

Alternate Computer Systems Validation Engineer H/F

 Working student

 Boulogne-Billancourt (92)

PRÉSENTATION

Peters Surgical, a French company, develops, produces and markets sterile single-use medical devices for the operating room and intended for surgeons.

As a European leader in medical devices, we have more than 800 employees worldwide. Our international dimension allows us to distribute our products in more than 90 countries.

As part of its CSR policy and aware of climate issues, Peters Surgical is voluntarily committed to a sustainable development approach in order to reduce its impact on the environment.

Joining Peters Surgical means integrating a dynamic structure and participating in the development of a company in full expansion. As such, we are looking for a:

Alternate Computer Systems Validation Engineer M/F
– 1 – 2 years | Domalain (35) – near Vitré and Rennes

DESCRIPTION OF MISSIONS

Reporting to the Validation Director, you participate in activities related to the validation of computerized systems.

1. The main missions are as follows:

- Conduct validations of computerized systems (VSI) according to the applicable normative and regulatory compliance to participate in maintaining ISO 13485: 2016 certification and the European MDR regulation "EU2017/745"
- Write risk analyses, validation protocols/reports and test sheets for validations carried out internally
- Study the protocols proposed by equipment suppliers and, in addition, draft risk analyses and internal test sheets if necessary
- Actively participate in Technical Support in the adaptation and configuration of ERP application programs
- Supervise and verify operational validation activities carried out by other departments or by third parties (suppliers, service providers, etc.)
- Have solid knowledge of the standards, guides and recommendations: ISO, BPF, GAMP 5 guide, FDA-21 CRF Part11.

SKILLS

- You are rigorous, pragmatic, autonomous, with strong organizational and relational skills.
- Dynamic and communicative, you adapt to any type of interlocutor and are a force for proposal.

YOUR PROFILE

- **Experience:**

With higher education, you have a first internship experience

- **Training:**

You wish to continue your studies in Master 2 or an Engineering level in Validation of Computerized Systems in the field of health and preferably in Medical devices.

- **Languages:**

English required

- **Additional information:**

The position is based in Domalain (near Vitré and Rennes).

Ref: STA/VAL – candidature@peters-surgical.com – ZA Vague de la Noé – 35680 DOMALAIN