Paul Chamberlain has accumulated substantial industrial experience in the development of biopharmaceutical products. This experience includes a broad scientific background, incorporating the application of analytical and bioanalytical technologies to the quality control of therapeutic proteins. At MDS Pharma Services Paul was responsible for providing expert consulting on strategies for biopharmaceutical development programs as well as leading development teams responsible for the execution of contracted analytical, bioanalytical, non-clinical, clinical and regulatory services. In this role Paul prepared briefing packages to support Pre-IND and other regulatory agency discussions and defined activities associated with pertinent stage-gates in the product development cycle – including lead candidate selection, manufacturability assessment and IND-enabling studies. He also served as a member of the Scientific and Regulatory Advisory Boards of different companies and was involved in due diligence assessments of various in/out-licensing opportunities.

Dr. Descotes, MD, PharmD, PhD, is Professor Emeritus of medical pharmacology at the Cl Bernard University and Consultant at ImmunoSafe. For the past 30 years he has been involved in the non-clinical and clinical safety evaluation of pharmaceuticals in particular from an immunotoxicological perspective. He is a fellow of the US Academy of Toxicological Sciences and a Eutox Registered toxicologist. Dr. Descotes is the author of 14 books devoted to immunotoxicology, human toxicology and drug safety, and over 300 original and review articles.

Objective
- To recognize the importance of immunogenicity assessment and the impact of ADAs and neutralising antibodies on clinical outcomes of the use of biopharmaceuticals
- To understand how to correlate immunogenicity findings to clinical parameters
- To understand which clinical parameters need to be considered in the planning of clinical studies for later use in the discussion of immunogenicity data
- To learn the characteristics of hypersensitivity, infusion-related, allergic reactions

Synopsis
This is the third immunogenicity-related workshop of EUCRAF. The first dealt with the scientific basis of immunogenicity, its immunological fundamental, the methods used in determining immunogenicity and the approaches available to engineer novel molecules towards low immunogenicity potential. The second workshop provided insights into how to present immunogenicity data in the regulatory dossier, how to prepare an integrated discussion of immunogenicity data and how regulatory agencies evaluate the immunogenicity data package as part of the benefit-risk assessment.

The third event of this series focuses on the clinical parameters that need to be considered in designing clinical studies to receive a database for the interpretation of immunogenicity data. Discussion into product-specific such as biosimilars will be addressed on how clinically significant signals can be complemented by post-approval monitoring. Upon completion of this session, attendees should be able to:
- Explain how anti-drug antibodies can affect PK/PD properties of biologics
- Describe which clinical parameters need to be built into clinical studies to discuss and interpret immunogenicity
- Analyse the anti-drug antibody response and its impact on clinical parameters
SESSION 1: IMMUNOGENICITY IN THE CLINICAL USE OF BIOPHARMACEUTICALS (JACQUES DESCOTES)
- Why should we be concerned about anti-drug antibodies in the clinical use of biopharmaceuticals?
- Which products are affected and why?
- Immunological and clinical characteristics of hypersensitivity, infusion-related reactions and allergic reactions

SESSION 2: DESIGNING CLINICAL STUDIES TO PREPARE FOR IMMUNOGENICITY CORRELATION (HARALD KROPSHOFER)
- Which clinical parameters need to be evaluated in clinical Phase I studies for interpretation of immunogenicity data?
- How to design Phase III studies to form a solid basis to interpret immunogenicity?
- What needs to be evaluated for short-term treatment durations versus long-term use and post-marketing requirements?
- Patient- and treatment-related factors influencing immunogenicity?
- Statistics consideration in detection of ADA in clinical studies?
- Detecting, characterizing and dealing with pre-existing ADA in patients?

SESSION 3: INTERPRETATION AND CORRELATION OF CLINICAL DATA AND IMMUNOGENICITY DATA FINDINGS (JACQUES DESCOTES)
- Correlation of clinical data with ADA findings?
- Distinguishing between hypersensitivity and infusion-related reactions?
- Discussion of the implications of immunogenicity on PK/PD, safety and efficacy?

SESSION 4: REPORTING OF IMMUNOGENICITY RESULTS (PAUL CHAMBERLAIN)
- Integrated assessment and data presentation in the CTD?
- Key elements of the immunogenicity risk assessment and management plan?
- Description of immunogenicity results in the labels?

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12 October 2015

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