Job title: Clinical Affairs Officer		
Department: Quality Assurance		Scope: 100%
Job holder	reports to:	Head of Quality Assurance
	supervises:	
	replaces:	Regulatory Leader
	is replaced by:	Head of Quality Assurance

1. Job purpose

The Clinical Affairs Officer supports the Quality Assurance, R&D and Marketing Teams by providing regulatory clinical expertise in the use of blood components and vaccines to drive product innovation and to ensure that the clinical regulatory requirements from MDR and other international regulations are met.

2. Responsibilities

- Provide expertise and guidance on the EU MDR regulation pertaining to clinical evidence generation requirements to support the safety and performance throughout the lifetime of medical devices
- Creation and maintenance of clinical evaluation plans and reports as per MDR requirements
- Creation of PMCF Plans, deployment of related activities, and creation of PMCF reports
- Identify opportunities and work with cross-functional partners to establish processes that assess alternative clinical data sources to support the clinical evidence needs for a given product
- Interact with regulatory agencies, as needed, and use scientific and medical knowledge to review or author responses and/or provide guidance to questions from regulatory bodies
- Interact with external professionals in the transfusion medicine to support risk evaluation in the scope of risk management
- Assessment of clinical risks as support to the risk management processes
- Support the PRRC in the creation of post-market surveillance reports
- Support the PRRC in ensuring that the reporting obligations as per medical devices regulations are fulfilled
- Support the Regulatory Leader in all activities related to registration of products worldwide
- Suggest product innovations derived from inputs related to the clinical use of blood components and vaccines
- Support marketing by identifying the clinical benefits of B Medical Systems products and identifying relevant scientific literature that can help generate application notes and white papers

3. Behavioural skills

- Ability to work well within a team and to collaborate with business partners across multiple functions
- Strong communication skills – both in writing and verbal
- Attention to detail

4. Technical skills

- Deep knowledge of international standards and regulations related to clinical affairs
- Knowledge of MS suite and ideally work experience with MRP/ERP software.
- Languages: English mandatory. German and / or French is an asset.

5. Education

- Advanced degree in Life Sciences, Public Health, Medical, Nursing, Pharmacy, Veterinary, Business, Technical or Medical Writing, or a related discipline

6. Experience

- 5 years in a similar position

	Surname	First name	Date	Signature
Head of Quality Assurance				
Human Resources				
Job holder				