

Advancing Pharmaceutical Technology Transfer

Navigating the complexities of pharmaceutical technology transfer requires a meticulous approach, ensuring seamless integration from development to global production.



Key Pillars of WHO Technology Transfer Guidelines

The World Health Organisation (WHO) provides comprehensive guidelines essential for robust technology transfer (TT) in the pharmaceutical industry.



Clear Terminology & Protocols

Standardised definitions and detailed protocols are foundational for unambiguous communication and execution.



Quality Risk Management

Proactive identification and mitigation of risks ensures product quality and patient safety throughout the transfer.



R&D to Production Streamlining

Emphasis on structured transfer from research and development into full-scale production, covering process, packaging, and cleaning.

Granularity in Technology Transfer Processes

Successful technology transfer demands attention to every detail, from raw materials to the final dosage form.



Active Pharmaceutical Ingredients (APIs)

Precise transfer of API synthesis routes, impurity profiles, and stability data.



Excipients & Finished Products

Ensuring consistent quality and functionality of excipients and the comprehensive transfer of finished product manufacturing.



Packaging Materials

Transfer of specifications, testing methods, and supplier qualifications for all primary and secondary packaging.

Ensuring Operational Excellence

Documentation & Traceability

Comprehensive documentation is critical for compliance, covering every stage from development reports to validation protocols.

- Detailed batch records
- Analytical methods and validation reports
- Equipment qualification dossiers



Infrastructure and Quality Control

Robust infrastructure and stringent quality control are non-negotiable for successful technology transfer.



Premises & Equipment

Ensuring facilities meet GxP standards and equipment is calibrated and suitable for new processes.



Qualification & Validation

Thorough qualification of equipment and validation of processes to ensure consistent results and product quality.



Quality Control & Analytical Transfer

Rigorous quality control processes and seamless transfer of analytical methods to maintain product integrity.

Regulatory Oversight and Commercialisation



■ Regulatory Approval

■ Market Access

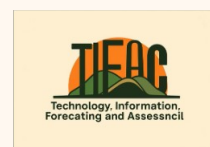
■ Logistics & Supply Chain

■ Post-Market Surveillance

■ Intellectual Property

Technology Transfer Agencies in India

India boasts several key agencies facilitating technology transfer, crucial for pharmaceutical innovation and manufacturing.



These organisations bridge the gap between research institutions and industry, promoting the adoption of new technologies.

Essential Technology Transfer Documentation

Robust documentation safeguards intellectual property and defines collaborative frameworks.

Confidentiality Agreements (NDAs)

Protecting proprietary information during initial discussions and evaluations.

Licensing Agreements

Formalising the terms of technology use, royalties, and intellectual property rights.

Memoranda of Understanding (MoUs)

Outlining the framework for collaboration and shared objectives.

Legal & Regulatory Issues

Addressing legal compliance, dispute resolution, and regulatory submissions for specific markets.