*symbiosis
Pharmaceutical Services

Tech transfers:
Strategies for successfully commercialising your drug product

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01

Navigating tech transfers to accelerate manufacturing

Bringing a new drug to market is a complex journey. A crucial step in this process is the technology transfer from the drug developer to a contract manufacturing organisation (CMO). Such transfer, governed by strict good manufacturing practices (GMP), ensures the seamless transition from lab-scale production to commercial-scale manufacturing. Intricate transfer processes involve the meticulous handover of knowledge, methods and quality control measures, ensuring the CMO can reliably produce the therapeutic while meeting the highest quality and safety standards.

This eBook will examine the critical aspects of tech transfers, highlighting the regulatory framework, key stages and best practices for a successful collaboration. It will explore the objectives of tech transfer and key regulatory guidance, emphasising the importance of gap analysis and collaboration for a successful partnership.

By understanding and implementing best practices, drug developers can ensure efficient and compliant commercial manufacturing, ultimately delivering safe and effective treatments to patients.



02 Key objectives for unlocking tech transfer success

The primary goal of a tech transfer is to effectively transfer knowledge of the product, including its manufacturing processes, from the developer to the CMO and within or between manufacturing sites. This knowledge forms the basis of the manufacturing process, control strategy, process validation approach and continual improvement. It ensures the CMO can reliably produce the drug at the required quality and scale while maintaining consistency with the developer's original product.

Critical objectives for a successful technology transfer include:



Enabling successful product realisation

Ensuring the CMO can reliably manufacture the drug to meet market demands and quality standards.



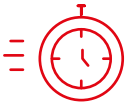
Facilitating comprehensive process knowledge transfer

Sharing all necessary information about the drug, its manufacturing process, quality attributes and control strategies, manufacturing procedures and instructions, analytical methods and specifications, raw material information and technology/ equipment specifications.



Maintaining quality and consistency

Ensuring that the CMO can replicate the manufacturing process and achieve the same quality attributes and standards as the original product developed by the drug developer.



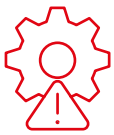
Optimising efficiency and speed

Minimising delays in production and time-to-market for the drug product through a smooth and efficient technology transfer.



Ensuring regulatory compliance

Adhering to all relevant regulations and guidelines, such as GMP, for both the developer and the CMO, with a tech transfer process designed to meet these requirements.



Mitigating risk

Identifying and mitigating potential risks associated with the transfer, such as process deviations, quality issues or delays.

