

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA

Process Raman spectroscopy for in-line monitoring of mammalian cell cultures in real time

Alexander Pitters

Kaiser Optical Systems, Inc., France

Mammalian cell cultures are complex processes where cells are cultivated under highly controlled conditions using media with a very high number of components. Current effort is focused on obtaining a better understanding of mammalian cell cultures by cultivating predominantly CHO cells for therapeutic protein production. To ensure a healthy progression of the cell culture, it is important to understand and monitor the stages of the biologic manufacturing. In order to build quality into a process a primary step is to analyze the process, understand what the critical quality attributes are, and monitor or rather control those factors. Consequently, there is a significant interest and value in techniques that provide instantaneous response for monitoring and analyzing biopharmaceutical processes. Molecular techniques - such as Raman spectroscopy are widely used for PAT applications, because they provide *in-situ* information in real-time. Real-time measurements within Bio-pharma are achieved for Glucose, Glutamine, Glutamate, Lactate, Ammonium, Viable Cell Density, Total Cell Density, Osmolality, Monoclonal Antibodies and Viability. The analyzer software enables a fully integrated bioprocess management and the instruments allow controlling 4 bioreactors from a working distance of 1 to 300 m. Raman spectroscopy is compatible with aqueous systems and spectra contain both chemical and physical information. Analyzers can be used to study solids, liquids or gas without sampling accessories or preparation. Kaiser Optical Systems is the leader in Raman instrumentation and advanced holographic components for spectroscopy. Products and services are positioned in pharmaceutical and chemical manufacturing around the world.

pitters@kosi.com

Evidence based research for quality control of Indian medicinal plants using HRMS and hyphenated LC/MS instruments

Brijesh Kumar, Awantika Singh, Renu Pandey, Vikas Bajpai, Preeti Chandra and Sunil Kumar

Central Drug Research Institute, India

Herbal medicines, also known as botanical medicines or phytomedicines, refer to the medicinal products of plant roots, leaves, barks, seeds, berries or flowers that can be used to promote health and treat diseases. Today, a vast range of drugs are either natural products or have been derived from them. Moreover increasing sales of herbal products indicate a worldwide concurrent surge of natural product use. Chemical fingerprinting has been demonstrated to be a powerful technique for the quality control of herbal medicines. A chemical fingerprint is a unique pattern that indicates the presence of multiple chemical markers within a sample. Similarly natural products containing inherently large structural diversity are still a major source of bioactive agents. However many bioactive compounds have been re-discovered from new sources of natural products. To avoid it the identification of known leads at the early discovery step is highly desirable, a process known as de-replication. This method provides an efficient tool for rapid and precise identification of molecular formula of small molecules, with some characterization of sub structures, without a cumbersome process of compound isolation. Application of HRMS and hyphenated LCMS techniques for qualitative and quantitative study of bioactive phyto-constituents in Indian medicinal Plants/parts/products (*P. betle*, *A. paniculata*, *Ocimum* and *Rauvolfia*), with their variations and identification of makers will be discussed during the seminar.

brijesh_kumar@cdri.res.in

Notes: