

SELECTING NIR EQUIPMENT TO MEET THE STRATEGIC REQUIREMENTS OF A GLOBALIZED PHARMACEUTICAL COMPANY

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Some two years ago our company undertook a project on manufacturing network rationalisation to maximise competitiveness through continuous improvement in manufacturing efficiency.

One key outcome was the recognition of the benefits that could be derived from timely application of new technology or novel use of existing technologies and even more importantly the need to develop company wide strategies to maximise the impact of such applications.

As a direct result an exercise was undertaken to identify the ten most promising technologies from a list of literally hundreds seen as having the capability of making a rapid impact on the manufacturing initiative.

One of the outcomes of this exercise was the identification of Near Infrared Spectroscopy as a pivotal technology for improving process understanding, performance, and control to deliver consistent product quality cost effectively with broad applicability across our product range.

While NIR had been in use in targeted areas on some of our sites for some years our new challenge was to develop a strategy to extend NIRs application, initially over 17 manufacturing sites, while concurrently expanding the NIR skill base company wide to ensure that the return on initial investment could be further maximised as shared applications across the remaining sites as required.

This presentation will provide an overview of how life cycle based user requirement specifications were developed covering:

- Spectrophotometers
- Sample interfaces
- Software
- Equipment and Software qualification
- Calibration transfer
- Ease of developing effective user interfaces and control for applications transferred to a production area
- User training
- World wide support

The presentation will also describe the process adopted for vendor selection to ensure maximum utilisation of the existing company wide NIR skill base and its future development to expedite applications of the technology in development, quality control and production areas.