frontiers in Chemical Engineering

EDITORIAL
published: 02 March 2022
doi: 10.3389/fceng.2022.865635

Editorial: Separation Processes in Pharmaceutical Manufacturing

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Keywords: separation processes, purification, biopharmaceutical, active pharmaceutical ingredient, pharmaceutical manufacturing

Editorial on the Research Topic

Separation Processes in Pharmaceutical Manufacturing

The pharmaceutical industry had a value of USD 1,597 billion in 2020 and was among the least affected economic segments last year, with a worldwide production value growth of 2.8% and profitability of 26% based on the 18 largest global economies (Svidler, 2021). However, the global production of pharmaceuticals is highly concentrated, with 90% of its value in the top 20 countries in 2020, with China the global production leader, followed by the United States with a solid bio-pharma industry.

Because of the highly intense competition, the process development in pharma faces productivity and cost pressures to address the market's requirements, driving a reduction in profit margins and stress on the product pipelines. Therefore, process development is one of the most important pieces to improve efficiency in this industry. Besides the increase in complexity of synthesizing active pharmaceutical ingredients (API), bio-based production elements such as microorganisms and cells impose more difficult separation processes and purification. The latter stages had historically accounted for 40 up to 70% of the capital and operating costs (Spear, 2006), being one of the most important areas to develop when trying to improve competitiveness.

Separation processes in the industry refer to separating a molecule used as a drug followed by removing impurities. The separation stage is applied to remove unwanted byproducts from API manufacturing, and the most used technologies are chromatography, nanofiltration, ultrafiltration, sublimation, de-sublimation, distillation, and crystallization. This stage is inevitably needed in the pharmaceutical industry, whether for purification of the API or intermediate products or for separating the biocatalyst post-biocatalysis, among others.

Separation processes are a key step, as reported by Opdensteinen et al., to obtaining molecules aimed at treating methicillin-resistant *S. aureus* (MRSA) infections. The authors depicted an interesting approach to produce immunoglobulin subclass IgG3 using *Nicotiana* spp as an alternative to microbial and mammalian cells. The expression of this molecule was tested in different cellular compartments and different chromatography conditions during separation and purification to yield a final product with >95% purity and around 10% recovery, which evidences the opportunity areas yet to be faced during post-production stages. This type of bioproduct will be important in facing the challenges that antibiotic-resistant bacteria impose on public health worldwide.

This special issue, also associated with bio-pharma production, includes the review by Alves et al., where the challenges and alternatives for the separation and purification of minicircles are explored. These non-viral delivery vectors represent promising features in gene therapy, with the challenge of

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Edited and reviewed by:
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Specialty section:
This article was submitted to Separation Processes, a section of the journal Frontiers in Chemical Engineering

Received: *30 January 2022*
Accepted: *04 February 2022*
Published: *02 March 2022*

Citation:
Chuck-Hernández C, Chew JW, Mayolo-Deloisa K and Chaudhuri B (2022) Editorial: Separation Processes in Pharmaceutical Manufacturing. Front. Chem. Eng. 4:865635. doi: 10.3389/fceng.2022.865635

having enough material to perform clinical trials, considering the higher transfection efficiency and transgene expression that the minicircle DNA has had in laboratory settings.

Improved separation and purification stages will also allow more similar natural alternatives for some antioxidants and nutraceuticals such as astaxanthin (ASX), where the bio-based alternative obtained from native producing microorganisms is preferred due to its superior therapeutic activity and zero toxicity when compared with those produced by chemical synthesis. Rodriguez-Sifuentes et al. describe a complete view of the production of ASX from its molecular characteristics, comparison between natural and synthetic products, relevant sources of this molecule, and all the downstream processes (cell recovery, cell disruption, separation, and purification), discussing state-of-the-art techniques and the opportunity areas to produce ASX for pharma applications.

We hope that the reader will find this Research Topic useful for reference to state-of-the-art techniques in separation processes in pharmaceutical manufacturing.

AUTHOR CONTRIBUTIONS

CC-H, JC, KM-D, and BC wrote and edited this editorial article.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.