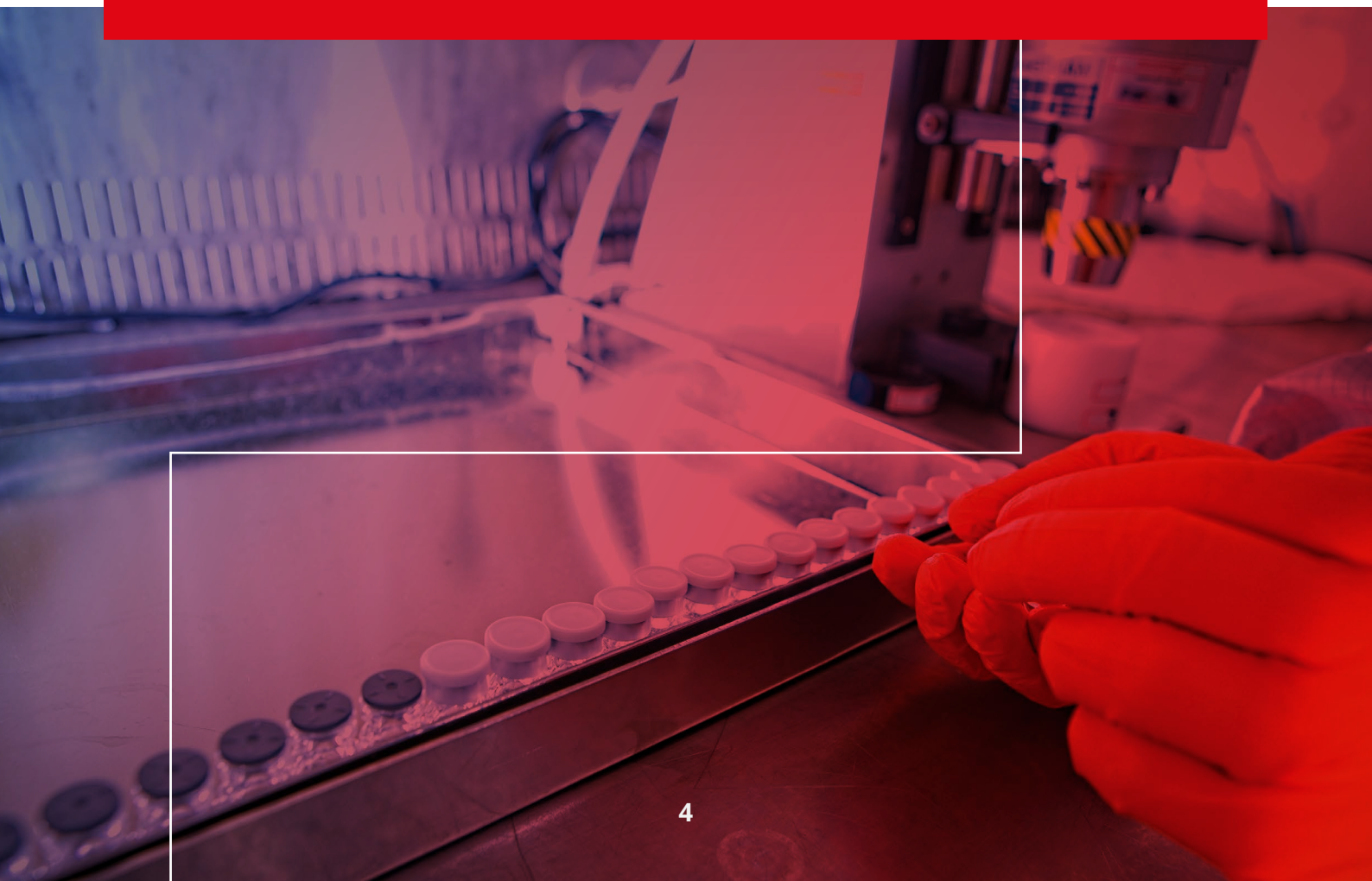
WHO tech transfer guidelines

The World Health Organisation (WHO) provides guidelines on tech transfer in pharmaceutical manufacturing to ensure quality and consistency in the production of medicines.
The guidelines are detailed in Annex 7 of the WHO Technical Report Series (TRS) 961[1].

Tech transfers are defined as a "systematic procedure that is followed to pass the documented knowledge and experience gained during development and/or commercialisation to an appropriate, responsible and authorised party" [1]. The key principles, according to the WHO, include:

* **Planned approach**
  Tech transfer requires a structured and documented approach with defined roles and responsibilities.
* **Trained personnel**
  Knowledgeable personnel trained in tech transfer principles should be involved.
* **Quality systems**
  The transfer should be conducted within a robust quality management system.
* **Documentation**
  Comprehensive documentation covering all development, production and quality control aspects is essential.
* **Collaboration**
  Effective communication and collaboration between the sending unit (SU) and the receiving unit (RU) are crucial.

By adhering to the WHO guidelines, pharmaceutical manufacturers can ensure the successful transfer of technology, leading to the reliable production of high-quality medicines.





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Tech transfer tool kit for a smooth handover

To ensure a successful technology transfer, drug developers need to equip CMOs with in-depth knowledge of the drug product. This goes beyond simply sharing the formula. It requires a comprehensive package encompassing the manufacturing process, critical quality attributes, analytical methods and relevant regulatory expectations. This collaborative approach paves the way for a smooth transition and the consistent production of safe and effective medicines.

