



CELL BY DESIGN

# A quality-focused process development roadmap for ATMPs

**Advanced Therapy Medicinal Products (ATMPs) are becoming a reality, and they have the potential to revolutionise the biotech industry.**

**However, of all ATMPs that have been authorised for the European market, forty percent has already been withdrawn and none have lasted more than five years, which is a worrying trend. If we want to ensure sector viability, something needs to change. Cell by Design® (CbD), a cloud-based software platform that facilitates scalable, cost effective and sustainable ATMP process development, can help.**

## CbD Focal points

The backbone of CbD is a quality-focused process development roadmap. Risk-based process assessments guide science and data-driven decisions in order to meet all pre-defined critical quality attributes of the ATMP. In addition to quality, manufacturability and scalability of the developed product and process are also key in CbD. Therefore, this is taken into account right from the start of a development trajectory, to ensure a hundred percent closed and automated process.

Finally, cost effectiveness is highly valued by CbD. E.g. QC often makes up a significant part of the manufacturing costs. By using CbD, it is possible to build a design space of the process and product and to apply cheaper parametric releases.

## CbD platform

The above is captured in an intuitive cloud-based software platform that is compatible with Industry 4.0 standards (remote monitoring & control and efficient data capturing and storage). This way of working facilitates process automation and allows for the implementation of machine learning methods and predictive modelling. The platform is in accordance with ATMP EMA documentation and it is 21CFR part 11 compliant.

## How can CbD help you?

The application of CbD can be tailored to your specific needs. It can range from a close collaboration (in which you have full access to the software and can count on specialists' advice in process development and in regulatory challenges) to any particular support you need for your specific ATMP product or process.



## Partnership

QbD and Antleron share the vision that there must be something better out there than the current ATMP development practices.

By combining the strengths of both companies and optimising and developing biotech production processes (Antleron) and QA, regulatory affairs and validation in life sciences (QbD), Cell by Design was born.



### Quality by Design NV

Fotografielaan 5, 2610 Wilrijk, Belgium  
T +32 3 844 45 01 / [info@qbd.eu](mailto:info@qbd.eu) / [www.qbd.eu](http://www.qbd.eu)



### Antleron NV

Bio-Incubator, Gaston Geenslaan 1, 3001 Leuven, Belgium  
T +32 16 75 13 71 / [info@antleron.be](mailto:info@antleron.be) / [www.antleron.com](http://www.antleron.com)

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