

TRANSFER EXCELLENCE – right prioritizing of transfer projects and implementing them right

Need for Action

Product transfers between sites can cover the complete finished product or only its subcomponents like packaging, bulk product, API or key starting material. Involved sites can belong to the internal production network or to an external contract manufacturer and the number of affected plants can be only two or several. Very often the technical topics to be solved during a transfer are demanding. Overall, scope and resulting complexity of transfers varied a lot and make the “transfer business” itself complex.

Today, many reasons trigger transfers: Market access, increasing cost pressure or risk management needs may lead to product re-allocations and consequently to transfers to sites in low cost countries and / or sites in emerging markets. Strategic decisions, e.g. focusing internal plant network on specific production technologies or capabilities, motivate transfers to third parties. Life-cycle management oriented product allocation in the plant network is very often an important cause for transfers and – last but not least – local / regional perspectives considering regulatory or trade environment also may enforce transfers.

What can be observed is, the “transfer business” is gaining importance and becomes a vitally important instrument for a successful site network management.

Transfer Excellence

JSC interprets “transfer excellence” as excellence in selecting the “right” transfers and as excellence in executing transfer projects compliant and with great efficiency, i.e. doing transfer projects right. These elements are the two sides of the “transfer excellence” coin and belong together.

The transfer selection process means that transfer ideas are systematically and comprehensively assessed based on an objective, transparent and lean procedure so that priorities in transfer project execution are soundly justified and possible project risk are timely identified.

Regarding transfer projects the classical project-related objectives must be fulfilled: a transfer project must close with a successful transfer considering defined scope and involved partners. Product quality must be safeguarded and market supply continuously guaranteed ... and for obvious reason a transfer project must be in time and in budget. Excellence in implementation requires standardized phase structure as well as clearly defined responsibilities and milestones of transfer projects, supported by operational methods and tools and a well defined project organization.

In this context, a transfer project of an established drug substance / product goes beyond the pure technology transfer. It includes the activities of all functions contributing to switching the product supply from the sending unit to the receiving unit ensuring product quality, compliance and uninterrupted supply - resulting in a multi-functional project team including sending and receiving sites as well as HQ.

A well defined and aligned concept covering all sketched components together with its consistent and sustainable implementation creates “transfer excellence”.

JSC Services

For transferring drug substances or drug products between manufacturing sites JSC consultants support clients in the following areas:

- Design and implementation of an effective transfer selection process – covering transparent evaluation and prioritization of transfer ideas involving all concerned parties to create a well defined transfer project portfolio to be decided by the upper management
- Design and launch of an efficient, phase-oriented and milestone driven transfer project implementation process – covering project organization, planning, monitoring and closure as well as technology, regulatory and supply chain transfer activities with clear tasks and responsibilities
- Development of selected client specific methods and tools including their training – e.g. for technical, regulatory and economic project assessment, prioritization concept, transfer protocol and report templates following ICH and WHO guidelines
- Provision of additional elements in order to start and continuously improve the new processes – e.g. establishment of an transfer expert pool, platform for “best practice” exchange, monitoring and regular reporting elements (incl. KPIs)
- Based on the introduced selection process support of transfer idea evaluations and prioritization – deriving a final management recommendation for the entire transfer portfolio to be implemented
- Support in complex transfer projects with many components to be transferred and a large number of sales countries and involved manufacturing sites – initial project planning, monitoring and reporting to the responsible line management, support in using instruments accordingly

JSC Contacts

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