


Arbeitsbeschreibung / Job Description	
Dokument / Document: QFB505 Dokumenttyp / Document type: QualiMed Formblatt (QFB)	Revision: Revisionsnummer / Revision number 02 Datum des Inkrafttretens / Effective Date: 30.07.2018



Eigenschaften/Attributes	Beschreibung / Description
Position/Titel / Position / title	Regulatory Affairs Assistance (RAA)
Abteilung / Bereich Department / area	Regulatory Affairs (RA)
Berichtet an / Reports to	Head of RA (HRA)
Sprache / Language	English / German
Primäre Aufgaben und Verantwortlichkeiten / Primary Tasks and Responsibilities	<ol style="list-style-type: none"> 1. Support for compilation (including printing) of Product Master Files and other filings for registrations worldwide. 2. Support on RA filings (e.g. DIMDI Notifications, Recalls, MDD Vigilance, PSUR reports, Annual Reports) 3. Support on development of regulatory affairs (RA) plans and strategies for existing and new products and foreign countries registration (RA) processes. 4. Support on collaboration on the development of product and process validation and verification plans as well as corresponding support of the development department and development processes including Design Control (12-Step Development Methodology) 5. Support of Quality Management (QM) in general (e.g. maintenance of the ISO 13485 /MDD based quality system) and especially in the area of overlapping tasks (e.g. LPI (labeling, packaging, IFUs), adjustment of QM system on FDA and GMP requirements, 6. Support on design, conduction and documentation of preclinical and clinical trials 7. If needed, participation on External Audits: Notified body, customers, legal authorities, 8. Support on the development of Risk Assessments (RIS) and Risk Management Plans (RMP) according to ISO 14971 9. Support for the execution of trainings, especially on RA and QM relevant topics
Fähigkeiten / Kompetenzen / Skills / Competencies	<ol style="list-style-type: none"> 1. Dokumentationsfähigkeiten / documentation skills 2. Kommunikationsfähigkeiten / communication skills 3. Teamfähigkeit / team skills 4. Selbstständige Arbeiten / independent working 5. Theoretische Grundkenntnisse im Bereich RA / basic knowledge in RA
Arbeitsbedingungen / Working conditions	QualiMed, RA Department

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Spezifische Qualifikationsanforderung / Any specific skill requirements	N/A	

	Signature & date	Name
Prepared by		