A robust tech transfer hinges on several key elements. These include:

Process description

- Detailed step-by-step instructions are specified for each stage of the manufacturing process, including equipment, operating parameters and critical process controls.
- Process flow diagrams — visual representations of the manufacturing process — show the operations and material flow sequence.
- Executed batch record templates document the manufacturing process for each batch, including raw material inputs, processing steps, and in-process controls.
- Standard operating procedures (SOPs) are also required for specific tasks and operations within the manufacturing process.
- A process development report summarises the development history of the manufacturing process, including the rationale for decisions made, any challenges encountered and the results of development studies.
- Annual product reviews provide updates on the performance of the process and drug product (DP) quality over time.

Product information

- This information includes details about the drug substance (DS) — the active pharmaceutical ingredient (API) — including its properties, source and quality specifications.
- Critical quality attributes (CQAs) must be provided to ensure the DP's safety and efficacy.
- DP information should also include detailed specifications of the quality standards.

Analytical methods

- These should include descriptions of the analytical procedures used to test the quality of raw materials, intermediates and the final DP.
- Method validation data is required to demonstrate the analytical methods' accuracy, precision and reliability.
- Reference standards, such as authenticated materials, are used for comparison in analytical testing.
- A test-method development report documents the development and validation of the analytical methods used.

Technology and equipment

- This encompasses equipment specifications in the manufacturing process, including its design, operating parameters and maintenance requirements.
- It also includes process control strategies for monitoring and controlling the manufacturing process.
- Cleaning and validation methods outline the procedures for cleaning manufacturing equipment and validating its effectiveness.

Quality and regulatory information

- This information should include the quality management system (QMS) used and its compliance with GMP regulations.
- Relevant regulatory filings, such as the Investigational New Drug (IND) or New Drug Application (NDA), are also crucial.
- Stability data should describe how the DP behaves under various storage conditions.

Packaging and secondary packaging specifications

- These define the specifications for the materials and processes used to package the DP, ensuring its protection and stability during transport and storage.

Training and support

- Training materials on the manufacturing process and quality control procedures should be included.
- Drug developer personnel should be offered on-site support during visits to the CMO's facility to provide guidance and support during the initial manufacturing runs.
- Mechanisms for ongoing communication and collaboration should be established between the drug developer and CMO to address any issues that may arise.

The specific content of a tech transfer package will vary depending on the complexity of the DP and the manufacturing process. However, the goal is always to provide the CMO with all the necessary information and support to manufacture the DP to the required quality standards. By including all the above elements in the tech transfer, the CMO is given a comprehensive understanding of the DP, its manufacturing process and the quality levels that must be met. This helps ensure a smooth and successful transfer, leading to the reliable production of high-quality therapeutics.





04 Avoiding tech transfer pitfalls to maximise efficiency

Technology transfer is a high-stakes endeavor where even minor missteps can have major consequences. Miscommunication, inadequate documentation and unforeseen technical challenges have the potential to derail a project. Failing to navigate these challenges effectively can lead to missed deadlines, cost overruns and compromised quality.

1. Transparency and open communication

Dedicated communication channels (such as regular meetings, project updates or a designated contact person) are crucial for seamless information flow and prompt issue resolution. Both sides of the transfer must be proactive and responsive, fostering a partnership built on trust and mutual understanding. Openly acknowledging and addressing potential roadblocks ensures proactive problem-solving and prevents costly delays.

2. Capabilities and expertise

Choosing a CMO with a proven track record in manufacturing similar products or employing comparable technologies is an important consideration. The CMO's facilities, equipment and capacity should align with the manufacturing process and production scale. It's also essential to verify that the CMO has a robust QMS in place and a strong record of GMP compliance.

