Thoughts on the Implementation of Analytical Determinations in Plant Environments I

By W. Jeffrey Hurst, PhD

The definition of in-line or at-line tends to be dependent on the organization. There is substantial analytical technology that can migrate from the laboratory to the manufacturing footprint and technically provides excellent data, there is one issue that has not yet been addressed. That issue relates to the implementation of the analytical determinations in the plant environment and there are several items that should be considered before progressing. The focus of this column is to provide you with some general thoughts but it will not be a “how to” column since that is technique and organization dependent. Items that one needs to consider include assay requirements, technical development, funding and support, personnel and continuing activities. In this installment of the column, I will discuss initial assay requirements and technical development with the discussion of the other issues continuing in another column. Finally, this column is being presented from the perspective of an internal analytical group who has this as one of their charters not a group with this as their primary objective.

One of the first issues when evaluating requests is the assay requirements. This items is the linchpin for this type of determination since this is where much can be clarified and many items that can cause confusion can be eliminated. One should first inquire as the reason for the assay. For example, is it to replace any existing manual method or is this a new process that needs monitored? If it is to replace an existing manual process, it can be extremely useful to inquire as to why since if the data requirement is only for 1 sample an hour and the current manual assay only takes 15 minutes, then maybe it is more useful to improve on the current method rather than embark on potentially costly new method. As in some of the early laboratory automation projects, there are some that feel it important to perform in/at line determinations because it seemed like the thing to do. Should this be some of the reasoning this should be vigorously fought against since these projects like their lab automation predecessors tend to be fraught with frustration and likely faulty implementation. Other issues that must be addressed in this phase of the project include requirements for data such as precision, accuracy, calibration intervals and calibration standard. Additionally, one should determine what final form is required for the data. Will it be used as is? Will it be sent to a LIMS, plant data information system or used as an input to a PLC? Will it be imported or exported to a local Excel spreadsheet or Oracle databases? When one has the answer to these questions, they will obviously beget others. One of the other items that are critical is the development of a timetable for the project. This is agreed upon by all involved and should include periodic update briefings that can address issues that could alter the final timetable and the efficient delivery of the application. Finally, in this discovery phase of the project, ensure that the process is iterative since a partnership is critical to a successful implementation.

Once agreement has been reached that there is indeed a true need for this assay, one can begin the work in earnest in technical developments although it is likely many of these activities will be accomplished in a parallel fashion since in the initial phase, there should be discussions about potential measurement alternatives. By the time one reaches this phase of the project, the technical requirements for the determination should have been established. This is not to indicate that there cannot be changes but major alterations in the matrix or method should not occur at this time. Based on earlier discussions, one will be able to ascertain whether the instrumentation will be purchased off the shelf and used as is, purchased off the shelf and modified or custom made. Each of these alternatives has its own set of concerns with the most straightforward of the choices being to use off the shelf instrumentation in an established application. This has the advantage of a straightforward implementation, vendor documentation, vendor support, likely less costly and more timely. In the second case, where one modifies an off the shelf instrument, the implementation can be less “clean” since one likely will need to develop a new application either

with vendor support or internally depending on a number of factors including number of instruments purchased, complexity of application and final timetable. In this case, one ends up with a compromise since there may be additional costs associated with the application development of potentially instrument modifications if these activities have been performed with a vendor. Should these items be accomplished internally, the amount of vendor support will likely be less and depending of the avenue chosen the laboratory partner can be more directly involved than in the first case. The third of the alternatives is the most challenging of the three since in this case one is embarking on an ambitious activity that will be more expensive than the first two and will likely require more “hand holding” than the other two options. In another column, I will continue with some additional thoughts on this topic.

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