

**DI Dr. Guenter Waxenecker, MDRA**

Head of the Department Biologicals, Preclinical & Statistical Assessment,  
Austrian Federal Office for Safety in Health Care



Günter Waxenecker studied food science and biotechnology and holds a Masters degree in drug regulatory affairs. He started in Vienna based SMEs and works since 2007 for the Austrian Federal Office for Safety in Health Care, acting as Head of the Department Biologicals, Preclinical & Statistical Assessment. He is member of the CHMP Safety Working Party and as European Expert he is primarily involved in scientific advice procedures and assessment of marketing authorisation applications submitted to the European Medicines Agency. In this frame he is primarily involved in nonclinical assessment, but also reviews immunogenicity assays as part of a multidisciplinary assessment team.