

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 ID: JP085

Reviewer's Comment for Publication.

The article gives an overview of technology transfer in the pharmaceutical industry. It explains how a product moves from the research and development stage to commercial manufacturing. The article discusses scale-up, receiving-site activities, exhibit batches, stability studies, regulatory approval, commercial batches, site transfer, post-approval changes, and the role of different departments in technology transfer.

Strength:

1. The topic is important and relevant to the pharmaceutical industry.
2. The article covers the major steps involved in technology transfer.
3. The role of R&D, QA, QC, Production and Engineering is explained.
4. Important documents such as TTD, MFR, MPR, SPS and STP are discussed.
5. Post-approval changes and site transfer are included.
6. The article explains the importance of regulatory compliance.
7. The conclusion summarizes the main points clearly.

Weakness:

1. The article is mainly descriptive and does not provide much critical analysis.
2. Some important concepts are explained very briefly.
3. The flow chart and tables need better formatting and clearer presentation.
4. There are several grammar, spelling and sentence-formation errors.
5. Some statements need proper references or supporting sources.

Overall assessment:

The article provides a basic and useful overview of pharmaceutical technology transfer and covers many important areas from product development to commercialization. However, it requires significant improvement in language, scientific accuracy, regulatory information, references, formatting and critical

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discussion. The article would be stronger if recent WHO, FDA, EMA and ICH guidelines were incorporated.

Recommendation: Manuscript accepted for publication after minor revision.