

## Glossary

**Advanced therapy medicinal products** are advanced therapies that are based on cell therapy, gene therapy and engineered tissues, sometimes in combination with a medical device.

**Critical quality attributes** are physical, chemical, biological, or microbiological properties or characteristics of a product that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

**Data-driven model** uses historical process data to build a mathematical model, such as cell counts, cell seeding densities or nutrient consumption rates, to predict the evolution of a biological system.

**Design-of-Experiment(s)** is a statistical method to study the relationship between multiple input variables and key output variables.

**Digital twins** are a virtual representation that serve as the real-time digital counterpart of a physical object or process.

**European Medicines Agency (EMA)** is an agency of the European Union in charge of the evaluation and supervision of medicinal products.

**Gene therapy medicinal products** contain recombinant nucleic acid administered to human beings for therapeutic, prophylactic or diagnostic effect.

**Material Attributes** are the properties of a material used in a manufacturing process, for example, the age of the cell donor or the glucose concentration in the growth medium.

**Mechanistic models** are predictions about a process based on the fundamental laws of natural sciences.

**Personalized medicine** is a medical model that separates people into different groups—with medical decisions, practices, interventions and/or products being tailored to the individual patient based on their predicted response or risk of disease.

**Pharmaceutical quality system** ensures that the medicinal product or drug is of the quality required for its intended use.

**Process Parameters** are the measured values of various parts of a process which are being monitored or controlled.

**Quality by design** is an approach that aims to ensure product quality by employing statistical, analytical, and risk-management methodology in the design, development and manufacturing of medicines.

**Quality control** is a process by which regulatory entities review the quality of all factors involved in production.

**Risk-based approach** is an approach that allows identification of potential risks of a process and develop strategies to avoid or alleviate them.

**Soft sensing** is a method that uses a software mathematical model to predict difficult to measure response variables. For example, the prediction of cell growth based on nutrient consumption rates in a biochemical process.

**Somatic-cell therapy medicinal products** contain non-germinal cells or tissues that have been manipulated to change their biological characteristics to cure, diagnose or prevent disease.

**Tissue-engineered medicinal products** same as Tissue-engineered product.

**Tissue-engineered product** is a therapeutic product containing engineered cells or tissues, which is intended to regenerate, repair or replace a human tissue.

**Unit operation** is a single step in a manufacturing process. A manufacturing or biological process is usually the combination of two or more-unit operations.

© Jan de Boer. All glossaries can be found at [www.jandeboerlab.com/TissueEngineering](http://www.jandeboerlab.com/TissueEngineering).

Some of this definitions were freely obtained and paraphrased from Wikipedia and Google.