

Paper 120-30

A Task and Problem Focused Approach to the Development and Regulation of Drugs

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ABSTRACT

The Task and Problem Focus (TPF) to the development and evaluation of drugs is an issues-oriented, intuitive approach that facilitates effective interactions between drug developers and evaluators from earliest studies in humans through marketing. It was the format of FDA's first pilot project (chaired by Dr. Steve Wilson) to examine the internet as a means of regulatory communication. TPF is based on the shared use of a constantly updated electronic task and problem list that includes all scientific and administrative issues requiring resolution. Each task or problem entry is precisely stated, only as available information allows. Resolution steps consist of appropriately restated expressions with links to the relevant data and communication on which each step is based. The electronic TPF file can be an easily assessable archive of the developer's proposals and responses and the entire FDA review. TPF is designed to facilitate record keeping, project management, and solid decision making. Review meta-analysis of multiple TPF files can identify good review practices (GRP) by examining how a given task or problem was resolved across many reviews. Ultimately the TPF approach could make FDA's therapeutic evaluation process more creditable, accessible and understandable to all FDA stakeholders. A standardized system of its kind would be a logical next step for utilizing electronic technology to re-engineer the drug regulatory and development processes and not just automate or enhance the existing processes. While conceived within the context of pharmaceutical development, this approach could support any complex enterprise.

NOTE

No paper was made available for publication. Please contact the author directly.

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