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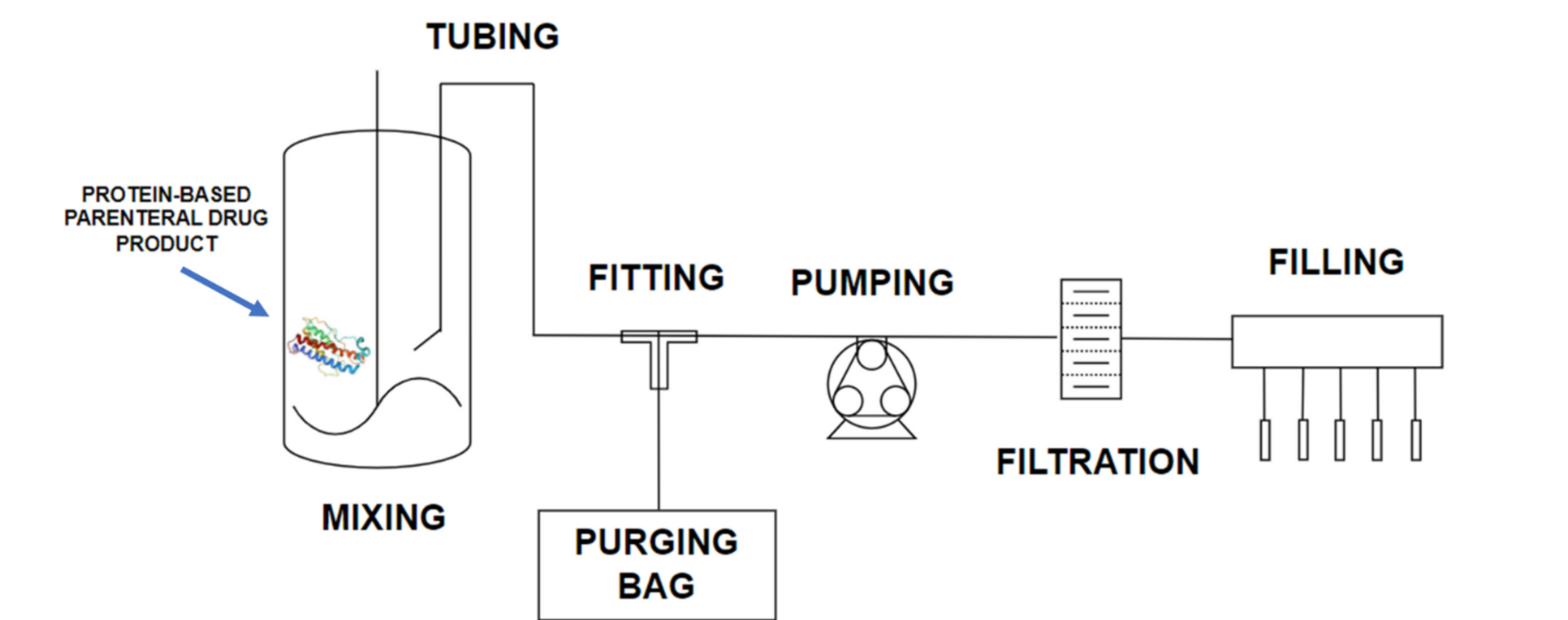
ANALYSIS OF THE SHEAR STRESSES IN A FILLING LINE OF PARENTERAL PRODUCTS