3. Well-defined scope and objectives

Specifying the exact components being transferred (such as processes, technologies, analytical methods or documentation) is vital. Realistic goals, timelines and deliverables should be set early, with clearly defined milestones and responsibilities.

4. Detailed documentation

As part of the tech transfer process, meticulous and comprehensive documentation should be provided, including process descriptions, batch records, SOPs, analytical methods and validation reports. These should use clear and concise language to avoid misinterpretations and be easily understandable and free from ambiguities.

5. Effective project management

It is a good idea to appoint dedicated, experienced project managers and teams from both sides to oversee the transfer process. A comprehensive plan with clear timelines, roles, responsibilities and communication strategies should be created. It is also essential to monitor progress against the plan, identify deviations and promptly address any issues.

6. Quality and regulatory considerations

Ensuring GMP compliance throughout the process protects product quality and patient safety. All regulatory requirements for the specific DP and target market must be addressed.

By diligently considering these factors, drug developers can ensure a smooth tech transfer, paving the way for the reliable manufacture of high-quality treatments.



Bridging the divide: Gap analysis in tech transfer

Gap analysis is a critical step in technology transfer, acting as a bridge between the drug developer and the receiving organisation (e.g., CMO). This process systematically compares the sending unit's requirements with the receiving unit's capabilities, highlighting any potential gaps or mismatches that could hinder a smooth transition.

What does a gap analysis typically entail?

- **Process mapping:** It starts with a detailed examination of the manufacturing process at both the sending and receiving units. This includes mapping the flow of personnel and materials, identifying potential bottlenecks and assessing any differences in equipment or facilities.
- **Safety evaluation:** A thorough review of potential health and safety issues associated with the transferred technology is conducted, along with proposed mitigation strategies.
- **Documentation review:** The analysis verifies the availability and suitability of essential documents, such as SOPs, batch records and analytical methods.
- **Personnel assessment:** Evaluating the skills and experience of personnel at the receiving unit helps pinpoint any training needs.
- **GMP impact assessment:** The potential impact of GMP requirements on existing projects at both sending and receiving sites is carefully considered.

Uncovering hidden obstacles

By meticulously examining these areas, gap analysis helps foster a shared understanding between the two organisations and uncover critical gaps that could derail the tech transfer. This evaluation then informs necessary mitigation actions and recommendations, paving the way for a smooth and successful transfer.

05

Meticulous regulatory adherence for tech transfers



In the heavily regulated pharmaceutical industry, adhering to regulatory guidelines is essential for successful technology transfer. These guidelines, designed to ensure the safety and efficacy of drug products, provide a framework for maintaining consistent product quality throughout the manufacturing process.

By complying with these guidelines throughout technology transfer, drug developers and manufacturers safeguard patient health and minimize the risk of substandard or contaminated products. This adherence is critical, as any deviation can compromise product quality and potentially cause harm. Compliance also ensures that the drug product meets predefined specifications and performs as intended, providing confidence in its safety and effectiveness after the transfer is complete.

Non-compliance during technology transfer can have serious repercussions, potentially leading to fines, product recalls, or even facility shutdowns. Therefore, prioritizing regulatory compliance throughout the entire technology transfer process is crucial not only to protect patients but also to build public trust in the pharmaceutical industry and reinforce confidence in the safety of its products.

Expertly navigating regulatory requirements

Outsourcing manufacturing to a CMO with specialised knowledge and extensive experience in navigating regulatory complexities allows drug developers to focus on their core competencies.

At Symbiosis, we possess a deep understanding of the regulatory landscape, ensuring your technology transfer process meets all relevant requirements. Our regulatory expertise allows us to proactively identify potential compliance issues and implement robust controls, minimising the risk of regulatory action and ensuring a smooth transition. This in-depth knowledge and our established systems also streamline filings and approvals, helping to accelerate your time to market.

