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Title: Biosimilars - perspective of a company that develops novel biopharmaceuticals as well as biosimilars.

Abstract: Novartis and its subsidiary Sandoz apply the same high quality standards to all products of its extensive pipeline of biopharmaceuticals, no matter whether novel or follow-on. Building on more than 25 years of experience in modern biotechnology and protein science, Sandoz has been setting the standards in the development of biosimilars, with two major products approved and marketed in the European Union and the United States - the only two biosimilars marketed in any highly regulated market thus far. This science-based approach is also reflected in the European Union's recently issued laws and guidelines on biosimilars. Sandoz will provide insights into the comprehensive development programs based state-of-the-art pharmaceutical and clinical science ("Quality by Design") that have passed the scrutiny of both, the European Medicines Agency (EMA) as well as the US Food and Drug Administration (FDA) - providing patients with high quality, safe, and efficacious treatment alternatives.