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► To cite this version:

Julie Veran, Michael Morrison, Florence Sabatier, Léa Chey, Fatou Mbodj, et al.. Quality control and batch release aspects of Advanced Therapy Medicinal Products. Annual Conference of the European Association of Health Law (8th EAHL-Conference), Apr 2022, Ghent, Belgium. halshs-03780272

HAL Id: halshs-03780272

<https://shs.hal.science/halshs-03780272>

Submitted on 19 Sep 2022

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QUALITY CONTROL AND BATCH RELEASE ASPECTS OF ADVANCED THERAPY MEDICINAL PRODUCTS

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Acknowledgements: This work has been supported by ANR-funded I-BioLex project (ANR-20-CE26-0007-01, coord. A. Mahalatchimy). M. Morrison is funded by the Leverhulme Trust through grant no RPG-2017-330.

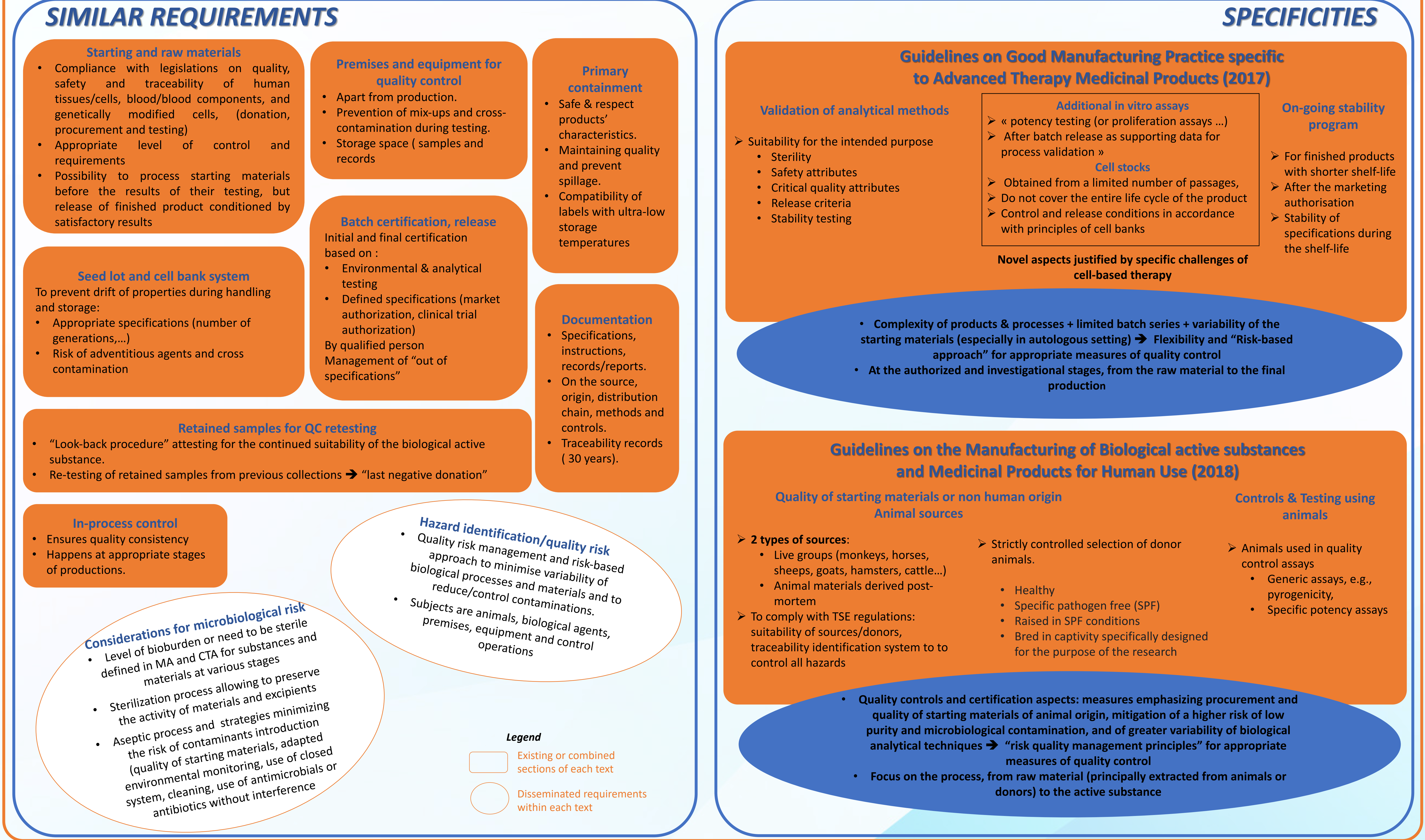
INTRODUCTION

Background: Biological medicinal products are products with an active substance produced or extracted from a biological source. Advanced Therapy Medicinal Products (ATMPs) are medicinal products based on genes, cells or bioengineered tissues that have been regulated in the European Union from 2007. Dedicated Good Manufacturing Practice (GMP) guidelines have been established from the European Commission in order to guarantee their quality, efficacy and safety from the development to the marketing authorisation. Consequently, GMP guidelines covering manufacture of *biological active substances and medicinal products for human use including biological active substances* (hereafter “biologicals”) have been revised in June 2018 to prevent overlapping scope. The manufacturing of biologicals and ATMPs has to comply with guidelines that are established by the European Commission.

