Consulting on Advanced Biologicals

Training Courses:
Potency and Comparability for Cell, Gene and Tissue Products

May 1st & 2nd 2017

Lancaster Hall Hotel, Paddington, London.

May 1st 2017

Overview of Course 1: Potency

Potency assays are an essential concept in determining the quality of any biological medicinal product/biologic. Extending this concept to cell, gene and tissue products is more challenging and often the most difficult aspect of characterising these products. The relevance of the approach taken is often challenged by regulators both during development and when seeking market approval. This workshop will lead you through the issues and how to develop an overall potency strategy to facilitate the implementation of successful potency measurements.

Workshop Learning Overview

- What is potency?
- Why is potency so important?
- How do I develop potency assays?
- What are the regulatory expectations for potency assays?
- Case studies: What can be learned from previous experience?
- Interactive exercise: develop a potency strategy for a worked example product.

May 2nd 2017

Overview of Course 2: Comparability

Change is inevitable and necessary both in development and over the post-approval product lifecycle. Whenever changes are made it is necessary to confirm they do not adversely impact the quality, and therefore safety and efficacy, of the product; this requires data beyond meeting current specifications. With any biological product this is challenging, for cell, gene and tissue products that cannot be fully characterised the challenges are greater still. Concerns about comparability undertaken during development are common issues raised during review and often delay market approval or contribute to failure. This course explains what comparability is and how to develop a successful comparability protocol.

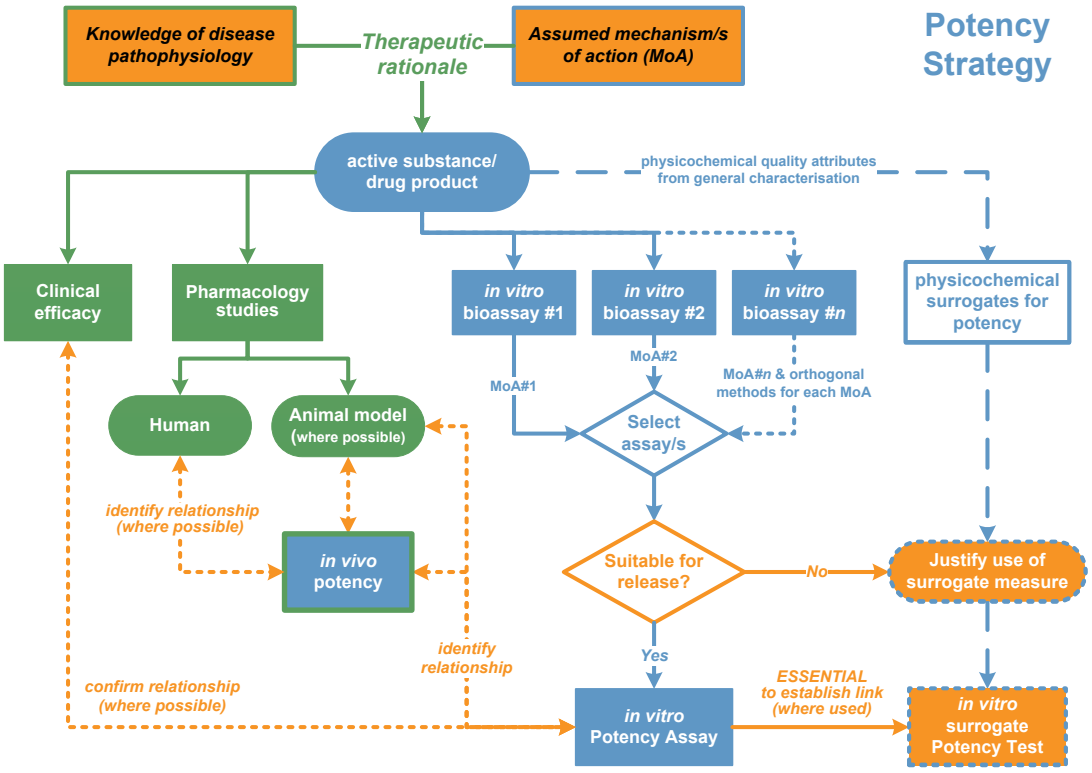
Workshop Learning Overview

- What is comparability?
- Why is meeting existing specifications not comparability?
- How do I apply the principles of comparability to highly variable products?
- Case studies: Common mistakes with comparability and their consequences.
- Interactive exercise: Spot the weaknesses and propose improvements to a worked comparability study.

