Parker domnick hunter

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A strategy for avoiding manual errors in biomanufacturing

Bioprocess variation attributed to operator error can be costly, leading to decreased process efficiency and reduced product quality. Parker domnick hunter explains how the application of the skill, rule & knowledge framework (Rasmussen, 1990) can be applied to classify such errors and determine the appropriate use of single-use automation to help prevent manual errors from occurring.

Applying SRK classification to biomanufacturing

The widely known skill, rule and knowledge (SRK) classification was developed by J Rasmussen as a means of identifying the types of errors that are likely to occur when performing industrial tasks. The classification of manual errors depends on the operational situation and the operators' level of conscious involvement. SRK classification can be used to provide insight into the reasons that errors can occur in the manufacture of biopharmaceuticals and hence, help guide the avoidance of such errors.

Knowledge-based operations

Some tasks will be performed by operators with a high degree of conscious involvement, such as when the activity is unfamiliar to the individual conducting it. This is a 'knowledge'-based operation. An example of this scenario within biopharmaceutical production might be the first time that a process is operated within cGMP (current Good Manufacturing Practice) manufacturing. During situations such as these, operators will likely perform the task slowly and with considerable effort.

The SRK framework describes how, in such situations, errors occur because operators become overloaded with information as they try to understand a task of which they have limited knowledge and awareness, while simultaneously attempting to perform it.

Skill-based operations

At the opposite end of the spectrum, some operators within the biomanufacturing industry will be functioning in the 'skill' model of the SRK classification. This is a fast and effortless mode used for the performance of routine tasks by operators who are highly practiced and where the task requires little conscious monitoring. An example of this scenario within biopharmaceutical manufacturing is during commercial manufacture when the same process is being operated routinely. Here, the types of errors that occur are through loss of attention due to distractions, when unfamiliar activities are suddenly added to workflows, or slips that occur where the operator's intention was correct but they failed to perform the task properly.

How can automation reduce manual errors?

Parker domnick hunter has worked on projects with biomanufacturing clients to address both types of errors. The automation of single-use bioprocesses can improve right first time manufacture when transferring processes into cGMP manufacturing, which is particularly useful to CMO (contract manufacturing organisation) clients that scale-up a large number of bioprocesses. Alternatively, when customers are in routine manufacturing such as commercial supply for the clinic, automation of bioprocessing steps helps to eliminate deviations attributable to loss of concentration or distractions and improve the quality and consistency of the final biopharmaceutical product. ■

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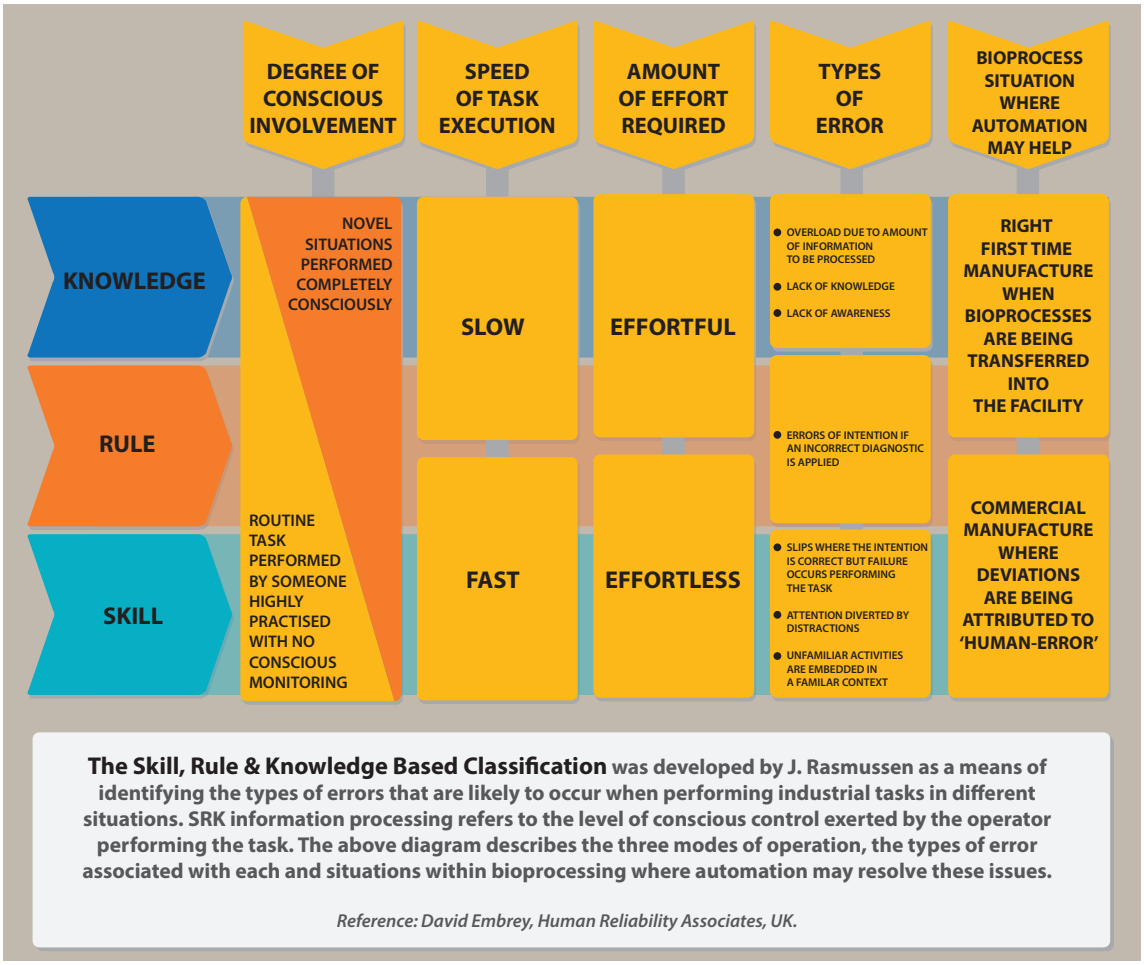

The Skill, Rule & Knowledge Based Classification was developed by J. Rasmussen as a means of identifying the types of errors that are likely to occur when performing industrial tasks in different situations. SRK information processing refers to the level of conscious control exerted by the operator performing the task. The above diagram describes the three modes of operation, the types of error associated with each and situations within bioprocessing where automation may resolve these issues.

Reference: David Embrey, Human Reliability Associates, UK.