

REVIEWER'S REPORT

Manuscript No.: IJAR-58903

Title: Pharmaceutical Technology Transfer Process: A Brief Review.

Recommendation:

- Accept as it is
- ✓ Accept after minor revision.....
- Accept after major revision
- Do not accept (*Reasons below*)

Rating	Excel.	Good	Fair	Poor
Originality		✓		
Techn. Quality		✓		
Clarity		✓		
Significance	✓			

Reviewer Name: Dr S. K. Nath

Detailed Reviewer's Report

Strength of the study:

- The topic is relevant to pharmaceutical manufacturing
- The basic technology transfer process is explained clearly
- Important stages from development to commercialization are discussed
- Key transfer documents are described
- Site transfer and post approval changes are included
- Roles of different departments are discussed
- The flow chart provides a simple overview of the process
- Regulatory considerations are briefly addressed

Weakness of the study:

- The review lacks a clearly described literature search method
- Recent and authoritative regulatory sources are limited
- Several statements are oversimplified or insufficiently supported
- Some regulatory information needs careful verification
- The discussion is mainly descriptive rather than critical
- Important international guidelines are not discussed in sufficient detail
- The manuscript contains frequent grammar and language errors
- References are few for such a broad topic
- Some sections repeat similar information

Reviewers Comments:

The manuscript provides a basic overview of pharmaceutical technology transfer and covers important areas such as technology development, scale up, exhibit batches, stability studies, regulatory filing, site transfer and post approval changes. The flow chart and discussion of responsibilities of R&D, QA, QC, production and engineering personnel are useful for readers who are new to the subject. However, the manuscript is largely descriptive and does not provide a clear literature search strategy or critical comparison of existing guidance and practices. Several regulatory statements, particularly those related to SUPAC and batch size changes, require careful verification and more appropriate references. The references are limited for the broad scope of the review, and some cited sources need better bibliographic details. Ethical clearance is not applicable because this is a literature based review without human participants. The manuscript also contains considerable grammatical, spelling, spacing and sentence construction problems. Overall, the topic is useful, but substantial scientific and editorial improvement is required.

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