

Analysis of the shear stresses in a filling line of parenteral products

Original

Analysis of the shear stresses in a filling line of parenteral products / Moino, Camilla; Scutellà, Bernadette; Albano, Andrea; Bellini, Marco; Bourlès, Erwan; Boccardo, Gianluca; Pisano, Roberto. - ELETTRONICO. - (2023). (2023 PDA Biomanufacturing conference Seville (Spain) September 12-13, 2023).

Availability:

This version is available at: 11583/2981374 since: 2023-08-29T14:29:38Z

Publisher:

PDA

Published

DOI:

Terms of use:

This article is made available under terms and conditions as specified in the corresponding bibliographic description in the repository

Publisher copyright

(Article begins on next page)

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

Camilla Moino¹, Bernadette Scutellà², Andrea Albano³, Marco Bellini², Erwan Bourlés², Gianluca Boccardo¹, Roberto Pisano¹

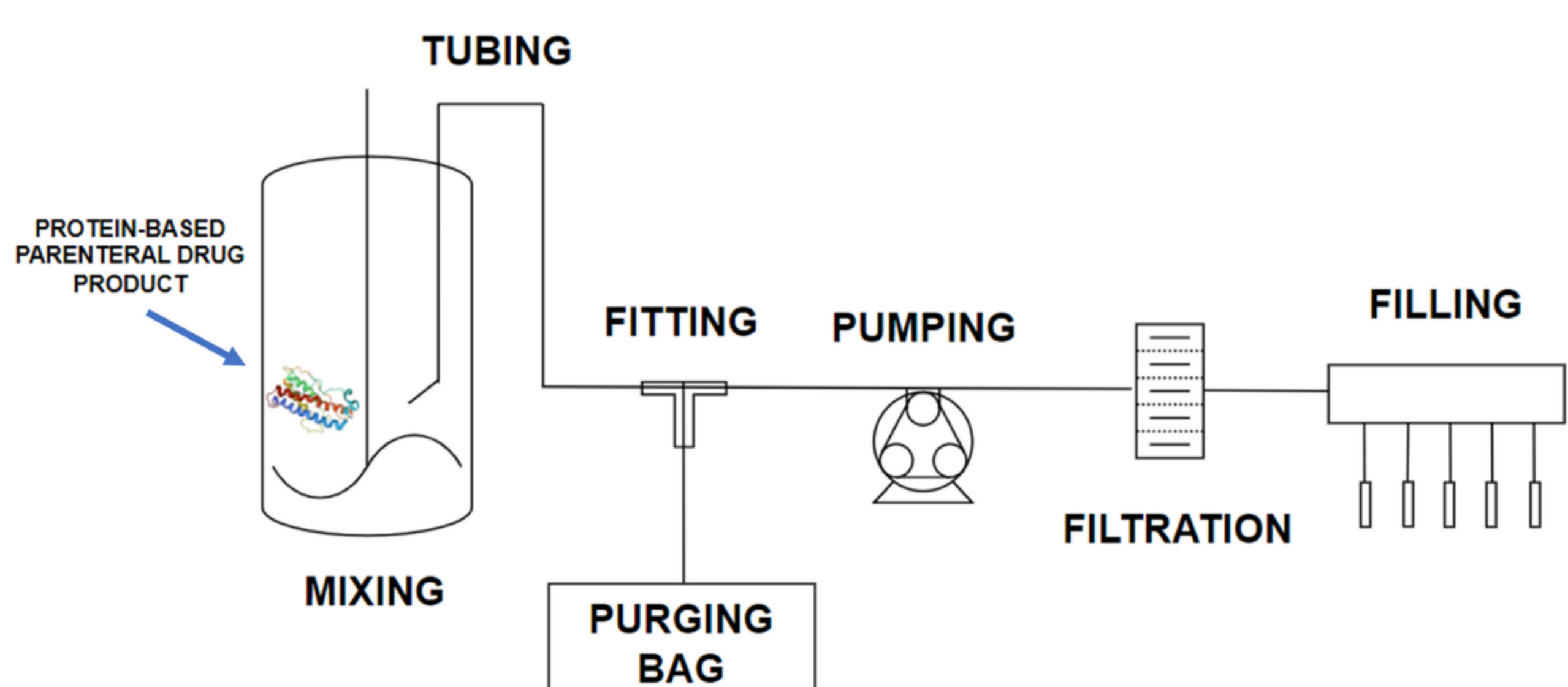
¹ Department of Applied Science and Technology, Politecnico di Torino, Italy

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

Fluid with **water-like** density and viscosity.

Incompressible, Newtonian fluid. Gravity is neglected.

OpenFOAM is used to solve and analyze the fluid dynamics.

Laminar and turbulent flow conditions are investigated.

Python is used to write the post processing codes.



