

An integrated approach to process qualification

T8-06 – Technical Session 8 – Modeling and Risk Assessment 2

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Abstract

In order to ascertain that processed food conforms to safety regulations, producers are required to conduct process qualification trials in which a battery of parallel data are collected. If, for each data series, a separate analysis is conducted, it is unlikely that all series will comply with the criteria. Since the statistical tests are conducted in parallel, however, there is no way of determining whether the non-conformities are purely random or manifestations of an out-of-control process. The question thus arises whether a more efficient process qualification can be achieved if the data analysis is carried out simultaneously on the basis of all available data series.

Accordingly, an “integrated approach” to process qualification was implemented in the statistical analysis of a process qualification trial. The aim was to examine whether the integrated approach affords deeper insights into the causes of observed non-homogeneities.

Data were collected for four different parameters across settings corresponding to three different production factors, three different time points and three different sampling locations. An appropriate variance components model was applied to the data in order to obtain estimates of the influence the different settings on the homogeneity.

For some parameters, the approach allowed the identification of a fundamental variability in the analytical component of total variability. Since this source of error does not concern the process, it was deemed legitimate to subtract the corresponding heterogeneity in the assessment of the quality of the process per se. Moreover, the variability of one of the production factors was found to be significantly higher than the others, thus providing crucial information in terms of improving process homogeneity.

It was concluded that the implementation of effective statistical approaches in process qualification can play an important role in enhancing the reliability of process qualification, thus ensuring that food safety criteria are satisfied.

Date: *Friday, the 31st of March, 2017*

Time: *9:45 a.m.*

Location: *314-316 (The Square)*

*****Meet Bertrand Colson and other members of the QuoData team. Visit us at Booth 16.*****

