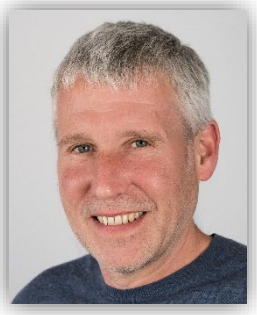
Christopher A Bravery, PhD

Consulting Regulatory Scientist



PROFILE

With a PhD and post-doctoral experience in Immunology Christopher embarked on a commercial career in Regenerative Medicine in 1997. Over the following years he has undertaken various roles and this combined experience has endowed him with a broad understanding of the issues that face Companies in this sector.

After greater than eight years in industrial R&D roles spanning large Pharma and start-up Biotech, Christopher moved to the UK's medicines agency, the Medicines and Healthcare products Regulatory Agency (MHRA), as a pharmaceutical (Quality/CMC) assessor in the biologicals and biotechnology unit. As an assessor Christopher was responsible for reviewing new license applications (MAA), variations (Type IB/II), clinical trial applications and scientific advice for both MHRA and EMA. Assessment work included monoclonal antibodies, recombinant proteins (including biosimilars) and other complex biologicals through the centralised procedure (EMA). With his strong background in cell therapy Christopher became a UK representative on the Cell Products Working Party (CPWP[1]) and through that, one of the authors of the EMA guideline on Cell-Based Medicinal Products and other related guidelines. Together with the Gene Therapy Working Party the CPWP also provided a scientific draft of the dossier requirements for ATMP's (Annex I, part IV[2]) including revised ATMP definitions. At the MHRA Christopher was a member of the Advanced Therapies Steering Committee.

Prior to founding Advbiols, Christopher worked for a medium-size consulting group working on over 30 projects including 11 ATMP's and a number of biosimilar products.

Christopher founded Advbiols in order to focus on novel and unusual biological products, including ATMP, and other products that require imaginative regulatory strategies. Project work includes preclinical (and nonclinical), quality (CMC) and EU regulatory (combined with a working understanding of US FDA). Activities include preclinical strategy, gap analysis, regulatory strategy, due diligence, agency interactions, CMC, nonclinical, clinical trial applications (CTA) and marketing authorisation. Time-permitting, Christopher also undertakes both in-house and externally supported research activities.

Time permitting Christopher is actively involved with a number of committees to promote understanding of regulatory science.

Christopher is regularly invited to chair, speak and run workshops and training at national and international conferences.

EDUCATION

Ph.D

Imperial College, London
Research into human T cell recognition of porcine endothelial cells.

B.Sc. (hons.)

Brunel University, London
Applied Biochemistry.

PROFESSIONAL EXPERIENCE

2009-Current

Consulting on Advanced Biologicals Ltd
Director/owner
London UK.

2021-Current

Amniotics AB
Non-executive board member

2014 - 2016

TrakCel Advisory Board
Cardiff, UK

2008 - 2009

Director of regulatory Affairs, ATMP.
ERA Consulting, London, UK.

2005 - 2008

Pharmaceutical Assessor, Licensing Division.
MHRA, London, UK.

2001 - 2005

Senior Scientist/Team Leader
Intercytex Ltd., Manchester, UK.

1998 - 2001

Laboratory Head
Imutran Ltd. (A Novartis Pharma AG Co.),
Cambridge, UK.

1996 – 1998

Research Fellow, Immunology Dept,
Guys Hospital, London UK.

1995-1996

Research Assistant, Dept Haematology,
Royal Free Hospital, London.

1990-1995

Research Assistant, Dept Cardiothoracic surgery,
National Heart and Lung Institute, London, UK.

[1] Working party no longer exists.

[2] Published by the EU Commission as Directive 2009/120/EC

PROFESSIONAL MEMBERSHIPS

British Standards Institute (BSI)
Biotech Committee BTI/1, ISO/TC 276 (2005-)

International Society for Cell Therapy (ISCT)
Chair (2019, member since 2008), European Legal and Regulatory Committee
Member Product and Process Development sub-committee (2010-)
Global Regulatory Perspectives (GRP) workshop (Annual meeting) organising committee (2012-).
Finance audit oversight committee (2016-2020).

Parenteral Drug Association (PDA)
Member (2015-)
Co-chair European ATMP meetings (2020-21).

International Alliance for Biological Standardisation (IABS)
ATMP regulatory committee (2021-)

United States Pharmacopeia (USP)
Volunteer expert, BIO5 (advanced therapies)

CONTACT DETAILS

cbravery@advbiols.com
Mobile: +44 (0)7773 427460

Selected Publications

The Delivery of Regenerative Medicines and Their Impact on Healthcare (2010)
Chapter 19: A Catalyst for Change. Regulating Regenerative Medicines in Europe
CRC Press Editor(s): Catherine Prescott and Dame Julia Polak.

Regulating interface science Healthcare products: myths and uncertainties
Christopher A **Bravery**
J. R. Soc. Interface December 6, 2010 7 Suppl 6 S789-S795

PAS 83:2012 (BSI), Developing human cells for clinical applications in the European Union and the United States of America. Guide.
Technical Author
Free Download

Potency assay development for cellular therapy products: an ISCT* review of the requirements and experiences in the industry".
Christopher A. **Bravery**, Jessica Carmen, Timothy Fong, Wanda Oprea, Karin H.Hoogendoorn, Juliana Woda, Scott R. Burger, Jon A. Rowley, Mark L. Bonyhadi, Wouter Van't Hof. Cytotherapy Volume 15, Issue 1 , Pages 9-19.e9, January 2013
http://dx.doi.org/10.1016/j.jcyt.2012.10.008.

"Reference materials for cellular therapeutics
Christopher A. **Bravery**, Anna French
Cytotherapy. 2014 Sep;16(9):1187-96.
http://dx.doi.org/10.1016/j.jcyt.2014.05.024.

Do human leukocyte antigen-typed cellular therapeutics based on induced pluripotent stem cells make commercial sense?
Christopher A **Bravery**
Stem Cells Dev. 2015 Jan 1;24(1):1-10.

Measurement reliability over the cellular therapeutic product lifecycle
Christopher A **Bravery**
Regulatory rapporteur, May 2015, 12(5), 12 – 16

Bravery, C. A. (2018). "Making the grade: untangling the myths of raw materials used for the manufacture of cell- and gene-based medicinal products." Cell Gene Therapy Insights **4**(3): 207-225.
http://dx.doi.org/10.18609/cgti.2018.022.

Bravery, C.A., Ball, O., Robinson, S.A. (2019) "EU market authorisation strategy – lessons from the first 22 ATMP submitted to the EMA" Cell Gene Therapy Insights http://dx.doi.org/10.18609/cgti.2019.088.

Elsallab, Magdi, **Christopher A. Bravery**, Andreas Kurtz, and Mohamed Abou-El-Enein. "Why Cell and Gene Therapy Products Fail to Perform Post-Approval? A Matched-Pair Analysis of Regulatory Submissions among Biologicals in the Eu." Molecular Therapy - Methods & Clinical Development (2020).
http://dx.doi.org/10.1016/j.omtm.2020.05.035.