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Real-time product release and process control challenges in the dairy milk powder industry

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Real-time release testing in the dairy milk powder industry may potentially be achieved by implementing process analytical technology. Research advances have focused on the application of spectroscopic sensors and multivariate data analysis, while neglecting suitable process control strategies and decision-making tools to control critical quality attributes. Due to the unique characteristics of this industry, real-time release, and process control challenges need to be considered before achieving the goal of real-time product release. For example, complex quality attributes can be inferred using proxy measurement; the dependence of advanced analytical sensors can be minimised by using standard pressure/flow/temperature sensors; and investment is required in additional resources and skills for advanced analytical sensors, multivariate models, and control strategy development.

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Introduction

This paper discusses process analytical technology research activities, prominent trends, real-time release and process control challenges in the milk powder processing industry. In this study, the milk powder industry based on bovine milk feed only was considered.

Like other process industries (e.g., pharmaceuticals), the dairy processing industry likes to release their products in real-time. Real-time release testing is defined as 'the ability to evaluate and ensure the quality of in-process and final product based on process data' [1]. There are several benefits of using real-time release testing for manufacturers such as shorter business cycle time, decreased analytical testing, and reduced inventories. The shorter business cycle time attainable through real-time release testing is because manufacturers do not need to wait for quality results to finish their production cycle and distribute their batch(es). However, other real benefits of real-time release testing for the process industries include increased process and product understanding.

The facilitating approach or system that can achieve real-time release testing in the process industry is known as process analytical technology (PAT). Process industries implement PAT for real-time release testing. The concept of PAT was originally introduced for the pharmaceutical industry in 2004 by the US Food and Drug Administration (FDA). The FDA has described PAT as 'systems for design, analysis, and control of manufacturing processes based on real-time process monitoring of critical quality parameters and performance attributes of raw materials and in-process products, to assure acceptable end product quality at the completion of the process' [2]. The term PAT is now applied in various other industries such as chemical, dairy processing, and other food industries [3••].

The concept of PAT is based on process understanding, science, and a risk-based approach. Under the PAT approach, process industries are not required to validate processes by providing repeatable quality. Instead, the approach focus is a science-based understanding of how critical process parameters impact critical quality attributes. The design of experiments approach [4] and multivariate data analysis are usually employed to determine relationships between critical process parameters and critical quality attributes (i.e., how variations in critical process parameters affect critical quality attributes), and the boundary limits of critical process parameters for desired product quality.

PAT components

According to the US Food and Drug Administration (FDA) [2], the PAT approach has three main components: process analysis, multivariate data analysis, and process control. At — line, in-line, or on-line process analysers are required to measure and monitor critical process parameters and critical quality attributes. Multivariate data analysis tools are used to understand critical process parameter' relationships with critical quality attributes, identify values of critical process parameters needed to achieve desired critical quality attributes, and identify dominant patterns in the data sets, such as groups, trends, and outliers. Process control tools (e.g., statistical process control performance monitoring) are used to monitor and execute control actions [5,6] based on critical process parameters and critical quality attribute measurements.

PAT in the dairy industry

This section briefly summarises recently published literature about real-time release testing or process analytical technology (PAT) activity in the dairy industry. Prior to commencing it is interesting to note that the dairy industry has unique characteristics which are quite different from other industries (e.g., pharmaceuticals) already implementing PAT. For example, the dairy industry raw materials (e.g., milk) are highly variable and heterogeneous in nature [7,8]. Critical quality attributes include multi-array functional properties which are hard to measure (e.g., taste and flavour). The dairy milk powder industry also uses mostly semi-continuous processing [9] and has a high-volume to low-value product ratio. It is important to consider these unique characteristics before implementing PAT in the dairy milk powder industry.

In the dairy industry, real-time release testing or PAT activity is mainly dominated by spectroscopic technologies for process analysis, the first of the three main PAT components [3••]. This observation might be due to the fact that spectroscopy can be used to predict product quality after statistically relating a measured signal to a reference signal. Spectroscopic technologies such as mid-infrared spectroscopy, near-infrared [10], and front-face fluorescence spectroscopy [11] have been applied in the dairy industry. Spectroscopic techniques are routinely applied in the dairy industry for compositional control to standardise the fat, protein and moisture content of the powder [12,13]. However, this is generally not reported on, as aspects of it are commercially sensitive.

Other than for compositional control in the process, one example of the application of spectroscopic PAT techniques is for monitoring the adulteration of infant formula. Melamine (2,4,6-triamino-1,3,5-triazine) addition to infant formulas in small amounts (up to 2.5 ppm) increases the apparent protein content reported by standard post production tests as because it is high in nitrogen. However, a high dose is toxic, and a recent incident of melamine contamination in infant formula resulted in more than 300 000 children being affected with renal complications in China [14,15]. Mauer *et al.* [16] evaluated the ability of near-infrared and mid-infrared techniques to detect and quantify melamine in infant formula rapidly. Models of spectral data of infant formula containing between 0.1% and 40% melamine were correlated with melamine concentration using partial least-squares models with regression coefficients, R^2, of more than 0.99. Furthermore, factorisation analysis of spectra was successfully used to differentiate between unadulterated infant formula from samples containing 1 ppm melamine. Mauer *et al.* [16] concluded that near-infrared and mid-infrared techniques are non-invasive, require little or no sample preparation, and can rapidly detect and quantify melamine in infant formula powders.

PAT applications in the dairy milk powder industry are not restricted to spectroscopic analyses or to compositional characteristics only. Milk powders are also quality tested for functional performance, sensory and microbiological attributes. These quality tests tend to be highly labour intensive and, often, as in the case of sensory and functional performance, subjective. Furthermore, they are usually carried out post-production with a significant time delay [17]. Nonetheless, it is still possible to implement PAT with these characteristics. For example, using particle size as a proxy measurement for inferring the dispersibility of powder during manufacture [18••]. The dispersibility test is one of a number of tests that measure the dissolution ability of instant whole milk powder, and is very labour and time intensive and often carried out post manufacture [18••,19]. However, the dispersibility of milk powder is largely dependent on the particle size distribution [19,20]. Thus Boiarkina *et al.* [18••] have proposed the use of particle size distribution measurement to infer whether the powder dispersibility specification is being met during manufacture. Boiarkina *et al.* [18••] found that particle size distribution measurement could be used for this purpose, however, due to the subjective nature of the dispersibility test itself, false-positive and false-negative test rates have to be factored in when using this proxy test. Particle size distribution of powder can be measured on-line, at-line or in-line, and a number of industrial instruments are available on the market, such as the MYTA® online particle size measurement (by Buhler Group) or the Insitec device (by Malvern). This creates the opportunity for large scale industrial plants that rely on post-production testing to be able to correct poorly dispersing powder during manufacture [18••].

However, from the review of the published literature about real-time release testing or PAT activity, it is evident that the implementation of PAT is heavily biased towards discussion of spectroscopic analysis. Many manufacturers are introducing advanced spectroscopic instruments to reduce outmoded laboratory systems but without closing the control loop. This can lead to a potential confusion and an incorrect perception that PAT is just a spectroscopic sensor integrated into a process.

Multivariate data analysis tools and applications also dominate PAT research activities in the dairy industry.