Focus on some case studies – tubing, fittings

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

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

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

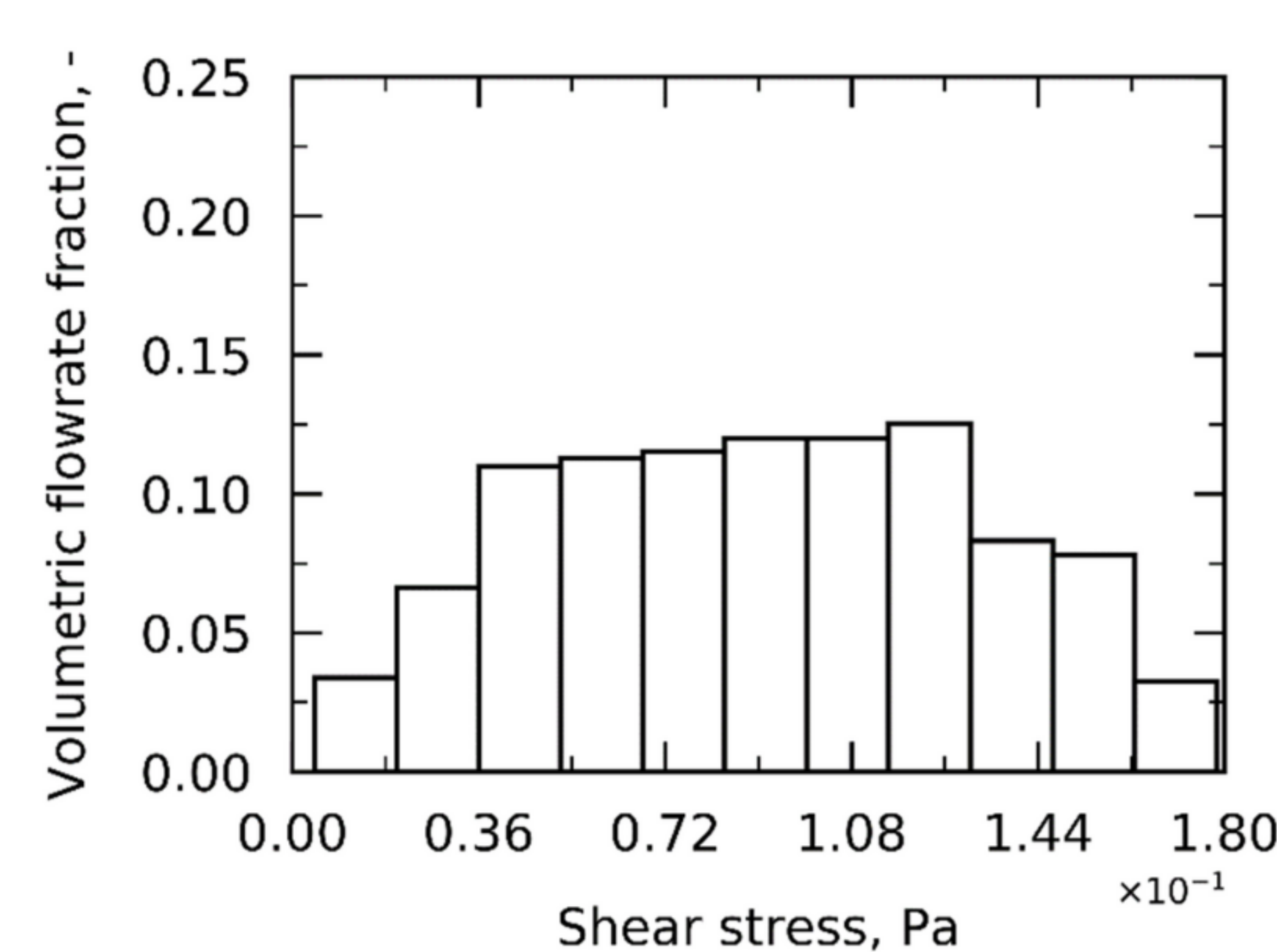
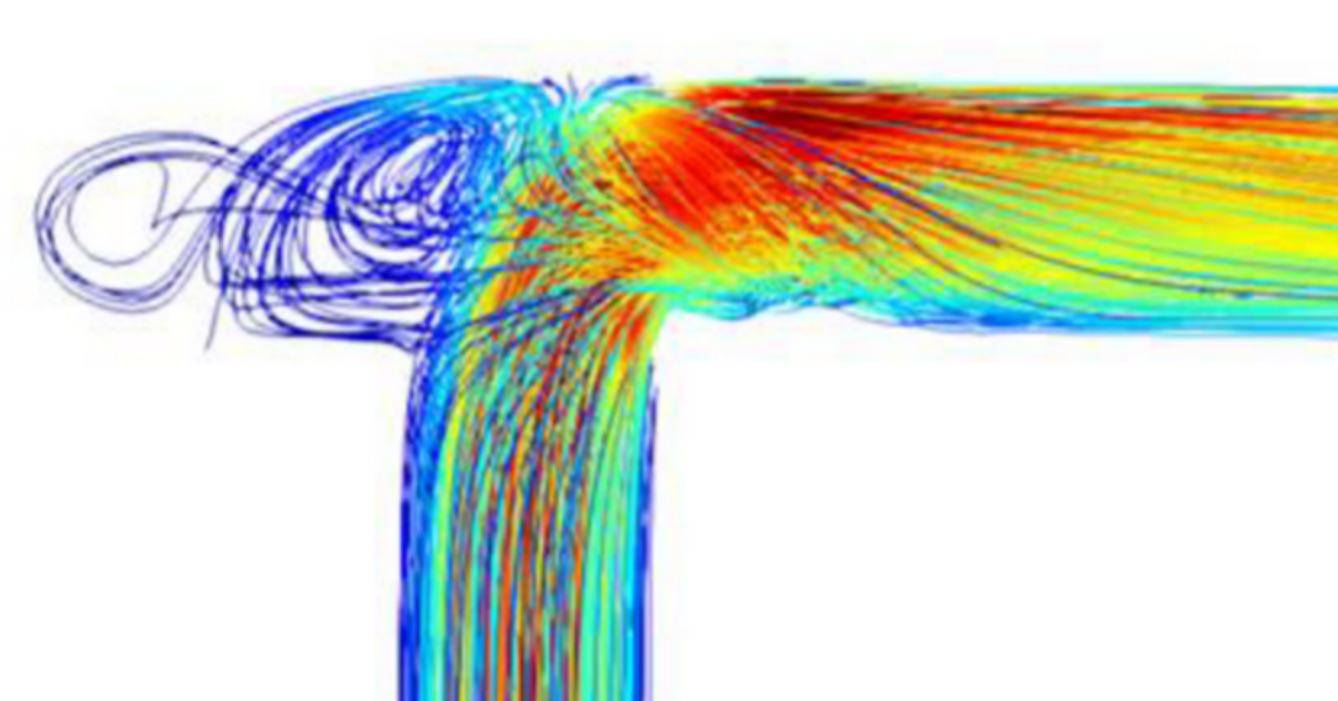
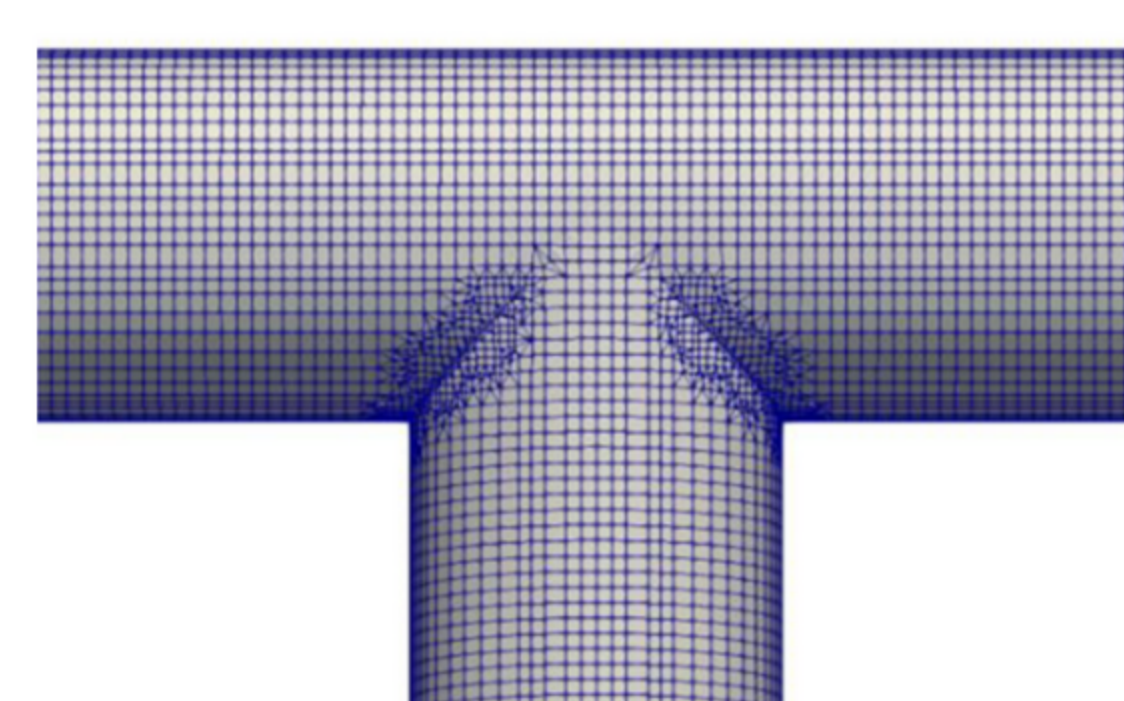
● **Geometry grid**

● **CFD simulation and postprocessing**

● **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.

Want to be up to date on the latest project results? Connect to learn more!



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

- Bekard, I. B., Asimakis, P., Bertolini, J. & Dunstan, D. E. The effects of shear flow on protein structure and function. *Biopolymers* **95** (2011).
 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).
 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 fittings. *Processes* **11**, 1797 (2023b).



Politecnico di Torino

