

# Exclusive interview with Julia Frese, TÜV SÜD released ahead of Pre-filled Syringes Europe

*SMi Reports: SMi Group are delighted to announce that Julia Frese, TÜV SÜD will be a speaker at the upcoming Pre-filled Syringes Europe Conference*

LONDON, LONDON BRIDGE , UNITED KINGDOM, November 21, 2020 /EINPresswire.com/ -- SMi Group is holding the 13th annual [Pre-filled Syringes](#) and Injectable Drug [Devices](#) virtual conference, taking place on the 13th and 14th January 2021, have confirmed Julia Frese, Department Manager Centre of Combination Products, TÜV SÜD as the round table leader and will be discussing “A regulatory perspective on lifecycle management for injectable devices requires a notified body opinion”.

Secure your attendance today! Pharma and Biotech companies can attend for free, register your place here: [www.pre-filled-syringes.com/einpr6](http://www.pre-filled-syringes.com/einpr6)

On the run up to the conference, Julia Frese, TÜV SÜD is interviewed by SMi Group to discuss her thoughts on the biggest growth area of the pre-filled syringes market.

Snapshot of Julia interview:

The Pre-Filled Syringes market has matured greatly over recent years, what key differences have you noticed in the last year regarding significant developments?

“The biggest impact on combined medicinal products and as such on pre-filled syringes are introduced by the EU medical device regulation as it is amending the medicinal product directive by introducing article 117. Marketing authorization applicant are required to involve notified bodies to confirm the device constituent of the combination to applicable general safety and performance requirements. This does apply to the medical device regulation particularly in terms of general safety and performance requirements. The so-called self-declaration by the



SMi Group Proudly Presents the 13th Annual...  
**Pre-Filled Syringes & Injectable Drug Devices**  
13th-14th January 2021

Speaking at the conference:  
**JULIA FRESE**  
Director, Medical & Health Services

  
TÜV SÜD Japan Ltd.

Register at: [www.pre-filled-syringes.com](http://www.pre-filled-syringes.com) Visit: @SMIPharm | #PFSSMi

Pre-filled Syringes and Injectable Devices 2021

marketing authorization applicants will become obsolete from May 2021.”

What current hot topic will you be addressing in your session and what would you say makes it relevant to 2021?

“I will focus more on the lessons learned and on the experience we as a notified body have gained over the last year. Some manufacturers have already obtained notified body opinions, and this is where I would report on. Additionally, as a Team-NB chair member we are working on several guidance documents so I would give an update on the status of those guidance documents. Maybe in this time we may have more clarification from the EMA stakeholder meeting between industry partners, notified bodies, competent authorities and European Medicines Agency.”

The brochure with the full interview, agenda and speaker line-up is available online: [www.pre-filled-syringes.com/einpr6](http://www.pre-filled-syringes.com/einpr6)

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