Director of Research and Development

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

r^2 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 for providing technical support internally and to customers, in accordance with the company Quality Policy and Objectives. Key activities include:

- Determine unmet needs of commercial potential for the clinical coagulation laboratory.
- Define customer, product design and process requirements to meet these unmet needs.
- Plan, execute, and analyze experimental designs leading to manufacturing formulations and processes for products meeting or exceeding these 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.
- Develop and maintain, together with QA/RA, 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 action 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 IVD products, preferably in the area of coagulation.
- 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