Clinical Trial Manager

ANPAC BIO-MEDICAL SCIENCE COMPANY USA – Sacramento

Anpac Bio-Medical Science Company is now accepting applications for a full-time, experienced, motivated, organized, and talented Clinical Trial Manager; that will help facilitate the safe, accurate, and successful clinical trials of Anpac’s proprietary, “Cancer Differentiation Analysis” medical devices, for eventual FDA approval and adoption for use in the United States.

Applicants must have extensive medical device clinical trial experience (IVDs preferred); as well as strong knowledge of GCP, FDA regulatory requirements, and demonstrated clinical trial management knowledge and practical application.

Among Anpac’s Clinical Trial Manager general duties include: representing the company in trial partnerships with hospitals and other medical institution collaborators, and FDA and other related consultants; supporting the FDA clinical trial planning and development; managing the company’s execution of FDA clinical trial operations, measurement, and reporting; and providing ongoing feedback and reporting for Anpac Research & Development teams related to the company’s CDA equipment and processes.

Job Roles & Responsibilities:

1. Planning, partnership management, and successful execution, of Anpac’s U.S. FDA clinical trials with medical institution and other collaborators.

2. Development and implementation of investigational research and clinical study.

3. Ensure all goals and objectives are met timely and effectively.

4. Track and report regularly on study timelines and trial budgets.

5. Plan the execution and monitor the completion of complex Phase I-IV assigned clinical research protocols.
6. Ensuring personal and company compliance with all Federal, State, Regional, and company regulations, policies and procedures for health, safety and environmental compliance.

7. Preparation of regulatory submissions, reporting, etc., to FDA.

8. Coordinate with medical group partners, FDA consultants, and internal groups, and other parties related to the FDA clinical trial process.

9. Create, manage, measure, and report timelines for milestone deliverables.

**Candidate Requirements:**

1. Minimum five years of clinical trial experience and two years' experience in research or similar role; IVD study experience preferred.

2. Experience in IVD product(s) development in a research environment.

3. Exceptional understanding of, and adherence to, intellectual property processes and protection.


5. Strong Knowledge of GCP and FDA regulatory requirements for clinical trial management.

6. Knowledge of software and electronic data handling, archiving, and storage.

7. Knowledge of health care delivery, administration, quality assurance, data management, personnel management, and budgetary management.

8. Knowledge of 21 CFR, GCP, CDASH/CDISC and FDA requirements regarding
clinical data management documentation and software.

9. Supervision or other similar experience in a leadership or team management position.

**Educational Requirements:**

A Master’s Degree in a Chemical, Physical, Biological, or similar clinical laboratory science from an accredited, educational institution.

Certification from HHS approved Board.

**Additional Skills:**

1. Strong organizational skills.

2. Self-motivated, team player.

3. Strong work ethic with stable employment history.

4. Ability to work in a fast paced, start-up environment, with demonstrated ability to manage numerous competing tasks and demands.

5. Ability to handle multiple projects / meet multiple deadlines.

6. Demonstrated leadership (or leadership potential), and logistic(s) skills.

7. Strong, sensitive, and thorough, verbal and interpersonal skills.

8. Enthusiasm and commitment to Anpac's corporate mission, goals and objectives.

9. Natural and continued scientific curiosity.

10. Proficiency in multiple languages a plus.
Salary dependent upon experience.

To apply for this position, please submit your resume or cv: HR@AnpacBio.com.

**About Anpac Bio-Medical Science Company:**

Anpac Bio-Medical Science Company is a pre-listing, multi-national, biomedical research and diagnostics company, currently developing break-through, early-stage cancer detection technology to help people win the battle against cancer. By analyzing simple, in vitro, whole “Blood Biopsies” with Anpac’s paradigm-shifting “Cancer Differentiation Analysis” (CDA) proprietary technology, and the company’s multi-level, multi-parameter, exclusive testing models, Anpac can identify at least ten different types cancers – usually at the disease’s earliest stages. To date, Anpac’s rigorous, published, research validity data from nearly 25,000 cases has demonstrated Anpac’s CDA technology successfully detecting and identifying early signals of threatening cancer – and the type of cancer (or where it is located in the body) with 75% - 90% accuracy.

Anpac Bio-Medical Science Company is now hiring experienced, talented, dedicated and innovative researchers, scientists, technicians, and other biosciences and technology leaders, for the company’s U.S. headquarters in Sacramento, CA. For more information and list of open positions, please check: www.AnpacBio.com.
Laboratory Manager

ANPAC BIO-MEDICAL SCIENCE COMPANY USA – Sacramento

Anpac Bio-Medical Science Company is now accepting applications for a full-time, experienced, motivated, organized, and talented Laboratory Manager; that will manage the safe, accurate, and successful launch and operations of Anpac’s proprietary, “Cancer Differentiation Analysis” technology and lab team.

Applicants must have extensive experience in laboratory management and team dynamics, as well as biochemistry. Experience and/or extensive knowledge of laboratory management related specifically to medical devices are plus.

