

Research Quality Assurance - Konstanze Frank

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For a thorough consideration in the field of Good Clinical Practice (GCP) the first title was chosen: Evaluate how the personnel in key roles in your organisation demonstrate fulfilment of their responsibilities as required by either GMP, or GCP, or GCP(v), or GLP. Propose one improvement in this respect, with a reasoned argument, for each role. With respect to the Standard Operating Procedures (SOPs) of my company, to my employment contract, and to my confidentiality statement I am not allowed to notify third parties of any real or assumed deficiencies within my organisation. Therefore, GCP key personnel and their key functions are identified according to applicable regulations (please refer to Section 7 References). Based on the example of a common German Clinical Research Organisation (CRO) working in the field of Phase I trials duties and fulfilment of responsibilities are discussed. Additionally, only presumed or theoretical deficiencies and their improvement are specified. However, please let me re-emphasise that all facts below are based on regulatory requirements and my experiences but do not allow any conclusions to the operational state of my organisation and to any current or former deficiencies. Author: Frank, Konstanze Publisher: GRIN Verlag Illustration: N Language: ENG Title: Research Quality Assurance Pages: 00012 (Encrypted PDF) On Sale: 2005-01-01 SKU-13/ISBN: 9783638394802 Category: Medical : Nursing - General

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