Contribution ID: **34** Type: **not specified**

Process transfer by design for shaping solid lipid nanoparticles

Thursday, 29 May 2025 15:44 (3 minutes)

The production of solid lipid nanoparticles (SLNs) in the pharmaceutical field presents significant challenges, particularly in terms of optimizing drug loading and colloidal properties, as well as enhancing product quality and manufacturing efficiency. This study aims to address these challenges by investigating the transfer of a process guided by Quality by Design (QbD) principles. Specifically, the transition from hot high-pressure homogenization (hot-HPH) to microfluidic production was explored, since hot-HPH is often associated with high energy and time consumption, limited scalability, and potential batch-to-batch variability, all of which can compromise therapeutic performance. In contrast, switching to microfluidics, driven by QbD, offers improved control, scalability, and efficiency, enhancing both product quality and therapeutic outcomes (1).

QbD provides a structured and systematic approach to understanding and controlling critical material attributes (CMAs) and critical process parameters (CPPs), which are essential to optimizing critical quality attributes (CQAs) in SLNs production. By integrating QbD principles, all relevant parameters are evaluated simultaneously and collectively, enabling a more effective optimization and ensuring a consistent, reproducible product quality.

A key component of this study is the use of failure mode, effects, and criticality analysis (FMECA) as a comprehensive risk assessment tool. FMECA is employed to systematically identify potential failure modes, evaluate their impacts, and prioritize associated risks using the risk priority number (RPN). This analysis focuses on the CPPs that could influence the CQAs, and will be conducted for both microfluidic and hot-HPH processes to allow an in-depth comparison of the transfer process (2).

By integrating QbD principles with FMECA, this study highlights the value of these tools in embedding quality into the manufacturing process and promoting continuous improvement. This integrated approach not only supports robust process optimization but also facilitates a seamless transition between different production technologies, ensuring a high product quality and process efficiency. Ultimately, this approach provides a comprehensive framework for optimizing complex SLNs production processes, making it easier to produce, compare, and transfer between technologies such as HPH and microfluidics.

References

1. Figueiredo J, Mendes M, Pais A, Sousa J, Vitorino C. Microfluidics-on-a-chip for designing celecoxib-based amorphous solid dispersions: when the process shapes the product. Drug Deliv Transl Res. 2025;15(2):732–52.

2. Mendes M, Branco F, Vitorino R, Sousa J, Pais A, Vitorino C. A two-pronged approach against glioblastoma: drug repurposing and nanoformulation design for in situ-controlled release. Drug Deliv Transl Res. 2023;13(12):3169–91.

Type of presentation

Poster

Primary authors: Ms VITORINO, Carla (University of Coimbra, Faculty of Pharmacy); Mr BRANCO, Francisco (University of Coimbra, Faculty of Pharmacy); MENDES, Maria (Faculty of Pharmacy, University of Coimbra); Ms ABDERAMANE-DILLAH, Rolel (University of Paris Cité, Faculty of Pharmacy)

Presenter: Ms ABDERAMANE-DILLAH, Rolel (University of Paris Cité, Faculty of Pharmacy)

Session Classification: Poster

Track Classification: Spring Meeting