and 510(k) filings, Technical File preparation, and CE Marking.
- In cooperation with other functional managers create, review and approve QS documents to ensure compliance with QSR, ISO and other regulatory requirements. Provide training on these systems/procedures.
- Initiate corrective and preventive action plans and participate in corrective actions completion by performing root cause analysis and verifying effectiveness.

### **Required Education, Experience, and Characteristics:**

- Bachelor's degree in the natural or life sciences (minimum).
- Extensive experience and demonstrated success in research, development, and commercialization of clinical coagulation IVD products.
- Expert knowledge in experimental design and statistical analysis.
- Expert knowledge of the development process and Design Control, of manufacturing processes, and of clinical laboratory assay design and execution.
- Demonstrated experience working with ISO, FDA, and other key regulatory bodies within the past 5 years.
- Ability to communicate at all levels in a diagnostic/manufacturing environment, project management skills, and good interpersonal skills.

Please send resume to Chris Duffin at [chris@enzymeresearch.com](mailto:chris@enzymeresearch.com)