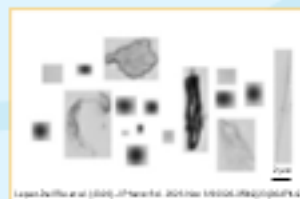




EIP
European Immunogenicity Platform



The EIP-Particle Characterisation Subcommittee (EIP-PCS)

Mission of the EIP-PCS:

Discuss and exchange experiences on protein characterisation and particle formation in the context of immunogenicity and safety, in order to increase our fundamental understanding of product-related causes of immunogenicity.

Aims of the EIP-PCS are:

- Define common strategies and methodologies for particle detection and characterisation
- Evaluate and assess current upcoming particle detection technologies, particle standard samples etc
- Prepare aligned evaluations of new technologies
- Discuss and exchange experiences, needs and suitability of different methods for protein characterisation and the detection, quantification and characterisation of the presence of particles in biologics
- Have a common, scientific founded understanding about for particle detection and characterisation in biologics

Working Groups:

- Non-Clinical Immunogenicity Risk Assessment (NCIRA)
- Immunogenicity Strategy
- Immunogenicity Risk Assessment
- Immunogenicity Assays
- Biosimilars
- Particle Characterisation

Pharm Res (2011) 28:920–923
DOI 10.1007/s12249-011-0291-1

COMMENTARY

Strategies for the Assessment of Protein Aggregates in Pharmaceutical Biotech Product Development

John den Engelsen · Patrick Garidel · Ronald Smulders · Hans Koll · Bryan Smith · Stefan Bessard · Andreas Seif · Oliver Harndt · Wim Jiskoot

John den Engelsen and Patrick Garidel contributed equally to this article.

J. den Engelsen · R. Smulders
Biological and Small Protein Development, MSD,
Olx, The Netherlands

P. Garidel · S. Bessard
Biological Aggregates, Protein Corp & Co. AG,
Department of Protein Science/BioPharmaceutical
Research at Boehr, Germany

H. Koll
Strategic Research – Protein Analysis
Roche Pharma Research and Early Development
Bohring, Germany

B. Smith
UCB
Sough, Belgium, UK

A. Seif · O. Harndt
Senior Biopharmaceutical Analytical Chemistries, Head AG
Chembrugg, Germany

W. Jiskoot
Chairman of Drug Delivery Technology
Ludwig-Maximilians-University Center for Drug Research
Ludwig-Maximilians-University
PO Box 7002, 8050 Munchen, The Netherlands
e-mail: w.jiskoot@ludw.uni-muenchen.de

Additional Topics:

- Additional topics are welcomed and proposed by the EIP-PCS members
- Your proposals....

Each EIP member can join one or more of the EIP working groups.

Membership is free if your organisation is a member of the EIP.

For more information related to the EIP-PCS please contact:

Patrick.Garidel@boehringer-ingenelheim.com

EIP homepage: <https://e-i-p.eu/>