

Accepted Manuscript

A fit-for-purpose strategy for the risk-based immunogenicity testing of biotherapeutics - a European industry perspective

Cathelijne Kloks, Claudia Berger, Pierre Cortez, Yann Dean, Julia Heinrich, Lisbeth Bjerring Jensen, Vera Koppenburg, Stefan Kostense, Daniel Kramer, Sebastian Spindeldreher, Hishani Kirby

PII: S0022-1759(15)00006-X
DOI: doi: [10.1016/j.jim.2015.01.003](https://doi.org/10.1016/j.jim.2015.01.003)
Reference: JIM 11959

To appear in: *Journal of Immunological Methods*

Received date: 1 July 2014
Revised date: 27 November 2014
Accepted date: 7 January 2015



Please cite this article as: Kloks, Cathelijne, Berger, Claudia, Cortez, Pierre, Dean, Yann, Heinrich, Julia, Jensen, Lisbeth Bjerring, Koppenburg, Vera, Kostense, Stefan, Kramer, Daniel, Spindeldreher, Sebastian, Kirby, Hishani, A fit-for-purpose strategy for the risk-based immunogenicity testing of biotherapeutics - a European industry perspective, *Journal of Immunological Methods* (2015), doi: [10.1016/j.jim.2015.01.003](https://doi.org/10.1016/j.jim.2015.01.003)

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Full Title: A fit-for-purpose strategy for the risk-based immunogenicity testing of biotherapeutics – a European industry perspective

Journal	Journal of Immunological Methods
Editorial Reference	JIM_JIM-D-14-00195
Complete List of Authors	<p>Kloks Cathelijne; MSD, Dept of Analytical Development & validation Berger, Claudia; Abbott Products GmbH, Preclinical Development – Nonclinical Safety & DMPK Cortez, Pierre; Sanofi, Research and Development Dean, Yann; NovImmune SA, NovImmune SA Heinrich, Julia; Roche Diagnostics GmbH, Pharma Research and Early Development Bjerring Jensen, Lisbeth; Novo Nordisk A/S, DMPK Koppenburg, Vara; Hexal AG, Sandoz Biopharmaceuticals Kostense, Stefan; Crucell BV, Clinical Immunology Kramer, Daniel; Sanofi, Research and Development Spindeldreher, Sebastian; Novartis Pharma AG, Pre-clinical Safety, Biologics Safety and Disposition, Bioanalytics Kirby, Hishani; UCB Celltech; DMPK Biologics</p>
Corresponding Author	<p>Daniel Kramer, Ph.D. Sanofi R&D Industriepark Höchst Building H831, Room B0719 D-65926 Frankfurt am Main Germany Phone :+49 69 305 27526 Mobile:+49 173 689 42 14 e-mail: daniel.kramer@sanofi.com</p>

Download English Version:

<https://daneshyari.com/en/article/8417532>

Download Persian Version:

<https://daneshyari.com/article/8417532>

[Daneshyari.com](https://daneshyari.com)