SCIENTIFIC AND REGULATORY CONSIDERATIONS FOR ASSESSMENT OF IMMUNOGENICITY RISK FOR GENERIC PEPTIDE AND OLIGONUCLEOTIDE DRUG PRODUCTS

Session 2: Innate Immunogenicity Risk Mitigation - Process-Related Impurities

Introduction and Moderator:

Eric Pang, PhD	Team Lead (acting), DTP I, ORS, OGD, CDER, FDA

Presenters and Panelists:

Andrew Graves, MS, SCYM	Director, Immunogenicity Assessment, Teva Pharmaceuticals
Jeremy Fry, DPhil	Director of Sales, ProImmune
Sofie Denies, PhD	Biostatistician, ImmunXperts
Noel Smith, PhD	Director, Head of Immunology, Early Development Services, Lonza Biologics
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CENTER FOR RESEARCH ON COMPLEX GENERICS at the University of Maryland, Baltimore and the University of Michigan

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