Among Anpac’s Laboratory Manager general duties include: the set-up, launch, management, operations, and ongoing reporting of Anpac Laboratory operations in the United States; ensuring all company policies, procedures, and regulatory requirements are fully complied; representing the company in operations partnerships with hospitals and other medical institution, and research collaborators; and provide ongoing feedback and reporting for Anpac Research & Development teams related to the company’s CDA equipment and processes.

Job Roles & Responsibilities:

10. Set-up, launch, manage, and measure Anpac U.S. laboratory.

11. Assist in preparation of regulatory submissions to FDA and other government and/or partnership requirements.

12. Manage efficient and productive scheduling of lab time; and all project timelines and projections related to laboratory operations and personnel.

13. Train and recognize potential testing failures; and determine need for appropriate verification, operations adjustments/repairs, and measurement/monitoring.

14. Update, maintain, prepare, review, issue, and file laboratory records and reports.
15. Perform regular inspections/verifications.

16. Comply with all company, government, appropriate partner and other policies, guidelines, and regulatory requirements.

17. Provide ongoing, practical, job function professional development and training to coworkers and staff as needed.

18. Maintain records of repair, time, materials used, and preventative maintenance, of all laboratory equipment.

19. Interface and maintain positive relationships with hospital and all other organizations and/or personnel offering samples for Anpac testing or operations.

20. Establish, manage, measure, and enforce organizational Standard Operating Procedures ("SOP").

**Candidate Requirements:**

10. Minimum three years of experience as Lab Manager or similar research and/or leadership role; IVD research and/or study experience preferred.

11. Experience in IVD product(s) development in a research environment a plus.

12. Understanding/familiarity of IVD machines, biochemistry, medical devices, or similar.

13. Competency in the testing and troubleshooting complex medical devices.

14. Ability to manage multiple projects, and meet multiple deadlines.
15. Exceptional understanding of, and adherence to, intellectual property processes and protection.

16. Possess excellent reporting, measurement, and documentation skills.

17. Strong work ethic, project management, and organizational skills.

18. Understanding of and/or experience with regulatory requirements (FDA, ISO, etc.) and generally-accepted safety and operations practices and procedures.

**Educational Requirements:**

Masters Degree or above in Biology, Chemistry, Biochemistry, and/or related areas.

**Additional Skills:**

11. Strong organizational skills.

12. Self-motivated, team player.

13. Strong work ethic with stable employment history.

14. Ability to work in a fast paced, start-up environment, with demonstrated ability to manage numerous competing tasks and demands.

15. Ability to handle multiple projects / meet multiple deadlines.

16. Demonstrated leadership (or leadership potential), and logistic(s) skills.

17. Strong, sensitive, and thorough, verbal and interpersonal skills.

18. Enthusiasm and commitment to Anpac's corporate mission, goals and objectives.
19. Natural and continued scientific curiosity.

20. Proficiency in multiple languages a plus.

Salary dependent upon experience.

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Medical Device Engineer

ANPAC BIO-MEDICAL SCIENCE COMPANY USA – Sacramento, CA

Anpac Bio-Medical Science Company is now accepting applications for a full-time, experienced, motivated, organized, and talented Medical Device Engineer; that will be responsible for launching, operating, assembly, calibration, troubleshooting, maintenance, repair, testing and modifications of Anpac’s proprietary, “Cancer Differentiation Analysis” (CDA) technology and medical devices.

Qualified applicants are expected to have high-level competency and extensive experience testing and troubleshooting complex medical devices. Ideal candidates will be proficient and knowledgeable of the most relevant, latest technical information related to or supporting IVD and Biochemistry equipment and testing.

Job Roles & Responsibilities:

21. Plan, assemble, troubleshoot, repair, modify, etc., all Anpac equipment and related devices.

22. Assemble electro-mechanical prototypes and test fixtures; including complex motorized systems, pushbuttons, switches, indicators, displays into enclosures, sensors, motors, etc.

23. Provide and/or facilitate ongoing training, professional development and guidance to/for Anpac technicians.


25. Collect appropriate data to assist with root cause analysis, among other metrics.
26. Diagnose system malfunctions and make repairs.

27. Perform electrical and other safety tests on all Anpac equipment and related instrumentation.

**Candidate Requirements:**

19. At least five years of demonstrated engineering experience/familiarity of IVD machines, biochemistry, medical devices, or similar research and/or technical equipment.

20. Experience in IVD product(s) development in a research environment a plus.

21. Competency in the assembly, testing, and troubleshooting of complex medical devices and other technical equipment.

22. Strong familiarity and knowledge of current medical device regulations, FDA QSR, OSHA, ISO 9000, etc., practices and other related safety requirements.

23. Experience in technical writing of formal test procedures.

24. Ability to read and understand schematic diagrams, wiring diagrams, and mechanical drawings, etc.

**Educational Requirements:**

BS Degree or higher in Mechanical Engineering, Electrical Engineering, or similar.
**Additional Skills:**

21. Strong organizational skills.

22. Self-motivated, team player.

23. Strong work ethic with stable employment history.

24. Ability to work in a fast-paced, start-up environment, with demonstrated ability to manage numerous competing tasks and demands.

25. Ability to handle multiple projects / meet multiple deadlines.

26. Demonstrated leadership (or leadership potential), and logistic(s) skills.

27. Strong, sensitive, and thorough, verbal and interpersonal skills.

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