

Implementation of Analytical Determinations in Plant Environments II

By W. Jeffrey Hurst, PhD

There are a number of issues that should be considered when implementing method in the plant environment. Previously I discussed assay requirements, timetable and some equipment considerations. I had hoped that those involved in these kind of implementations were well aware that it was not as simple as taking a method or instrumentation developed in the laboratory and moving it to a manufacturing footprint but based some comments from colleagues that is not the case. To apply this same logic, one could take a synthesis developed in the laboratory and then apply some conversion factor or in the home environment, try taking a recipe for a family of four and making enough to serve 100. Obviously this kind of misstep is a recipe for disaster and should be avoided at all costs. During this next installment on the topic, I will briefly remark on regulatory methods, environmental and siting concerns, management commitment communications, and personnel issues.

In the previous column, I had some comments about methods and potential choice of methods but failed to address some issues related to those in regulated industries where methods need approval by some governmental agency since this could limit the options available. For those not in this area, a method/instrument chosen for a plant environment would likely need to be reviewed by an internal review group to ensure all involved in agreement.

After the choice of a technology or instrumentation one needs to determine if there are any special siting or environmental concerns that need to be fulfilled. These might include conditioned power, uninterrupted power through the use of a UPS, temperature requirements for components which may mean air conditioning or even a dedicated phone line that could be used for remote troubleshooting and potentially remote operations. One should also review siting issues. For example, if all the equipment's cleaned with steam each shift will the instrumentation stand up to this type of treatment?

Management commitment is a critical linchpin to the successful implementation of method or technology since without it again the activity is destined to fail. It may be appropriate to provide a management overview of the technology chosen since some tend to use terms like NMR, NIR, FTIR and others without thinking about their meaning but to one who doesn't use these everyday, they may resemble a foreign language. This review doesn't need to be in excruciating detail but should be sufficient so those involved are informed. This has two complimentary benefits with the first of this being that there should be no surprises to management and those directly involved will likely have an umbrella of support. To paraphrase an old Holiday Inn ad, "The best surprise is no surprise at all"

Communications is another one of the items that if not done well can create substantial problems for a project. My recommendation is to err on the side of providing too much information since the opposite approach is fraught with problems. With respect to communications, not only should there be sufficient in quantity but one should ensure they are of sufficient quality since one doesn't want the GIGO syndrome. One final comment related to communication is that it should be 360-degree communications ranging from the instrument operator to the project manager and above.

As in every project, people make the difference and this type of implementation is no different. The choice of those involved in the project team needs to be carefully accomplished since it needs to be the correct mix of those familiar with the method and instrumentation and those familiar with plant operations. For example, is the method going to be an at-line or in-line method? While both types of methods occur in the manufacturing area, one type might need a small laboratory while the other is performed in a production stream. These choices would

obviously have been made early in a project but can impact some of the personnel choices. In the previous column, I addressed the issue of data and where it might be used and that would impact the personnel requirements. After these questions have been answered, one can then determine does the individual need to be a trained scientist or would a better approach be to train a member of the operations staff? There are pros and cons to both approaches and that discussion is beyond this modest column but these are points for consideration. In a similar vein, one should also address the type of training that is going to be required such as on- site, off-site, Internet or some hybrid of these since one needs to again get management commitment to ensure the training can be accomplished in a timely manner and is not looked upon as a “spare time” activity. Finally under this topic, one should ascertain what type of follow up training is going to be required.

On final item in this second installment is to ensure what type of follow up will be required. For example, regular phone calls and emails are a given but what else might be appropriate. Should someone on the project team visit the installation on a regular basis and if so, what is the best timeframe? While some of these issues have likely already been decided earlier, ensure that this activity is accomplished and yes! This is a part of the 360-degree communications.

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