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Dr. Marcel Hoefnagel is Chair of the Quality Innovation Group (QIG) at EMA. The QIG supports the translation of innovative approaches to the design, manufacture, and quality control of medicines. Dr. Hoefnagel is trained as a Biologist, with a PhD in (Plant) Biochemistry at Leiden University. He works as a Senior assessor of Biopharmaceuticals (including vaccines and Cell and Gene therapy products) at the Dutch Medicines Evaluation Board (MEB). He is also chair of the HMA Substance Validation Group (SVG). The SVG is involved in development and maintenance of EU-SRS; a database with all ingredients in medicinal products in their molecular structure (allowing AI and Big Data approaches). Besides, he’s involved in various research projects to support the assessment of (bio)pharmaceuticals and other regulatory activities.