VALIDATION ENGINEER

A. Company Introduction:

B. Braun Vietnam, a subsidiary of B. Braun Melsungen AG Group - one of the world's leading manufacturers of medical devices and pharmaceutical products and services - now operates one of the largest medical complex in Vietnam and has become a prestigious trademark in Vietnam healthcare market. With more than 1,400 employees nationwide, we develop high quality “made in Vietnam” products, especially our infusion solutions, hemodialysis solutions and plastic medical devices have widely been used and appreciated in international and domestic markets. Every service provided by B. Braun Vietnam incorporates the entirety of our knowledge and skills, the company's deep understanding of users' needs and extensive expertise. Our mission is to PROTECT and IMPROVE the health of people around the world. Let’s become a part of the B. Braun family and share your expertise.
www.bbraun.com.vn

B. Job function:

To plan, conduct and follow-up validation exercises in accordance to B. Braun‘s Validation SOPs and Validation Master Plan such as Installation Qualification, Operation Qualification, Performance Qualification and Releasing Final Validation Report for all products produced in assigned production facility.

This includes to:

- Be responsible to establish and approve the Validation Plan/ Report respectively, Calibration Plan for production processes/equipment used for producing and quality controlling at the plants of BBVN,
- Co-ordination with the process owners to make risk assessment then define and perform outcome activities related to Qualification and Validation of equipment and

processes according to Validation Master Plan or department's requests, as well as WHO GMP/ISO 13485 requirements.

- Monitor and co-ordinate with the process engineer to undertake quality engineering projects in co-operation with Production, Quality Control and the relevant department according to guidance from the Superior and the Management. To ensure that the validation and calibration activities are undertaken objectively based on clear technical aspects.
- Co-ordinate Complaint Handling and Change Control with relevant departments, initiation of corrective action and preventive actions and follow-up on implementation.
- Follow up on corrective actions and preventive actions and documentation availability at production in accordance to ISO 13485, WHO GMP, GSP, GLP
- Assist for performing process audit corrective actions implementation.
- Participate in any project which involves Risk Assessment for project, product and process where applicable.
- Plan and execute qualifications to product, process, equipment, and other as request
- Provide training to relevant persons on process controls documentation
- Assists supervisor on CAPA management process, Risk management, Complaint Handling, Change Control process and other quality issues whenever required.
- Prepare validation document to support drug registration activities (if any).
- To be responsibility for Data Integrity and Computer Software Validation in accordance to B. Braun‘s Validation SOPs and Validation Master Plan.
- Creation of company specific data system list for computerized systems.
- Prepare common default user requirement specification for new computerized systems.

The job function listed is not exhaustive and shall also include any responsibilities as assigned by the Supervisor from time to time.

C. Job requirements:

- Graduated from universities with technical engineering background (Automation Engineer, Mechanical engineer, Chemistry technology engineer or biological technology engineer can be referred)
- Good command of English both in communicating & writing
- Have at least 6 months working experience in validation, calibration or equivalent (especially in Computer Software Validation and Data Integrity).
- Have working experience in pharmaceutical/ medical device manufacturing is an advantage.

- Have knowledge in Program Logical Control (PLC) will be preferred
- Able to use Auto Cad, Photoshop or other relevant software is a plus

D. Strive for more…

Motivated and competent employees are our most important assets. We are committed to invest in our people, through continuous career development, on-the-job training and professional qualifications. The opportunities are endless at B. Braun, as we are in a continuous growth phase. You can really drive your own career here and are trusted to do a fantastic job.
Whatever role you are in, you are in some way, shape or form contributing to protecting and improving the health of people around the world. Our team love that they genuinely make a difference!"

E. How to apply

Please send your updated CV to: recruitment.vn@bbraun.com

F. For more information, please visit:

www.bbraun.com.vn

www.facebook.com/bbraunvn

www.linkedin.com/in/bbraunvncareer/

Or contact our Hotline: +84 24 3357 1616 (Ext. 1129)

"Candidates are always welcome at B. Braun Vietnam. We are an equal opportunity employer and commit to ensure fairness and transparency during selection process as well as in your development later on with us".