WHY NANOFIBRES ARE A GOOD ADSORPTIVE SURFACE – FUNDAMENTAL UNDERSTANDING AND INDUSTRIAL APPLICATIONS FOR MAB BIOPROCESSING

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Over the years, chromatography has proven to be a powerful and versatile technique for the purification of high value biotherapeutics. Yet, today's preparative chromatography of biologics still, in principle, looks the same as it did several decades ago. Any improvements made have been incremental; constrained by the stationary phase format (porous beads), associated column size (bed height and pressure drop), and historical modes of operation. To address future manufacturing challenges such as high cost of goods, diversity in product portfolios, market dynamics and manufacturing flexibility, new, more radical approaches to the development of chromatography materials and towards associated modes of operations are needed.

With the biotechnology industry maturing, wide spread adoption of new high tech tools/products such as high throughput analytics, automated process control, single use materials and real time data analysis is already taking place, which in turn will lead towards revisiting and a subsequent improvement of how chromatography will be operated in the future. Examples of such improvements that are already considered include high productivity operations such as simulated moving bed and rapid, or extreme, cycling regimes.

The work presented here focuses on: i) the physical properties of a cellulosic electrospun fibres as a base matrix for preparative chromatography applications to be operated in high productivity regimes, and ii) the relationships between these properties and other chromatography attributes, such as: surface chemistries, prepacked formats, scale of operations, etc., and optimum process conditions. The challenges associated with the development and use of the nanofibres will be discussed from both the theoretical and practical perspectives.

Examples of industrially relevant applications for the nanofibre based chromatography material will be presented and relevant data from process development and scale-up (1000x) experiments will be reviewed.