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

Session 5: Synthetic Oligonucleotide Therapeutics

Introduction and Moderator:

Deyi Zhang, PhD Senior Chemist, DTP I, ORS, OGD, CDER, FDA

Presenters and Panelists:

Markham C. Luke, MD, PhD Director, DTP I, ORS, OGD, CDER, FDA

Kui Yang, PhDSenior Research Scientist, DPQR II, OPQR, OPQ, CDER, FDA

Hobart (Bart) Rogers, PharmD, PhD Research Officer and Reviewer, DTPM, OCP, OTS, CDER, FDA

Sudhir Agrawal, DPhil, FRSC Founder and President, ARNAY Sciences; Affiliate Professor, Depart. of

Medicine, University of Massachusetts Chan Medical School

Pharmaceutical Scientist, DPQR IV, OPQR, OPQ, CDER, FDA

Senior Global Toxicologist, Sandoz Global Development (Ljubljana, Slovenia)

Ha-Na Lee, PhD Filip Kolenc, MS



Hybrid Public Workshop October 7-8, 2024

