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PERSPECTIVE

Pharmaceutical Engineering Strategy for Quality Informatics on the IDEF0 Business Process Model

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Abstract
Introduction Intricate modern pharmaceutical business activities strive to achieve lean development for the desired quality level by applying the quality by design (QbD) approach.
Methods To engineer suitable information flows for quality development by this approach, a business process model written in the type 0 method of integrated definition language (IDEF0) was created for biopharmaceuticals development activities by analyzing actual company activities.
Results and Discussion The model comprises engineering activities of product quality design, recipe development, process engineering, and production. In the QbD approach, the activities are hierarchized into five stages. Information flows that trigger plan–do–check–action (PDCA) cycles beyond the stages (vertical PDCA) as well as those in the same stage (horizontal PDCA) are defined.
Conclusion With the model as reference, it becomes possible to design an extensive information sharing system applying the QbD approach to the activities necessary for a series of functions.

Keywords Quality by design · Informatics · Engineering activity model · Pharmaceutical product development · IDEF0

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Introduction

In the pharmaceutical and other industries, quality by design (QbD) systems have become important in developing highly value-added products [1]. Speedy development of multiple high-quality products based on the proposed strategy has enabled a doubling in research and development investment over a recent 10-year period, from $22.7 billion in 1999 to $45.8 billion in 2009 [2]. As investment increases and development speeds are enhanced, the need for system that enables industries to focus their business activities on quality by design has arisen. Suresh and Basu [3] showed that fundamental research in the science of pharmaceutical product development and manufacturing will not only improve the quality of pharmaceuticals but also reduce time to market and possibly save $20–50 billion annually in the cost of goods for the entire industry. In addition, such fundamental research helps regulators to develop science-based regulatory policies. However, the results of the fundamental research on quality by design have not been broadly applied to pharmaceuticals production because the industry has not developed models for effectively applying the research findings.

In 2005, the International Conference on Harmonization (ICH) Q8 proposed the quality by design (QbD) concept in final form. [4]. According to ICH Q8, the quality of pharmaceuticals cannot be tested into products but must be designed into the manufacturing process. This approach should consistently deliver the required product performance based. Nasr [5] summarized the QbD approach as beginning with the definition of the desired clinical performance of a product. The product quality attributes necessary to achieve the desired product performance are enumerated, and critical quality attributes are determined. A production recipe is developed to meet these quality attributes. The recipe defines critical process parameters, e.g., compositions of the medium and buffers, testing items, and test procedures. Ultimately, continuous improvement is achieved