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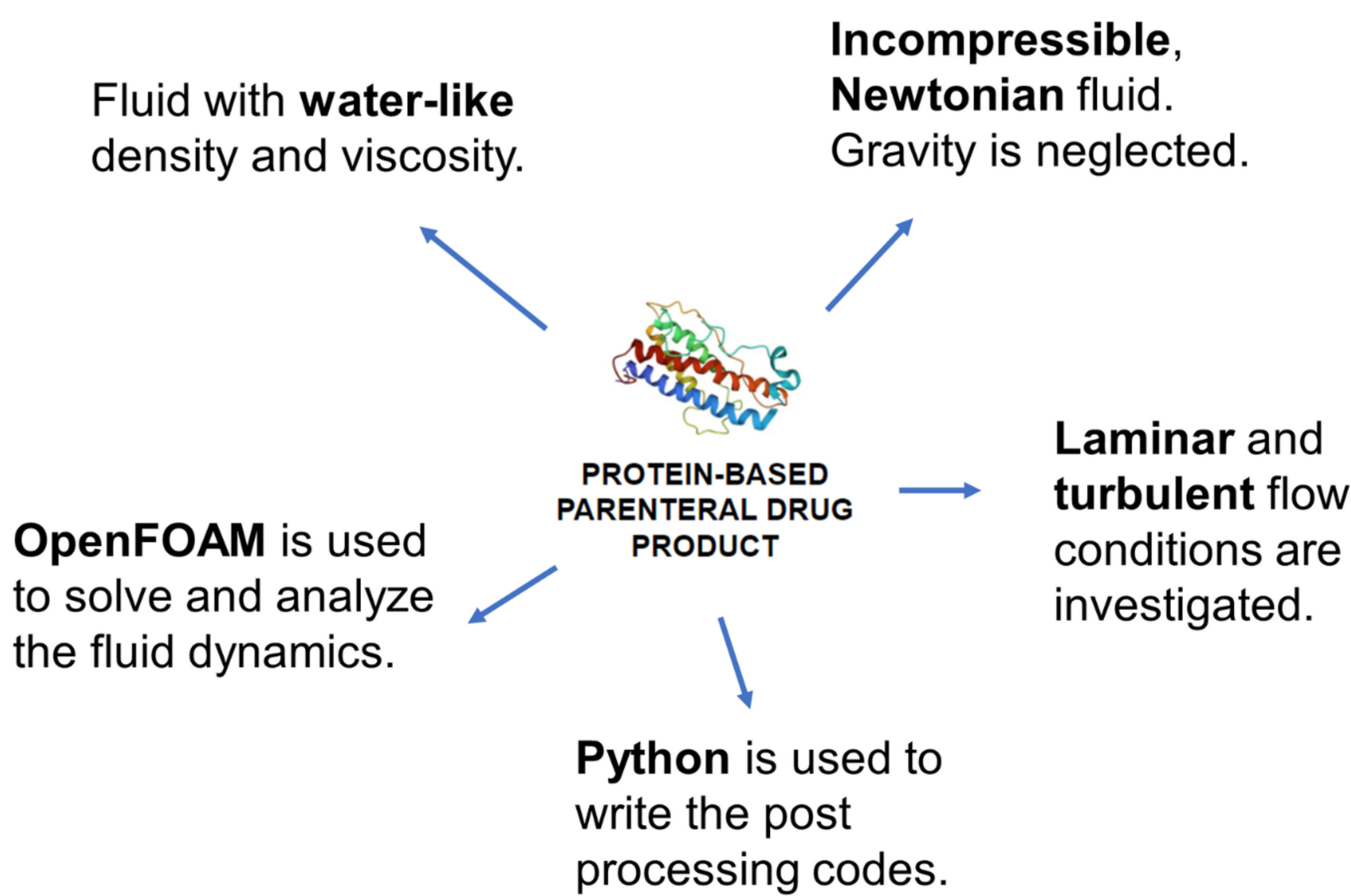
Introduction and problem statement

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.

