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Automated harvesting and 2-step purification of eight 1-L unclarified mammalian cell-culture broths containing antibodies using a novel configuration on ÄKTA™ pure

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Therapeutic antibodies represent one of the fastest growing segments in the pharmaceutical market. The growth of the segment has necessitated development of new efficient and cost saving platforms for the preparation and analysis of early candidates for faster and better antibody selection and characterization. We report a new integrated platform for unattended harvesting and 2-step purification of antibodies expressed transiently in HEK293T-cells at the 1-liter scale. The system consists of two bench-top preparative chromatography instruments connected to a central unit with eight disposable filtrations devices used for loading and filtering the crude biomass feeds. Our end-product QC analysis demonstrates that the quality of the material prepared by the 2-step automated purification is fully comparable to the material purified by standard manual 2-step purification. Average recoveries were also comparable to those obtained by manual purification, indicating that this automated system allows the cost-efficient preparation of therapeutic antibodies in the 20-200 mg range, and covers the requirements for early *in vitro* and *in vivo* profiling of drug candidates.

Biography

Fabian Holenstein holds an Engineering degree in Biotechnology and a Master's in Pharmaceutical Biotechnology. He works as a Senior Scientist in the section of protein production and antibodies at Novartis Institute for Biomedical Research in Basel/Switzerland.

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