

Job Title **R&D Engineer – MD Validation**

Job Description	<p>Within the System and Validation Department, which is responsible for all specifications and testing of the Robocath system, the Validation Engineer is responsible for testing and justifying the following designs:</p> <ul style="list-style-type: none"> ✓ Definition of the high-level validation strategy ✓ Management of preclinical tests ✓ Management of usability tests ✓ Creation and management of 'patient' model simulations <p>The engineer works closely with system engineers to define the product risk scenarios</p>
Type	Permanent contract
Duration (except permanent)	N/A
Salary Range	From €45.000
Bonus	Target bonus
Desired Start Date	As soon as possible
Job Location	Rouen
Business Trips Frequency	Rare
Required Profile & Desired Level of Education	<p>Desired level: Master's degree or higher. General or biomedical undergraduate degree. Minimum of 5 years of experience in risk management or preclinical testing required (any experience in usability management is a plus). Knowledge of writing and maintaining risk documents such as AMDEC, Risk Management Plan, or Preliminary Hazard Analysis. Knowledge of writing and designing test plans and protocols. Fluent in English. Knowledge of the following standards is a plus: IEC62366-1 and ISO14971.</p>

ABOUT ROBOCATH

Founded in 2009 by Dr. Philippe Bencteux, Robocath designs, develops, and markets robotic assistance solutions dedicated to the treatment of cardiovascular diseases. A player in the robotic transformation of the medical sector, these developments aim to increase the gesture performed thanks to precise technologies that are complementary to current interventional methods.

R-One™ is the first robotic solution developed by Robocath. R-One integrates a bionic, unique and proprietary technology to secure and optimize coronary angioplasty with robotic assistance. This medical procedure consists of revascularizing the heart muscle through the implantation of one or more implants (stents) in the arteries that irrigate it. An operation of this type is performed every 30 seconds worldwide. R-One is designed to intervene with precision and perform very specific procedures, all in an improved work environment. Thanks to its open architecture, R-One is compatible with most coronary angioplasty devices and catheterization rooms.

In a prospective, controlled, and randomized pre-clinical study, the efficacy and safety of R-One was demonstrated with a 100% technical success rate and no major adverse cardiovascular events (MACE). The device was CE marked in February 2019 and its clinical application started in September 2019. The solution is now present in Europe and Africa.

Ultimately, Robocath ambitions to become the world leader in vascular robotics and to develop remote vascular emergency management (VEM) to ensure the best care path for all. Based in Rouen, France, Robocath has more than 70 employees.