BAP Pharma GmbH
An der Kohlplatte 23,
89420 Höchstädt,
Germany

Job Description – Clinical Proposal Writer	
Job Holder Signature:	Manager Signature:
Date Signed:	Date Signed:

Job Description

This position is responsible for writing the proposal between BAP Pharma and the client to detail the work to be performed by BAP Pharma to support the client's clinical studies from a packaging, labelling, and distribution perspective. Close liaison with the client and interpretation of the study protocol specifications are essential to ensure the proposal is accurate and the study requirements are met.

Responsibilities

- Engages with clients to determine the specific requirements for receipt, storage conditions, initial study packaging and labelling designs, randomisation, packaging resupplies, QP services including release, distribution and depot network strategy, returns, and destruction of clinical supplies
- Interacts with the business development team during the proposal writing phase for study design and specifications
- Writes, revises, and edits proposal drafts including executive summaries, conclusions, and organisation credentials
- Responsible for providing internal senior management and clinical project managers with an overview of proposals that are in the pipeline and those that are ready for execution to enable the team to effectively schedule the upcoming packaging operations
- Gathers proposal information by identifying sources of information, coordinating the collection of information, and identifying and communicating risks associated with proposals
- Responsible for checking calculations, appropriateness of components (for example: labels, shippers and temperature monitors) and other details to ensure accuracy
- Maintains quality results by using templates and following proposal-writing standards including readability, consistency, and tone. Maintaining proposal support databases
- Obtains approvals by reviewing proposal with key providers and project managers
- Improves proposal-writing results by evaluating and re-designing processes, approach, coordination, and templates
- Liaises with Operations and Quality Assurance representatives to further define requirements for packaging & labelling, release, and distribution activities
- Meets proposal deadline by establishing priorities and target dates for information gathering, writing, review, approval, and transmittal
- Performs other duties as required

Requirements

- Relevant diplom or equivalent
- Must be fluent in German and English with excellent written and verbal communication skills
- Excellent interpersonal, numeracy and IT skills
- Excellent knowledge of all SOPs related to storage, packaging, labelling, distribution, release, returns, and destruction
- Familiarity with the pharmaceutical industry
- Knowledge of EU cGMPs and GDP
- Experience of working independently and in a team-oriented, collaborative environment is essential
- Must work well with all employees by being persuasive, encouraging and motivating
- Able to easily deal with changing priorities, demands and timelines through analytical and problem-solving capabilities

- Able to present relevant material internally and externally, lead meetings and participate in training sessions
- Must be able to learn, understand, and apply new technologies
- Able to effectively prioritise and execute tasks in a high-pressured environment

Competencies

- Excellent communication skills in German and English
- Excellent numeracy and IT skills
- Self-aware and can manage situations with sensitivity
- Ability to meet deadlines
- Results focused
- Attention to detail and thoroughness
- Flexible and adaptable
- Maintain high standards of quality
- Tenacious

Work Conditions

- Reports to the General Manager
- From time to time overtime may be required
- Ability to work under own initiative and in a team