Course 1: Potency

Scientific Content

This course covers the scientific principles of potency assays for biological medicinal products, as identified and defined in ICH Q6B. These principles are agreed between the European Union, United States, Japan, Canada, Switzerland, Brazil, Republic of Korea and followed by many other countries (including Australia, India, Mexico, Russia, and Singapore) in addition to the WHO. Extending this general concept to cell, gene and tissue products is more challenging and often the most difficult aspect of characterising these products.



Developing a potency strategy

This workshop will discuss scientific and regulatory expectations and practical considerations for developing a potency strategy. The relevance and importance of potency for product release, stability, compatibility and extended characterisation when establishing comparability will be explained.

The course leader will share lessons from his experience, including case study examples of potency assay approaches.

Your Turn

The course includes an exercise (which will be provided prior to the course) covering a range of model cell, gene and tissue products. During the course you will work together in small groups to develop a potency strategy for your chosen product. Then you will role play a scientific advice meeting between the developer and regulator and either present your strategy or challenge the strategy presented.

Recommended Pre-reading

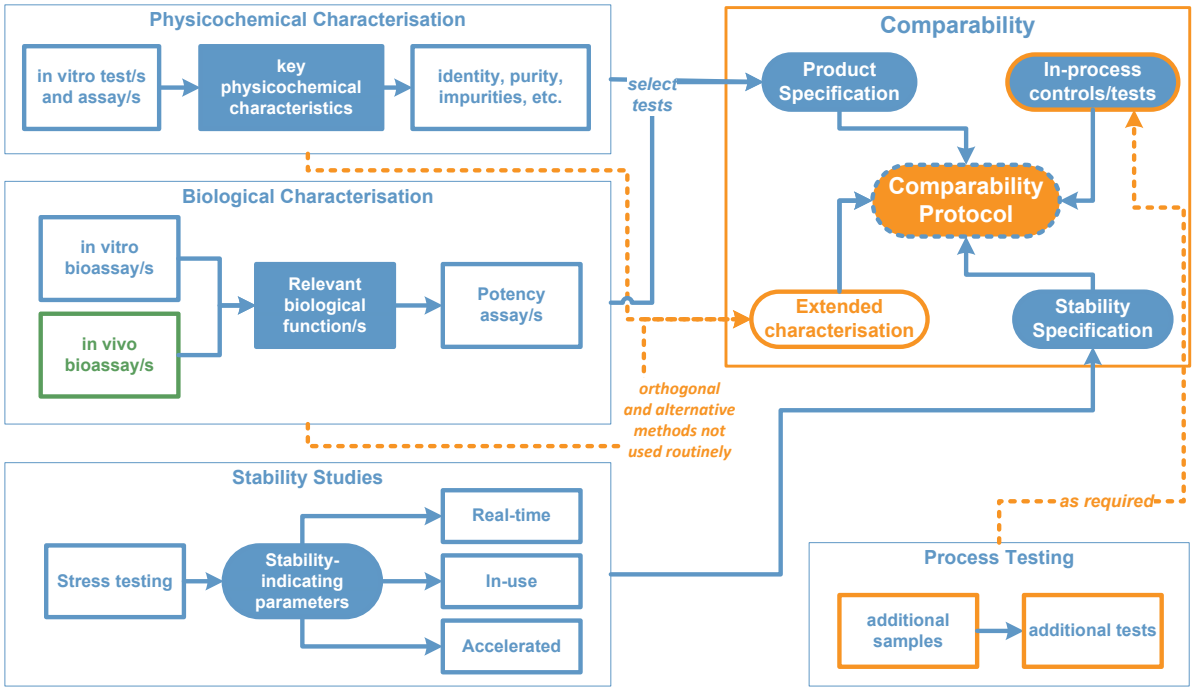
BRAVERY, C. A., *et al.*. W. 2013. Potency assay development for cellular therapy products: an ISCT review of the requirements and experiences in the industry. Cytotherapy, 15, 9-19.

http://dx.doi.org/10.1016/j.jcyt.2012.10.008

Course 2: Comparability

Scientific Content

This course covers the scientific principles of comparability for biological medicinal products as described in ICH guideline Q5E. These principles are agreed between the European Union, United States, Japan, Canada, Switzerland, Brazil, Republic of Korea and followed by many other countries (including Australia, India, Mexico, Russia, and Singapore) in addition to the WHO.