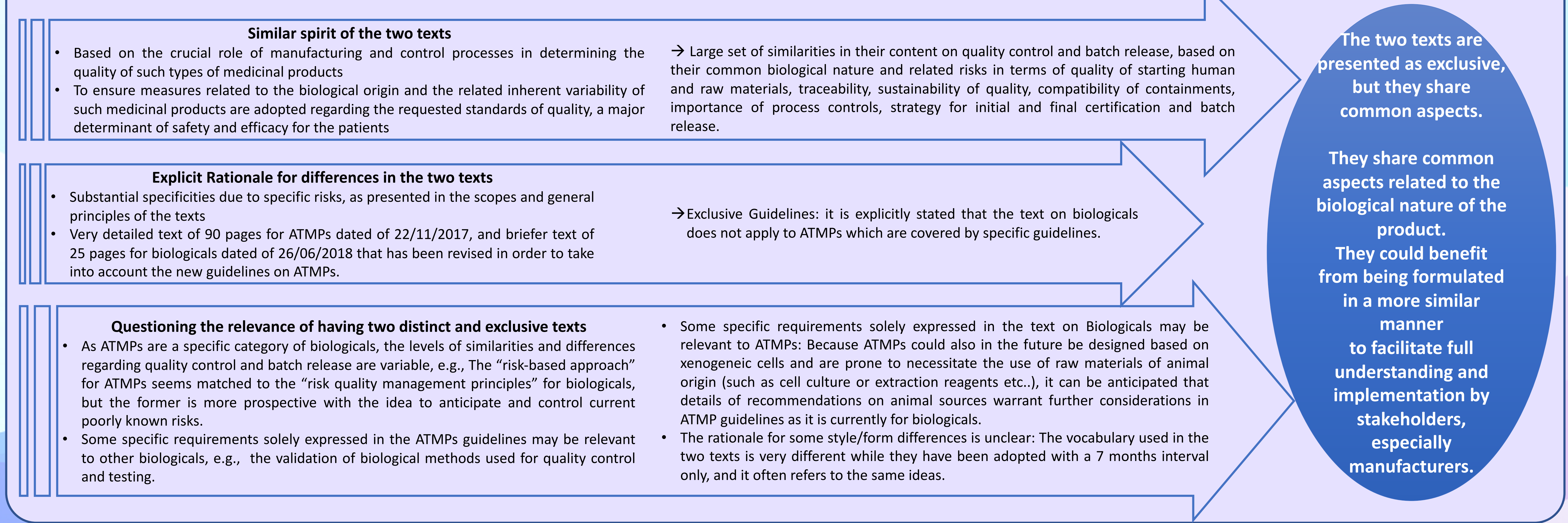
Research question: We hypothesized that due to biological nature of ATMPs, similarities in part of these guidelines related to quality control and batch release aspects could be evidenced in the texts. This analysis will help to understand why two different texts have been elaborated by analyzing whether they are actually based on specific considerations in terms of quality control and batch release arising from the nature of the products and the processes differences between ATMPs and other biological medicinal products.

Methods: We conducted a comparative analysis of the two following regulatory texts : *Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products (focuses on from chap. 10 QUALIFICATION to the end)* and *Manufacture of Biological active substances and Medicinal Products for Human Use*. In a first systematic approach, we identified the similarities and the specificities of texts outline (paragraph and section titles). Then, we analysed contents based on chosen relevant key words that may be diversely used in two texts (control, quality control, strategy of control, certification, release, in process control, quality risk management, analytical technics/methods, testing etc) in order to highlight similarities and specificities in all aspects related to quality control and batch release.

RESULTS



DISCUSSION/CONCLUSION



REFERENCES

- European Commission, Good Manufacturing Practice specific to Advanced Therapy Medicinal Products, 22 May 2018.

- European Commission, Manufacture of Biological active substances and Medicinal Products for Human Use, 26 June 2018.

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, *OJ L* 102, 7.4.2004, p. 48–58 (and following complementary Directives).

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, *OJ L* 33, 8.2.2003, p. 30–40.

- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance), *OJ L* 125, 21.5.2009, p. 75–97.

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/269/EEC - Commission Declaration, *OJ L* 106, 17.4.2001, p. 1–39.