RONDAXE
Pharmaceutical CMC Consulting and Software

Core Principles of a Successful Technology Transfer

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How Your Organization Can Streamline Your Next Technology Transfer

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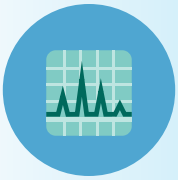
The Key Drivers of Technology Transfer

Technology Transfer Plan

Risk Assessment

Automation



Gap Analysis

Technology Transfer Report

Analytical Methods Transfer

Technology transfer is the heart of moving pharmaceuticals from research to production and getting therapies to patients faster. A typical technology transfer is composed of independent pieces; each handled differently with differing employees, functions, locations, and goals. Consequently, a successful technology transfer requires a collaborative effort among cross-functional teams, with focused and open communication as a critical contributor to success. Accelerating this process and improving technology transfer requires six core conditions:

• Technology Transfer Plan: A good plan outlines transfer activities and responsibilities in sufficient detail. From the outset, the entire team must have a clear understanding of what the transfer includes; a site visit is nearly always required.

• Gap Analysis: A thorough technical gap analysis between the receiving and sending site must be executed. Identifying the comparability of critical elements such as raw material specifications, equipment, raw materials, and packaging materials can prevent unpleasant (and expensive) surprises. This is the time to build a list of all critical and missing documentation.

• Analytical Methods Transfer: The first information to be transferred should be the analytical methods since small scale and development batches need to be tested early in the process. Analytical methods are one of the most common trouble spots encountered in even the smoothest technology transfer. Analytical methods should be robust and reproducible. Analysts need to understand procedures and be appropriately trained in their use.

• Risk Assessment: A thorough risk assessment identifies potential problem areas. A solid risk assessment encompasses multiple areas, from materials and equipment to potential supply chain problems.

• Technology Transfer Report: Tie it all together in a detailed, concise report. Ensure the report mirrors the plan, and the goals and path to reach them are clear to all team members.

• Automation: Engineering controls are usually more effective in removing sources of error in a process than human controls. Consider automation and software solutions wherever practical in your technology transfer.

Technology Transfer Gone Bad: A Case Study

Issue: Transfer from Internal Manufacturing to CMO - Changing Horses Midstream is Tricky

ABC Biotech purchased an asset from Big Pharma, who wanted to divest manufacturing responsibility. ABC Biotech found itself in the unenviable but not unusual position of needing a new CMO and reworking the entire transfer plan--quickly. As with many biotech companies, ABC Biotech did not have the internal resources to manage the process. The company needed a reliable consulting partner to maximize the opportunity for cost improvements, provide consistent support, and increase the speed of the process. With so much at stake, the company needed a reliable partner to provide strong support and fast results, so they drew on a long-standing relationship with Rondaxe.

Action: More Data, More Problems

Enormous amounts of data, in various states of (dis)organization, are one of the biggest obstacles during a technology transfer. In this case, not only was there an extraordinary volume of data, but that data resided in various notebooks, was possessed by disparate groups and employees, and in some cases, resided solely at outside organizations. To improve efficiency and eliminate error, Rondaxe leveraged the benefits associated with technology for manufacturing processes:

- Improved communication
- Reduction of human error
- Continuity in performance
- Higher and consistent quality
- Increased efficiency
- Visual tracking of goals and progress
- Insight into process performance
- Comprehensive reporting and analytics

Increased automation of the technology transfer allowed the Rondaxe/ABC Biotech team to identify key problems quickly, efficiently, and decrease potential sources of error.

Result: Successful Technology Transfer! Back on Track, Fast

With assistance from Rondaxe, ABC Biotech was able to pull together a successful technology transfer with minimal delay. The team gathered and summarized relevant data, engaged and vetted a new CMO, and transferred critical knowledge as a team, providing extensive support. The partnership led to successful demonstration and validation campaigns. The most important part? No shortage of supply for the market despite losing the support of the original manufacturer.

