MANAGING AND MITIGATING RISK IN BIOLOGICS PROCESS TRANSFER

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A repertoire of tactics has been developed over the past two decades to facilitate successful transfer of biologic processes into clinical and commercial production facilities. However, the application of the full set of tactics for every process transfer is often not warranted. Product quality and process performance must fulfil expectations in every process transfer, but the tactics to achieve these goals are typically product/project-dependent.

Two important factors to consider when allocating tactics (and the associated resources) to a particular process transfer are the probability of an initial process transfer delay, and the impact to patients and the company of such a delay. The probability of an initial process implementation problem is heighted under a number of circumstances: for example, when the transfer is to an unfamiliar plant, when the process is non-platformed in some aspect, or when there has been a change of equipment or automation software in the plant. The impact to patients and financial impact to the company of a process start-up delay is also project specific.

Janssen Pharmaceuticals transfers bulk biologics processes to a variety of internal and external, clinical and commercial production facilities around the world. In this presentation, we will discuss our menu of process transfer tactics, and our business process for allocating tactics and resources to each process transfer. The presentation will be illustrated by examples from recent clinical and commercial process transfers.