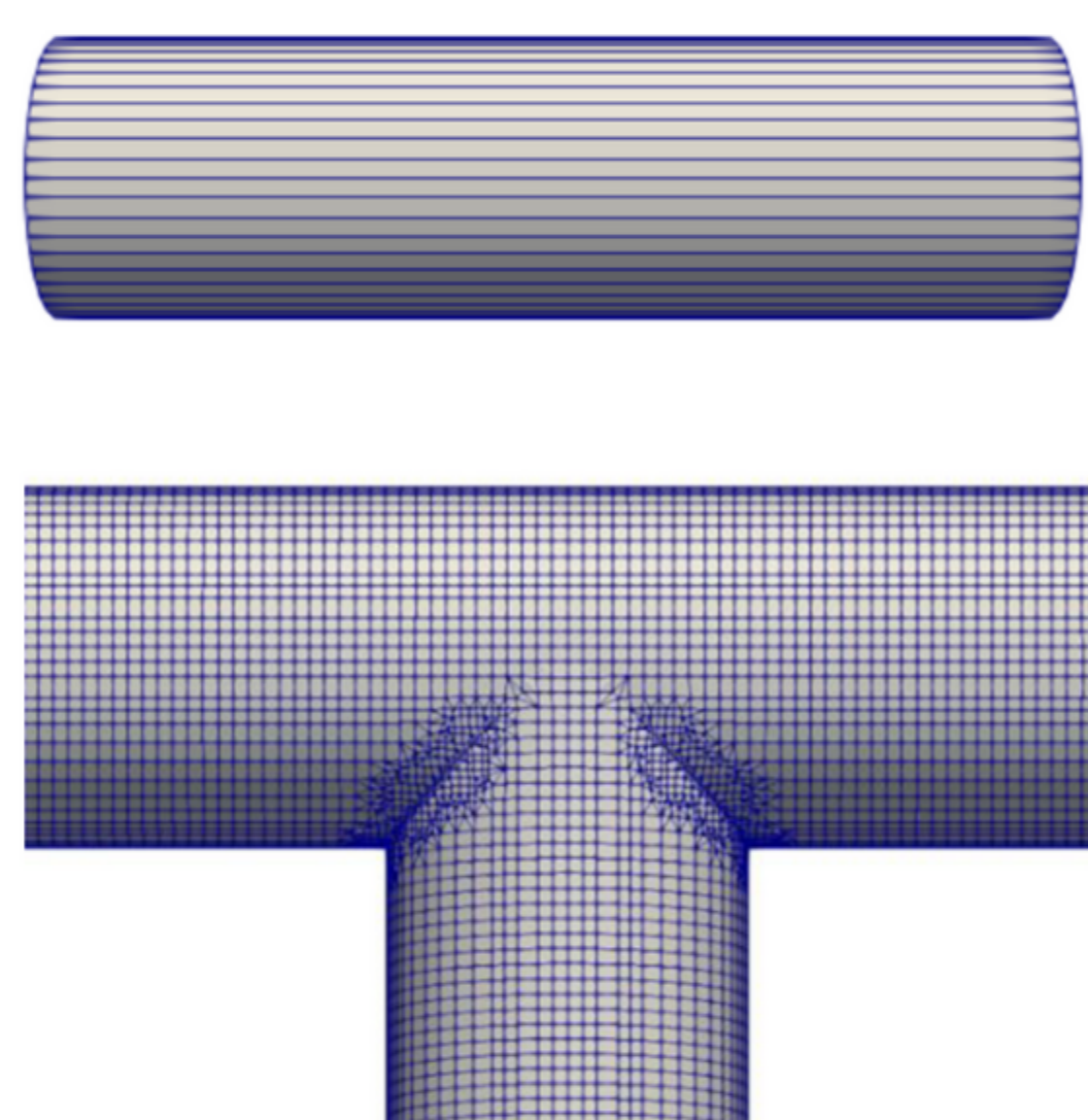
Methods



Focus on some case studies – tubing, fittings

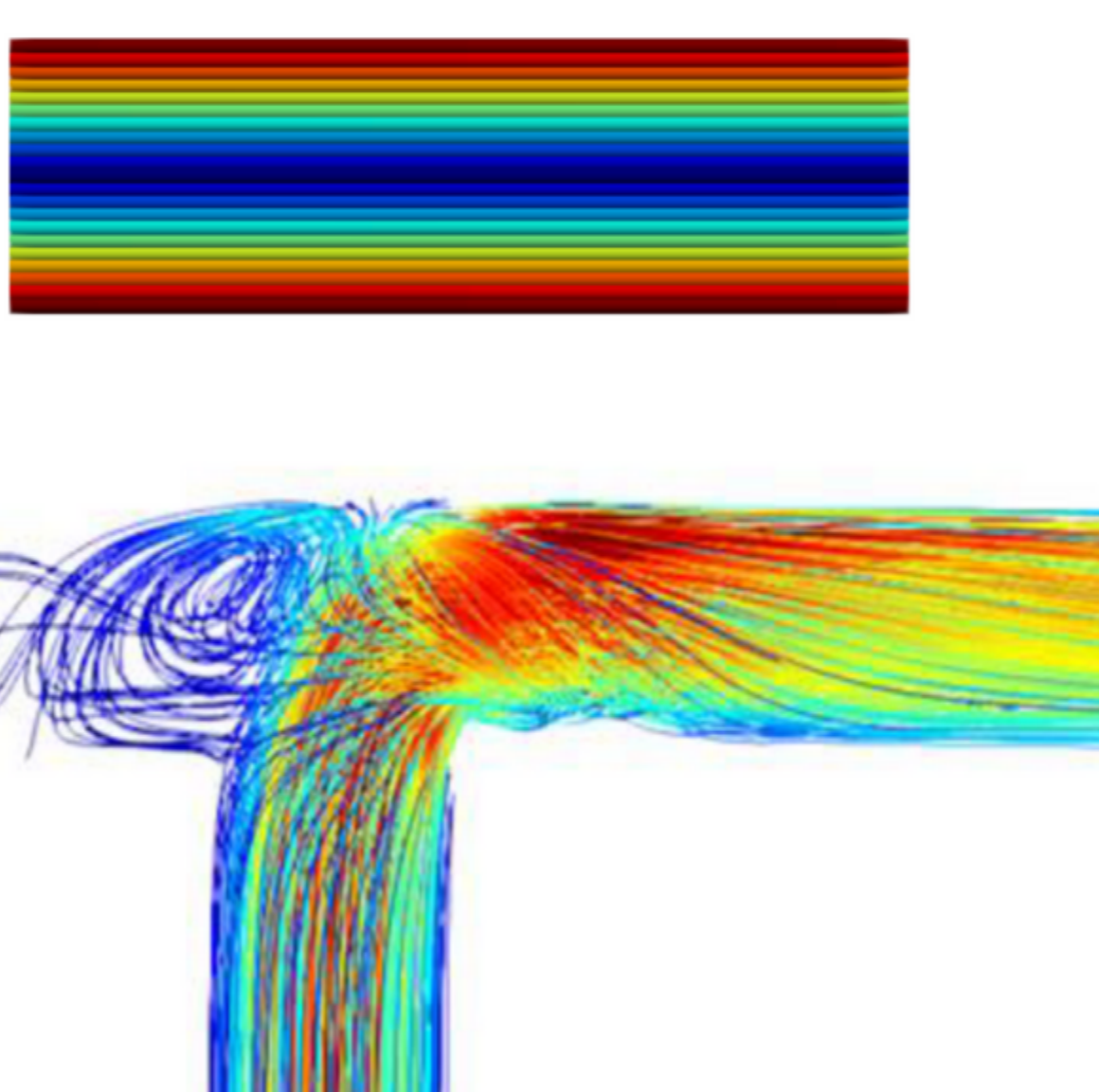
- Geometrical information from supplier.
- Case study is developed.
- Appropriate mesh is built with CFD mesher.

