

## Guidelines for Transfer of Technology in Pharmaceutical Sector: Key Considerations and Compliance Requirements

written by King Stubb & Kasiva | March 15, 2023



The pharmaceutical sector is continually changing, and technology transfer is an important part of its expansion and development. The practice of transferring knowledge, skills, and expertise from one organization to another is referred to as technology transfer. Transfer of Technology in Pharmaceutical Sector entails moving manufacturing techniques, analytical procedures, and other technical information from the research and development stage to the commercial manufacturing stage.

Technology transfer guidelines are necessary to ensure that transferred technology is applied effectively and efficiently while retaining quality, safety, and efficacy. These standards set the stage for the transfer process, which includes documentation, risk assessment, training, and validation. Following these recommendations is critical to ensuring that the finished product fulfills the needed quality standards and regulatory requirements. In this light, this article seeks to provide an overview of technology transfer in the pharmaceutical sector as well as the significance of technology transfer guidelines.

Additionally, to ensure that such legal matters are handled properly, it is important to engage the services of a qualified information technology lawyer from a reputable technology law firm. King Stubb and Kasiva stands out as a top-tier technology law firm in India, boasting a team of highly skilled information technology lawyers.

- The Guidelines
- Key Provisions
- Compliance with Guidelines
- Preparation of Technology Transfer Agreement

- Approval Process
- Post-Approval Compliance Requirements
- Challenges and Opportunities
- Challenges
- Opportunities
- Conclusion
- FAQs
- What Are The Compliance Requirements For Technology Transfer In The Pharmaceutical Sector?
- What should be included in a technology transfer agreement in the pharmaceutical sector?
- How can one ensure the quality and safety of the technology being transferred in the pharmaceutical sector?

#### The Guidelines

Guidelines for the Transfer of technology in the pharmaceutical sector are necessary for ensuring the rapid and successful transfer of technical knowledge and experience. The World Health Organization (“WHO”) and other regulatory agencies have produced standards that serve as a foundation for pharmaceutical technology transfer.[1] In India, the Indian Council of Medical Research has also issued “Guidelines for Technology Transfer and Revenue Sharing.”[2] The guidelines explain the methods and regulations that organizations must follow during technology transfer to assure the final product's quality, safety, and efficacy.

#### Key Provisions

The guidelines address numerous fundamental provisions that are essential for successful technology transfer. They are as follows:[3]

1. **Scope and Applicability:** The guidelines define the scope and applicability of the technology transfer process, as well as the types of technology transfer covered, the parties engaged, and the regulatory requirements.
2. **Types of Technology Transfer:** The guidelines also define the many types of technology transfer, such as internal transfers, inter-facility transfers, and transfers between companies. Each sort of transfer has its own set of standards and processes to follow.
3. **Obligations of the Parties:** The guidelines list the obligations and responsibilities of each party involved in the technology transfer process. The transferor, transferee, and any other persons involved in the transfer are all included. The rules also outline the roles and responsibilities of quality assurance and quality control staff.
4. **Documentation and Reporting Requirements:** The guidelines require the transferor and transferee to keep complete documentation of the technology transfer process, including methods, data, and results. The standards also outline the reporting criteria that must be met both during and after the transfer procedure.

The technology transfer standards provide a thorough framework for the transfer of technical information and expertise in the pharmaceutical industry. Organizations can guarantee that the transfer process is efficient, effective, and compliant with regulatory requirements by following these guidelines.

#### Compliance with Guidelines

Guidelines for technology transfer in the pharmaceutical sector cover the following in addition to the major provisions indicated above:[4]

## Preparation of Technology Transfer Agreement

The guidelines necessitate the creation of a technology transfer agreement outlining the terms and conditions of the transfer procedure. This agreement should specify the scope of technology transfer, intellectual property rights, confidentiality, payment terms, and dispute resolution processes.

## Approval Process

There are various stages to the approval procedure for technology transfer.

The guidelines outline the two steps as follows:[5]

1. Review by the Department of Pharmaceuticals ("DoP"): The DoP is in charge of analyzing and approving technology transfer agreements. The guidelines demand that the technology transfer agreement be submitted to the DoP for approval before the transfer process can commence.
2. Review by the Foreign Investment Promotion Board ("FIPB"): If the technology transfer involves foreign investment, the FIPB must assess and authorize it. The FIPB assesses the transfer process to ensure that it meets regulatory criteria and does not endanger national security.

## Post-Approval Compliance Requirements

After the technology transfer procedure has been approved, the standards require both the transferor and transferee to comply with post-approval compliance obligations. These include regular reporting to regulatory agencies, keeping complete records of the transfer process, and conducting audits to guarantee compliance with regulatory obligations.

