Version: 1.0 *Author:* *Vanessa Vankerckhoven*
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Function Description: Clinical & Regulatory Affairs Specialist

Applicable procedure: PRC_3

1 Function Description

1. Function: Clinical & Regulatory Affairs Specialist

2. Reports to: Chief Quality Assurance & Regulatory Affairs

3. Team member of: Quality Assurance & Regulatory Affairs

4. Responsibilities:
    a. (Pre)Clinical evaluation/verification of medical devices, clinical aspects of the devices
    b. Execute (pre)clinical development strategies
    c. Plan and execute clinical research and clinical studies
    d. Execute on Post Market Clinical Follow-up (PMCF) activities
    e. Regulatory Affairs in Post-market Surveillance (PMS)
    f. Support Risk Management
    g. Execute on writing grant proposals to fund research & clinical studies in collaboration with R&D

5. Tasks
    a. Participation in concept generation of new devices in collaboration with R&D.
    b. Support business development by supporting clinical discussions with KOLs and customers
    c. Planning, execution, and follow-up of research projects including clinical investigations
        i. Set up (pre)clinical studies, including clinical investigations, performance, safety, and usability studies
        ii. Ensure conformity to ISO 14155 on Clinical Investigation, Good Clinical Practice (GCP), EU General Data
        iii. Protection Regulation (GDPR), MDR 2017/745 and MDCG guidelines
        iv. Develop and submit research protocols and dossiers for ethical and regulatory approval
        v. Plan and conduct experiments and analysing or interpreting the results
        vi. Keep accurate records of work undertaken
        vii. Use specialist computer software to analyse data and to produce diagrammatic representation of results
        viii. Discuss clinical research progress with engineering, production, and marketing
        ix. Write and submit progress reports to funding bodies that support clinical research
        x. Write original papers for publication in peer-reviewed medical or scientific journals
    d. Create and maintain Clinical Evaluation Plan & Report, PMCF, support of PMS
    e. Create clinical documentation for registrations (CE, FDA, FAGG, etc.)
    f. Assist in writing of submit applications to funding bodies that support clinical research
    g. Share clinical data with colleagues through presentations at team meetings and conferences
    h. Screening clinical databases, e.g. clinicaltrials.gov and clinicaltrialsregister.eu/
    i. Participate in both external and internal inspections and audits
    j. Support science marketing communications and strategic marketing
    k. Other tasks deemed appropriate for a Clinical & Regulatory Affairs Specialist

2 Function Requirements

1. Diploma / degree: Master Biomedical Sciences, Pharmacy, BioEngineering, Public Health sciences, Medical Doctor, or equivalent through relevant research experience. GCP certification.

2. Essential know-how:
    a. Clinical Research & clinical Trial Management
    b. Know-how on vaccinology/virology/dermatology/skin properties (or alike)
    c. Biostatistics/Analysis of data

d. Medical devices / medical sector in general
e. Clinical investigations/trials (ISO 14155), Performance studies (ISO 20916), Usability studies (ISO62366) & Human Factors Engineering, EU Medical Device Regulation 2017/745 (MDR)
f. EU General Data Protection Regulation (GDPR) in clinical trials
g. Knowledge on submission of dossiers for ethical approval
h. Computer literate and good knowledge of Microsoft Office package
i. Excellent written and oral communication skills
j. Languages:
    i. English: Excellent writing, reading, conversation
    ii. Dutch: Basic writing, reading, and conversation is considered a plus
    iii. French: Basic writing, reading, and conversation is considered a plus
    iv. Other: not necessary, but considered a plus

3. Expertise:
    a. Clinical affairs
    b. Methodical approach to work & writing protocols
    c. Writing (clinical) reports
    d. Clinical investigation/trial management
    e. In vivo and ex vivo research (animal models, etc.), Lab experiments (under L2 conditions) is considered a plus
    f. Working in an ISO certified environment

4. Profile:
    a. Team player
    b. Agile
    c. Analytical mind
    d. Dynamic personality
    e. Organisational skills
    f. Problem solver
    g. Accept flexible working hours