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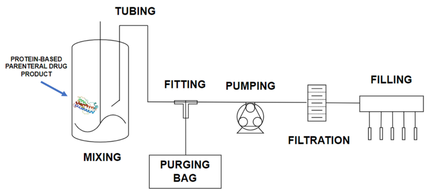
ANALYSIS OF THE SHEAR STRESSES IN A FILLING LINE OF PARENTERAL PRODUCTS

Camilla Moino[1], Bernadette Scutellà[2], Andrea Albano[3], Marco Bellini[2], Erwan Bourlés[2], Gianluca Boccardo[1], Roberto Pisano[1]

[1] Department of Applied Science and Technology, Politecnico di Torino, Italy
[2] GSK Vaccines, Rixensart, Belgium
[3] GSK Vaccines, Siena, Italy

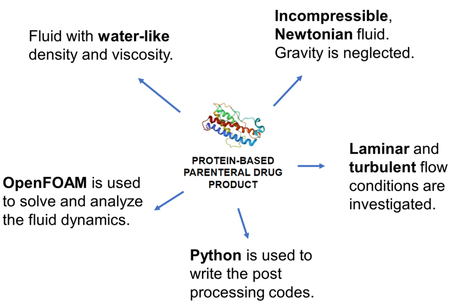
Introduction and problem statement

Protein-based parenteral drug products are exposed to high velocity gradients during standard filling operations. These gradients result in high shear stresses, generally believed to affect product stability.



Here, **CFD** modelling is used to analyse the fluid dynamics within some of these operations and quantify **shear stress** exposure.

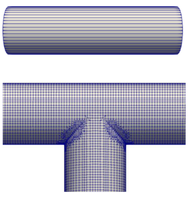
Methods



Focus on some case studies – tubing, fittings

Geometry grid

- Geometrical information from supplier.
- Case study is developed.
- Appropriate mesh is built with CFD mesher.



CFD simulation and postprocessing

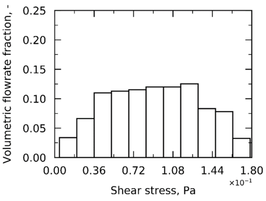
- CFD is used to analyse the fluid dynamics.
- Particles are tracked through their trajectories.
- Local properties, i.e., shear stress, are detected.

Mathematical modeling

- Shear stress distribution models are proposed.
- Numerical validations and comparisons are drawn.

$$\bar{\sigma} = \frac{1}{Q_{tot}} \sum_i \sigma_i Q_i$$





- The model provides a realistic picture of **shear stress** ($\bar{\sigma}$) **exposure**.
- Shear stress exposure on the product is not constant.
- Comparison with shear stress in other unit operations is possible.

Conclusions and perspectives

A new approach has been proposed for the estimation of the shear stress distribution exerted on the product when flowing through standard filling lines' unit operations.

The next step will consist of performing experimental tests to assess the impact of such shear stress on product stability.

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Conflict of interest and Funding
Bernadette Scutellà, Andrea Albano, Marco Bellini, Erwan Bourlés are employees of the GSK group of companies. Camilla Moino is holding a Doctorate studentship and collaborates with GSK as part of her PhD. This work was sponsored by GlaxoSmithKline Biologicals SA.

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