We offer a comprehensive suite of services to expedite your technology transfer, including in-house quality control facilities, visual inspection and automated filling lines. Our business model fosters collaborative partnerships, providing rapid access to manufacturing slots and reducing timelines from years to months or even weeks.

Tech transfer legislative landscape

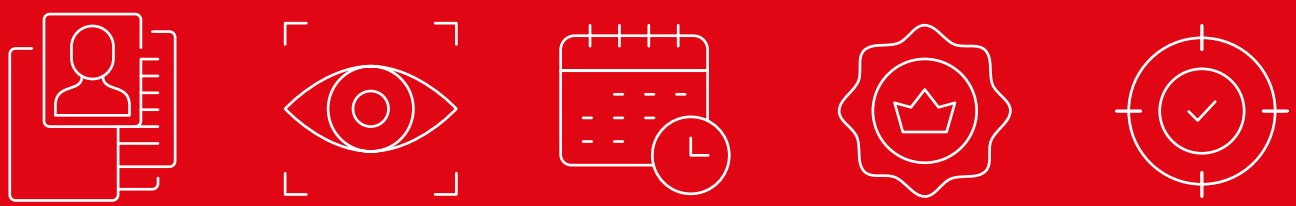
The U.S. Food and Drug Administration (FDA) and the International Conference on Harmonisation (ICH) provide critical guidance to ensure successful and compliant tech transfers. The following guidance emphasises meticulous planning, execution and adherence to quality standards throughout the transfer process:

- Q7A Good Manufacturing Practice for Active Pharmaceutical Ingredients outlines GMP requirements specifically for API manufacturing [2, 3]
- ICH Q5C Quality by Design for Active Pharmaceutical Ingredients guides implementing quality by design (QbD) principles in API development and manufacturing
- ICH Q9 Quality Risk Management recommends applying quality risk management (QRM) principles to pharmaceutical development and manufacturing, including technology transfer[2, 4, 5]
- ICH Q10 Pharmaceutical Quality System provides guidance on implementing a robust pharmaceutical quality system, essential for successful technology transfer (2, 6)

Companies should diligently review these and other resources to ensure full compliance with applicable regulations and maintain the highest patient safety standards.

The ALCOA principles

The ALCOA principles —attributable, legible, contemporaneous, original and accurate — are guidelines for ensuring data integrity in regulated industries, particularly pharmaceutical development and manufacturing. The FDA developed them in the 1990s, and other regulators in many countries and regions, including the European Medicines Agency (EMA), have adopted them since.



Attributable **Legible** **Contemporaneous** **Original** **Accurate**

Both the FDA and the EMA incorporate ALCOA principles into their guidance documents and regulations for GMP. Inspectors and auditors use ALCOA to assess the quality and reliability of data generated by organisations.

These fundamental data principles provide a foundation for robust data management and documentation practices. This ensures the accuracy, reliability and completeness of data used in drug development, regulatory submissions and post-market monitoring. By adhering to ALCOA principles, pharmaceutical companies worldwide can demonstrate their commitment to data integrity and protect the quality and safety of their products.



06 All the knowledge your tech transfer needs

Tech transfer is critical in commercialising DP, bridging the gap between innovation and patient access. As this eBook has explored, successful tech transfer requires careful planning, open communication and a detailed understanding of the regulatory landscape.

Adhering to established guidelines, such as those provided by the WHO, FDA, and ICH, drug developers can smoothly and efficiently transfer knowledge, processes, and quality standards to CMOs and within or between manufacturing facilities. This not only ensures the production of high-quality treatments that meet stringent regulatory requirements but also fosters trust and collaboration between partners.

By embracing the best practices outlined here, drug developers can confidently navigate the complexities of tech transfer, ultimately accelerating the delivery of safe and effective treatments to patients worldwide.

To discover how to plan and execute a smooth tech transfer and get your product to market quickly, get in touch with the expert team at Symbiosis.

Find out more

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