Geometry grid



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

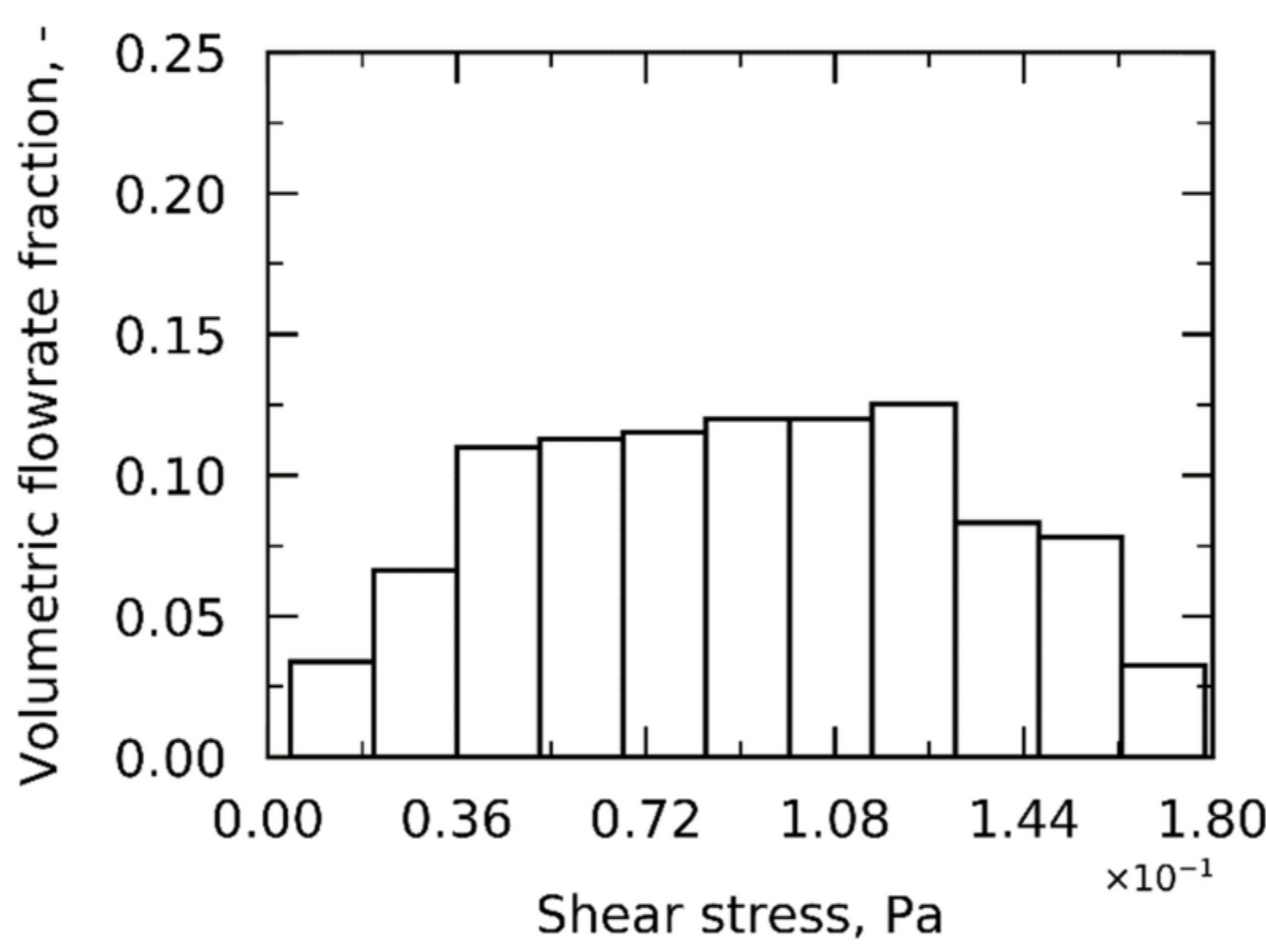
CFD simulation and postprocessing



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

Mathematical modeling

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



- 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.

References

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Moino, C., Scutellà, B., Bellini, M., Bourlés, E., Boccardo, G., Pisano, R. Analysis of the shear stresses in a filling line of parenteral products: The role of tubing. *Processes* **11**, 833 (2023a).
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