

## Downstream processing of gene therapy vectors and vaccines using monolithic columns

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Production of high value biological therapeutics usually involves complex manufacturing processes with high process variability. Additionally, development of robust and reliable bioprocesses can be challenging. PAT aims to enhance bioprocess understanding and implies a holistic approach to ensure that quality is built into products by design. Efficient PAT therefore calls for fast and robust analytical techniques which enables to assess high quality information about critical quality attributes and key performance indicators as parallel as possible to the manufacturing process. PATfix™ is unique HPLC system for routine gradient separations that enables every analytical task. Equipped with bio-inert ceramic pump heads is deliberately tailored to meet the demands of analytical applications covering wide range of biomolecules. Highly sensitive and fast multi-wavelength detector enables to detect component peaks even in very fast gradients.

### Recent Publications

- E LIMONTA, Miladys, et al. "Comparison of CIM® C4 HLD monolithic column with Sartobind phenyl membrane column for pIDKE2 purification." Chinese Journal of Chromatography 1028: 1036.

- Vincent, David, et al. "The development of a monolith-based purification process for Orthopoxvirus vaccinia virus Lister strain." Journal of Chromatography A (2017).
- Lesch, H. P., et al. "Production and purification of lentiviral vectors generated in 293T suspension cells with baculoviral vectors." Gene therapy 18.6 (2011): 531-539.

### Biography

BIA Separations is the leading developer and manufacturer of Convective Interaction Media (CIM) monolithic columns for fast purification of biomolecules. Our goal is to provide the best solutions in downstream processing and analytics, with the goal of saving our customers valued time and costs during the production of their desired biomolecules. We have over 20 years' experience in chromatographic purification of large biomolecules including viruses, VLPs, phages, pDNA, antibodies (IgM, IgG), proteins, as well as removal of viral particles, endotoxins and proteins from different biological matrices. We provide products that range from small analytical columns to large industrial pre-scale columns (including cGMP and disposable units in IEX, HIC, affinity and customized formats) as well as method development services.

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