## Challenges and Opportunities

There are various challenges as well as opportunities for technology transfer in the pharmaceutical industry. They are as follows:[6]

### Challenges

Compliance with regulatory standards is one of the biggest challenges in technology transfer. The pharmaceutical sector is heavily regulated, and any non-compliance can result in serious penalties such as production activities being halted, product recalls, and legal action. Differences in regulatory requirements between countries, changes in regulatory requirements over time, and varied interpretations of legislation by regulatory authorities can all pose compliance issues. Another problem is ensuring that the transfer process does not jeopardize the finished product's quality, safety, or efficacy. This necessitates a full grasp of the transfer process as well as the capacity to identify and manage any hazards along the way.

### Opportunities

The pharmaceutical industry can benefit from technology transfer in a variety of ways. It enables organizations to expand their product lines and reach new markets by leveraging current experience and skills. Technology transfer can also save money by reducing duplication of efforts and R&D investments. Furthermore, technology transfer can foster innovation by allowing organizations to create new goods by integrating their technologies with those of other organizations. This can lead to the discovery of novel or improved therapeutic characteristics in products, greater patient outcomes, and higher market share.

## Conclusion

Transfer of technology in the pharmaceutical sector is critical because it allows companies to capitalize on existing expertise, develop product lines, and enter new markets. However, it presents various hurdles, including regulatory compliance and ensuring the final product's quality, safety, and

efficacy. To overcome these, it is critical to adhere to the pharmaceutical industry's technology transfer criteria. These guidelines provide a complete framework that encompasses all parts of the transfer process, from technology transfer agreement drafting through post-approval compliance obligations. Following these guidelines can help to guarantee that the transfer process is efficient, effective, and per regulatory standards.

Furthermore, technology transfer presents several opportunities, including innovation, cost savings, and improved patient outcomes. Companies that can successfully handle the challenges and capitalize on the opportunities afforded by technology transfer will profit from greater competitiveness and sustained expansion in the global pharmaceutical market. Overall, technology transfer is a difficult process that involves meticulous preparation, implementation, and adherence. The pharmaceutical industry can continue to create and provide life-changing medications to patients all around the world by adhering to the criteria and capitalizing on the opportunities presented by technology transfer.

#### FAQs

**What Are The Compliance Requirements For Technology Transfer In The Pharmaceutical Sector?**

The compliance requirements for technology transfer in the pharmaceutical industry are:

1. Adhering to regulatory norms
2. Establishing a technology transfer agreement
3. Obtaining regulatory permissions
4. Keeping detailed records
5. Conducting audits

**What should be included in a technology transfer agreement in the pharmaceutical sector?**

A pharmaceutical technology transfer agreement should include the following:

1. Information about the transfer procedure
2. Intellectual property rights
3. Confidentiality, the parties' duties
4. Quality requirements
5. Dispute resolution mechanisms

**How can one ensure the quality and safety of the technology being transferred in the pharmaceutical sector?**

The following steps can be taken to ensure the quality and safety of pharmaceutical technology transfer:

1. Performing a risk assessment
2. Establishing quality standards
3. Conducting regular audits
4. Maintaining clear communication between the parties involved

[1]<https://extranet.who.int/pqweb/key-resources/documents/who-guidelines-transfer-technology-pharmaceutical-manufacturing-trs-961>.

[2][https://main.icmr.nic.in/sites/default/files/upload\\_documents/ICMR\\_Technology\\_Transfer\\_and\\_Revenue\\_Sharing\\_Guidelines07072021.pdf](https://main.icmr.nic.in/sites/default/files/upload_documents/ICMR_Technology_Transfer_and_Revenue_Sharing_Guidelines07072021.pdf).

[3]<https://unctad.org/system/files/official-document/psiteiitd28.en.pdf>.

[4]<https://apctt.org/sites/default/files/2020-07/APCTT-CSIR%20workshopSahu2.pdf>.

[5]<https://pharmaceuticals.gov.in/sites/default/files/Approved%20Guidelines%20of%20scheme%20Strengthening%20of%20Pharmaceutical%20Industries%20%28SPI%29%20>

011032022.pdf.

[6][https://www.wipo.int/edocs/mdocs/aspac/en/wipo\\_ip\\_han\\_11/wipo\\_ip\\_han\\_11\\_ref\\_30.pdf](https://www.wipo.int/edocs/mdocs/aspac/en/wipo_ip_han_11/wipo_ip_han_11_ref_30.pdf).

King Stubb & Kasiva,

Advocates & Attorneys

Click Here to Get in Touch

New Delhi | Mumbai | Bangalore | Chennai | Hyderabad | Mangalore | Pune |  
Kochi | Kolkata

Tel: +91 11 41032969 | Email: [info@ksandk.com](mailto:info@ksandk.com)