Dear BPI-Boston 2018 Attendees,

JNC America Inc, a manufacturer and global supplier of Cellufine chromatography media, is excited for this year's symposium with a great scientific program.

We would like to cordially invite you to the following events we will be hosting throughout the symposium at our **Booth # 1819:**

Cellufine Chromatography Media Abstract: BPI-West 2018 Conference.

The Cellufine™ product line offers a broad range of chromatography resins for the purification of proteins, enzymes, and biomolecules. The media based on spherical cross-linked cellulose beads, which exhibit high chemical stability / mechanical strength, higher flux and inherently bio-compatible. Applications include mAb /protein / polysaccharide purification, endotoxin removal, and used worldwide purifying vaccines, therapeutic enzymes, and virus concentration / purification. Cellulose media have significantly lower Leachables than comparable polymeric beads.

Workflow platforms include; Gel filtration, IEX, Affinity, Mixed Mode and HIC. These media resins are available for broad range of biomolecules and applications. Customized Cellufine media / ligands, and bead sizes available for challenging purification process.

When Purity is Paramount - Cellufine™ Media Delivers.

Poster Presentation #1

By: Natsuki Okaniwa[1], Eri Narita[1], Naoki Yamanaka[1], Masami Shiina[2], Yoshihiro Matsumoto[1], Malcolm G. Pluskal [3] and Shigeyuki Aoyama[1]
From: [1]JNC Corporation, R&D, Yokohama, [2]Manufacturing Research, Minamata, Japan and [3]JNC America, Cellufine Application Lab, Littleton, MA

Title: Development of novel 70µM cross-linked cellulose bead based rProtein A capture resin of high capacity for improved Mab purification at shorter residence times.

Abstract:
A new product development approach will be described for the affinity capture of Mab's from cell culture materials employing a novel base stable rProtein A ligand with up to six available Fc binding sites. The resin is based on a 70 µM size stable cellulose bead with excellent flow properties combined with a high capacity affinity rProtein A ligand immobilized at multiple sites. The new Cellufine™ SPA-HC resin offers higher binding capacity > 65 mg/mL at 4 min residence time to increase throughput in the new continuous chromatography workflow format. These resins have been developed to retain > 95% of their original binding capacity after >100 cycles of re-use under 0.1M NaOH CIP conditions. Resistance to 0.5M NaOH CIP conditions will also be reported. Polyclonal and monoclonal antibodies show efficient elution at pH 3.5 with a 0.1M Glycine HCL or 60 mM Acetic acid buffers. Carry-over of CHO-HCP has been measured after base CIP and will be reported. This new Cellufine SPA-HC resin developed by JNC, will offer flexibility for future continuous workflow formats as well as being compatible with existing chromatography systems.

Poster Presentation #2

By: Naoki Yamanaka[1], Shoya Tagami[1], Malcolm G. Pluskal [2,] Shigeyuki Aoyama [1] and Masami Todokoro[1]
From: [1]JNC Corporation, R&D, Yokohama, Japan and [2]JNC America, Cellufine Application Lab, Littleton, MA

Title: Investigation of NaOH sanitization of chromatography hardware and resins with a panel of microbes in a pre-packed *Super Edge* Column format.

Abstract:
This poster will describe the development of a simple NaOH base CIP methodology for sanitization of the new JNC Corp. *Super Edge* Mini column hardware (6.7 mm ID x 3cmL) pre-packed with Cellufine™ chromatography media. This small volume format will be compared to a larger format Easy Column (100mmID x 50cmL) packed with Cellufine MAX S-h. A microbial challenge sample consisting of three bacterial and one yeast strain was prepared, and a fungal spore suspension added to contaminate the system. Sanitization was carried out by circulating 0.1 – 1.0 M NaOH for up to 2 hours in up flow and downflow directions for the Easy Column 100mmID format. The smaller Mini column test was carried out by passing just downflow for 30-60min with 0.1-0.5M NaOH. After sanitization, the column hardware and resin were sampled for the presence of viable microbial cells. No viable bacteria and yeast were detected (6 x fold log reduction) with 0.1M NaOH base treatment while fungal spores required 0.5M NaOH to achieve the same log reduction. This result suggests that the base CIP methodology developed using the *Super Edge* Mini column format is an effective simulation of NaOH base sanitization in larger production columns.

Booth Exhibition #1819

Date:
September 5th-7th 2018
Location:
Hynes Convention Center
South Boston