Developing a comparability protocol

Change is inevitable and necessary both in development and over the post-approval product lifecycle. Whenever changes are made it is necessary to confirm they do not adversely impact the quality and therefore safety and efficacy of the product; this requires data beyond meeting current specifications. With any biological product this is challenging, for cell, gene and tissue products that cannot be fully characterised the challenges are greater still. Any development program should therefore aim to ensure the tools are in place to allow changes to be implemented. How characterisation and process development provide these tools will be discussed.

The course leader will share lessons from his experience, including case study examples of the consequences of mistakes with comparability studies.

Your Turn

The course includes an exercise (which will be provided prior to the course) for a process change to a cell product, including data. During the course you will work together in small groups to review the approach taken and discuss its sufficiency and propose any further work that might be necessary. Then you will role play a scientific advice meeting between the developer and regulator and either present your strategy or challenge the strategy presented.

Recommended Pre-reading

ICH-Q5E: Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process, 2004. http://www.ich.org

Further Course Details and Booking

Course Leader

Christopher Bravery

Christopher founded Consulting on Advanced Biologicals Ltd at the end of 2009 in order to focus his activities within the Regenerative Medicine sector. Advbiols provides EU regulatory services to the regenerative medicine industry, in addition to business and regulatory research and analysis to identify and focus on the real barriers to commercialisation of regenerative medicine. Christopher has a PhD in xenotransplantation immunology and spent 8 years in biotech before joining the MHRA as a quality (CMC) assessor (biologicals and biotechnology unit). During this time Christopher was involved with national implementation of the new Advanced Therapies Regulation and, through his participation in the CHMP's cell products working party (CPWP), was also involved in implementation at the EMA level, including drafting guidelines.

Who Should Attend?

Anyone involved in manufacturing, quality control, quality assurance, regulatory and/or R&D, including scientists, managers and directors, of cell gene or tissue products that are regulated as medicinal products, biologics, drugs or similar.

May prove useful for developers of other complex biological medicinal products/biologics.

This course is not intended for those who work in cell and tissue transplantation.

Book Your Place

The course will run from 9am to 5pm on Monday May 1st 2017.

- One Course: GB £400 excluding VAT (£480 incl. VAT @ 20%)
- Both Courses: GB £700 excluding VAT (£840 incl. VAT @20%)
- **Includes:** refreshments, lunch, and course materials.
- **Excludes:** travel and accommodation.

To book email training@advbiols.com

Booking form can also be downloaded from here.

See also http://advbiols.com/Training.php

Terms: Course success depends on a minimum number of attendees, consequently Consulting on Advanced Biologicals Ltd reserves the right to cancel one or both courses if the minimum number of registrants is not met. ~~You will be informed by Monday 17th April if this is the case, and any payment refunded~~. **BOOKING WELL.**

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Course Location and Travel Details

Hotel website: http://www.lancaster-hall-hotel.co.uk/rsp/rsp-about-us.html

Arriving from London Heathrow

From Heathrow T5 the Heathrow Express can take you to T2/3 for free, and from T2/3 the Heathrow Express continues on to London Paddington if you purchase a ticket; this journey takes approximately 15 minutes. While tickets can be purchased on-board it is cheaper to buy these before boarding or via the Heathrow Express phone app.

Alternatively there are cheaper local Heathrow Connect trains to London Paddington, these take around 30 minutes.

It is also possible to use London Underground; from T2/3 take the Piccadilly line (dark blue) to Hammersmith and change to either the Circle (yellow) line towards Baker Street or Hammersmith & City (pink) line towards Barking. This will take approximately 50 minutes and may involve stairs.

The Lancaster Hall Hotel is approximately 5 minutes' walk from Paddington station. For directions click this link https://goo.gl/maps/Qn7goJqeeCp

For further London travel information see https://tfl.gov.uk.