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ItPS Friday Seminars

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Process intensification for the purification of

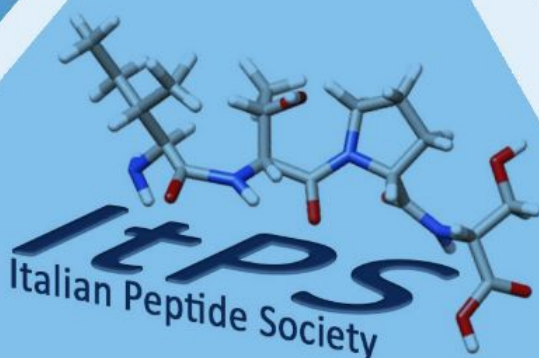
Therapeutic peptides are considered one of the most promising class of biopharmaceuticals. Their industrial production (upstream processing) has exceptionally advanced in the last ten years, especially for what regards solid-phase synthesis.

However, these advancements have not been matched by equivalent improvements in purification procedures (downstream processing) which still represents the bottleneck, in terms of both cost, time and sustainability of the entire production process.

Purification of therapeutic peptides in biopharma industries is usually carried out through single-column preparative liquid chromatography and more chromatographic steps are often required. Indeed, solid-phase synthesis do not lead only to the target peptide but also to a series of product-related impurities which have very similar chemo-physical properties, as well as chromatographic behavior, to that of the target. However, single-column processes suffer of intrinsic limitations in terms of, e.g., yield-purity trade-off. This lecture will show some effective solutions that can be adopted to partially overcome this issue.

The first one is based on the intensification of the single-column process by employing innovative mixed-mode stationary phases (which bear both hydrophobic and charged groups on the surface). It will be shown that thanks to more favourable thermodynamics, mixed-mode columns could lead to a simultaneous increase in both recovery and purity with respect to traditional hydrophobic columns.

Another strategy is based on the employment of multicolumn countercurrent continuous (or semi-continuous) chromatographic approaches. The use of two or more identical columns, working either in parallel or interconnected, allows for the internal recycle of the product into the system. The greatest advantage of this approach is that the purification process can be completely automated, with minimum need of human intervention and considerable saving of time. Meantime, the reproducibility of the process is improved, and solvents consumption is reduced. This communication will show, through a series of case studies, the great potential of multicolumn countercurrent platforms to boost the downstream processing of therapeutic peptides.



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