Technology Transfer Trends

To survive in the modern global pharmaceutical marketplace, organizations must focus on top-down management of technology transfer to mitigate time lost in production, quality, regulatory and supply-chain issues. Regulatory issues, information storage, and communication are just a few issues that arise in the pharma world during a technology transfer. Minimize the risk of deviations and significant roadblocks in your project, or in the worst-case scenario, failure to bring your product to market. Shorting the market doesn't just mean lost revenue for downtime; it means the loss of exclusivity and maximum profit that can never be recovered, and competing compounds now have a chance to steal market share. Be very careful about evaluating the full cost of lost sales.

50%

The amount of time knowledge workers waste hunting for data, finding and correcting errors, and searching for sources for data they don't trust.

Conclusion

Investment in pharmaceutical research is driving a significant uptick in the pipeline of new chemical entities. Timelines for CMC and technology transfers have shortened dramatically, and movement from development to commercialization has become frenetic. Speed is now part of the equation, and a biotech companies financing and ability to thrive depends on successful technology transfers – in and out.

The estimated cost to develop a new drug is $2.6 billion, and approval rates for drugs entering clinical development are less than 12%. Global regulatory requirements, coupled with competition from generics and biosimilars, means that successful products have reduced market exclusivity. This period of exclusivity is where pharmaceutical companies regain the bulk of return on their development investment. Overcoming technology transfer challenges has become a critical step in this rapidly moving market. A smooth technology transfer can help increase a biotech's valuation and bring life-saving medicines more quickly where they are needed: into the hands of physicians and ultimately the essential link in the entire chain - the patient.

References

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[3]. https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.htmlnology

Who We Are

RONDAXE

Rondaxe is one of the largest and most experienced international CMC consulting groups in the world. We assist virtual pharma/biotech companies and multi-national pharmaceutical clients from early development through commercial manufacturing. Services include comprehensive CMC solutions, drug development, manufacturing, and global regulatory strategies. [Re]source™ is our proprietary software that allows our clients to accurately and efficiently model Cost of Goods, perform should-cost analysis, safely and accurately organize data for Tech Transfer, and gives our users full transparency and traceability.



Kenton Shultis, MSChE

Ken Shultis began working with Rondaxe Pharma in 2006 and became Managing Partner in 2007. He has more than 35 years of experience in pharmaceutical process development and manufacturing. Ken started his career at Abbott Laboratories in fermentation development and went on to work for Merck and Bristol-Myers Squibb. He then began American Advanced Organics, a custom fine chemicals company that he sold to AMRI and became General Manager of Manufacturing. Ken rejoined his former colleagues from Bristol-Myers Squibb in the recently established Rondaxe Pharma consultancy, where he has led the Rondaxe software products effort. He holds a BSChE from the University of Wisconsin and an MSChE from the University of Minnesota.

Brian James, Ph.D, MBA

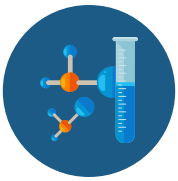
Brian James is the Chief Operating Officer at Rondaxe Pharma. After earning a Ph.D. in Organic Chemistry at UC Santa Barbara and an NIH fellowship at Colorado State, he has greater than 22 years in the pharmaceutical industry. With broad-ranging expertise from early clinical development to commercialization, he helped clients bring novel treatments from development all the way to the market. Brian has leveraged his extensive business and chemistry knowledge assisting clients with their needs in finance, quality assurance, technology transfer, process development.

Shelly James, Ph.D.

Shelly James is the Senior Director of Technical Operations at Rondaxe Pharma. She obtained her Ph.D. in Chemistry at Syracuse University and has years of experience in radiopharmaceutical chemistry, process development, GMP compliance, and business communications. Shelly has worked in molecular imaging and has diverse experience in environmental chemistry and analytical chemistry. She has written multiple publications and grants and has volunteered extensively in STEM education for children.

Rondaxe Tech Transfer Solution

The Rondaxe Technology Transfer platform is a web-based server application designed to save money, time, and effort. Our innovative software facilitates the accumulation and accurate transmission of process information to ensure a successful technology transfer. Learn More.



Questions?

Wondering what Rondaxe and our team of experts can do for you? Discuss how your company can streamline your next technology transfer, or schedule a demo and see for yourself.

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