# V&V Manager (Medical Device Manufacturer)

Salary Range: £41,000 to £55,000 Location: Harrietsham, Kent

## Hybrid Working Opportunity

This role is hybrid, requiring the successful candidate to attend our Harrietsham office three days per week, with the flexibility to work from home up to two days a week once deemed competent to work independently. Applicants must be UK-based and live within a practical commutable distance of our office.

## Interviews

The job advert closes on **25th March 2025**, with 1st stage telephone interviews during the week commencing **3rd April 2025** and 2nd stage face-to-face interviews during the week commencing **10th April 2025**.

## The Story:

Established in 1976, Bedfont is an award-winning medical technology company based in Harrietsham, Kent. Its breath analysis medical devices are exported globally thanks to its network of carefully selected distributors.

## The Challenge:

Healthcare is evolving and the market for breath analysis monitors is expanding. Bedfont are looking for hard-working, like-minded, and passionate individuals to join the Bedfont Family to help achieve its goal of innovating healthcare worldwide.

## The Benefits:

- 25 days paid holiday plus bank holidays
- Private medical insurance
- Subsidised health checks
- Annual optical allowance
- Pension scheme
- Bonus scheme
- Hybrid working
- Employee Assistance Programme (EAP)
- Rewards app
- Referral bonus
- Charity days
- Home office setup allowance
- Social events
- Well-being warriors
- Well-being garden and room
- Cycle to work scheme
- Employee awards
- Free on-site parking
- Training & development opportunities
- Free uniform
- Subsidised Celler8 device
- Subsidised kids club
- Time in service annual leave bonus
- Enhanced Maternity and Paternity Pay

## Your Mission:

As a Verification & Validation (V&V) Manager, you will manage the V&V team and hold a pivotal position in safeguarding the quality, safety, and effectiveness of our medical devices through rigorous V&V procedures. You will work closely with cross-functional teams to design, develop, and execute comprehensive test plans, while adhering to regulatory standards and industry best practices.

## Roles and Responsibilities:

- Assist in the design, procurement and commissioning of test equipment, jigs and fixtures
- Report any errors or bugs in the relevant queue or issue register to ensure prompt resolution
- Analyse test results and compile comprehensive reports, maintaining technical documentation
- Perform regular quality control testing of test equipment and organise test data for analysis

*Our family, innovating health, for yours.*

**Bedfont® Scientific Ltd.**
Station Yard, Station Road, Harrietsham, Kent, ME17 1JA, England. Tel: +44(0)1622 851122 Fax: +44(0)1622 854860 Email: ask@bedfont.com

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- Draft protocols and V&V test plans, using product knowledge to determine required outputs and assess compliance with predefined criteria
- Manage a small V&V team of an engineer and technician
- Conduct comprehensive V&V testing of product software, hardware (Electronics & Mechanical) and firmware
- Create and maintain V&V procedures, test software and templates
- Provide evidence of both internal and external regulatory compliance
- Develop and execute usability engineering processes (with IEC 62366-1/FDA guidelines) to ensure safety and efficacy of medical devices for end-users
- Ensure adherence to ISO 13485 standards (training will be provided)
- Complete the testing section of technical files prior to product launch
- Articulate comprehensive justifications for determining sample sizes
- Collaborate with Quality, Regulatory & R&D department
- Participate in Technical Team Innovation Days specifically focused on developing cutting-edge technology.

## Qualifications:

- A bachelor's degree in engineering (such as Electrical, Mechanical, Software, or Systems Engineering) or a related field or relevant experience in V&V and quality assurance
- Preferred 5+ years of experience in V&V, testing, quality assurance or similar role
- Experience leading a team
- Knowledge of industry standards and regulations related to V&V processes preferred, such as ISO standards, FDA regulations (for medical devices)

## Desirable Expertise:

- Leadership skills to coordinate a small team
- Knowledge of the Software lifecycle and Software Verification requirements (IEC 62304)
- Experience with ISO 14971 (Risk Management) & IEC 60601 (Medical Electrical Equipment)
- Detail-oriented and analytical thinker to quickly detect issues, fix discrepancies and propose solutions
- Experience with report writing, planning and documentation
- Enthusiasm for engineering and staying up to date with industry trends
- Communicative, articulate, and self-motivated
- Proficient with Microsoft Project
- Skilled in test plan development, protocol creation, and execution using statistical tools
- Strong problem-solving and data interpretation skills
- Collaborative experience in manufacturing processes

In addition, employees may be required to undertake other duties as may reasonably be required of them. In these circumstances training will be given where it is considered.

Bedfont® Scientific Ltd. does not and will not discriminate in the recruitment or managing of staff on the basis of race, colour, religion, gender, age, disability, marital status, sexual orientation and more. We are an equal opportunity employer and Bedfont® regards every employee as a member of the Bedfont®

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family and is committed to providing a fair, safe, diverse and welcoming atmosphere. Our application process has been designed so that everyone is able to demonstrate their skills and how they meet the criteria required for the job advertised. All successful candidates will be subject to a digital ID and DBS check. If you are interested in applying for this role, please visit https://www.bedfont.com/careers to apply.

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