

## **Abstract**

# **Implementing near infrared analysis throughout the biopharmaceutical process: a survey of applications**

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## **Introduction**

Biopharmaceuticals account for 15% of the pharmaceutical stream today and their importance in medicine will undoubtedly grow. A challenge to manufacturing large and complex molecules using biological systems is the inherent batch-to-batch variability. NIR is used to monitor nearly all aspects of the biological production of useful products from raw materials, through product synthesis and eventual purification. Information included in this presentation will survey a variety of applications where NIR is used to monitor and control bioprocesses.

## **Materials and Methods**

Various methods and applications are presented and represent a wide variety of the possible implementations of NIR in bioprocessing. Cell cultures used include eukaryotic cell systems such as yeast, Chinese Hamster Ovary (CHO) cells, Green Monkey Kidney (VERO) cells and Human Embryonic Kidney (HEK) cells. The individual applications are typically multiday analysis of dynamically changing, aqueous-based complex cell cultures. NIR instruments typically used are the Antaris NIR industrial analysers using diffuse reflection or transmission measurement probes.

## **Results and Discussion**

Tracking of multiple components in growing cell cultures requires high quality equipment and a great deal of appropriate standards. The inherent variability in biological systems poses particular challenges in obtaining good quality and consistent data. Cell density, viable cell counts and lactate dehydrogenase are tracked to monitor general culture health and progress. During cell growth, glucose, lactate and other components are controlled to optimise target molecule production. Additionally, protein concentrations are measured during cell growth to provide information on successful target production.

## **Conclusion**

The use of NIR in cell cultures is emerging as an important PAT tool for controlling a challenging and highly variable production system. Cell cultures are used to produce many valuable products including foods or biopharmaceuticals. The use of NIR to control the process from beginning to end is proving to be a key part in successful production.