Regulatory Issues to Watch for During Tech Transfer Between Sites

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Introduction

- ✓ Some general guidance in USP <1046> Cellular and Tissue-Based Products*
- ✓ Assumptions used in following slides:
  - ✓ Tech transfer of a GMP process to another site
  - ✓ Transfer doesn't involve changes to the process (additional work may be required in that situation)
- ✓ Plan, plan and check the plan, then check again.
- ✓ Protocol
  - ✓ Work to be done
  - ✓ Pre-defined acceptance criteria

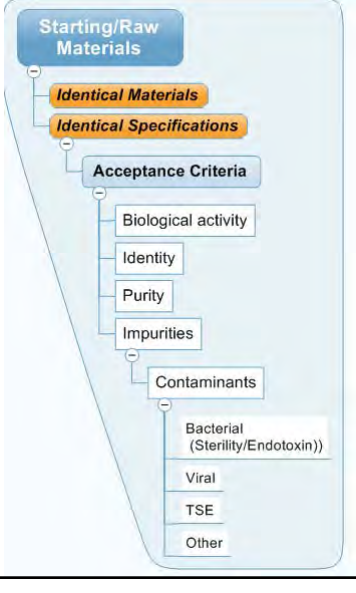
*effective Dec 2011

Comparability Overview

CAB

Consulting on Advanced Biologicals

Staring and Raw Materials



General

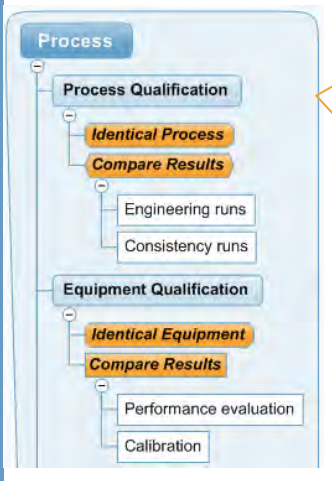
- Same materials
- Same specifications

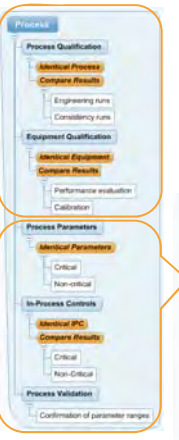
Starting material

- Same where possible:
  - cell bank (allogeneic)
  - large tissue/cell donation
- Where starting availability is limited consider;
  - pooling
  - ‘normal’ donor
  - cadaveric
  - other (animal, cell line etc?)
- Shipping qualifications

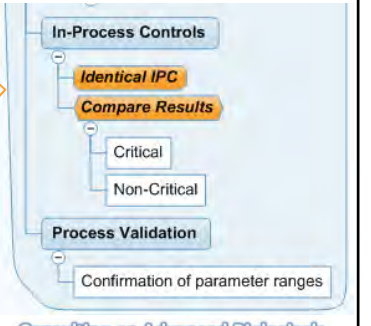
Consulting on Advanced Biologicals

Process



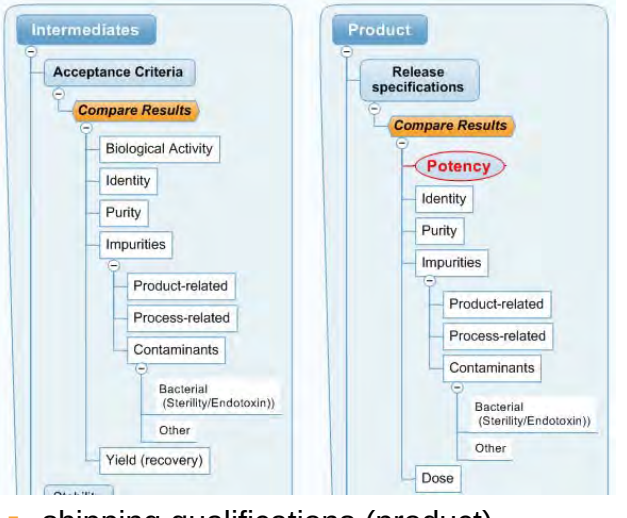


- aseptic process validations
- sterile media fills
- cleaning validations



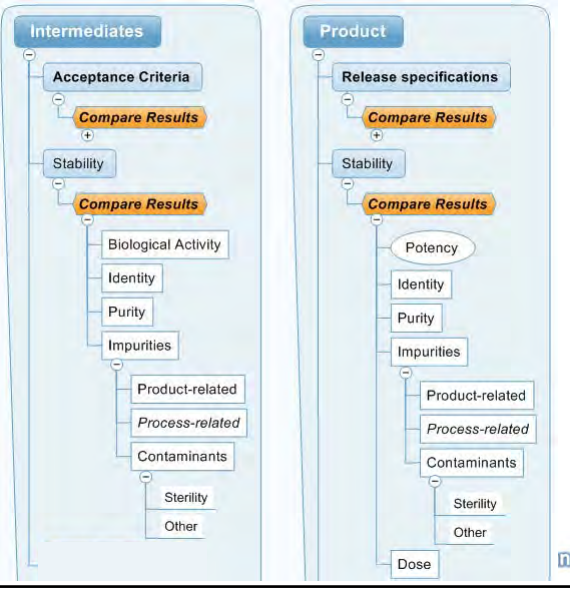
- Training

Product and Intermediates



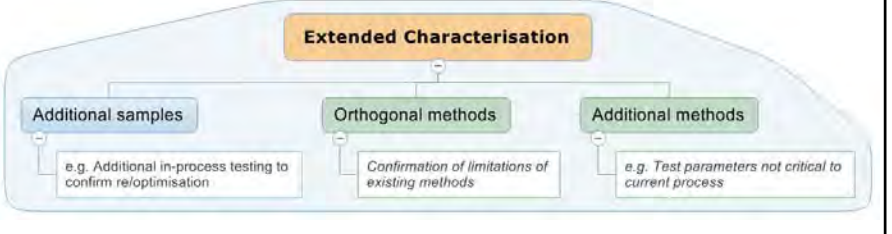
- shipping qualifications (product)

Stability



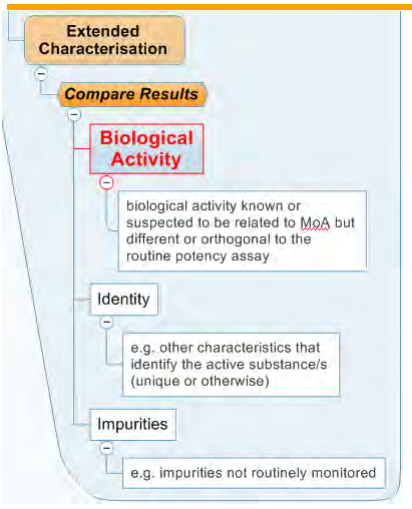
nced Biologicals

Extended Characterisation

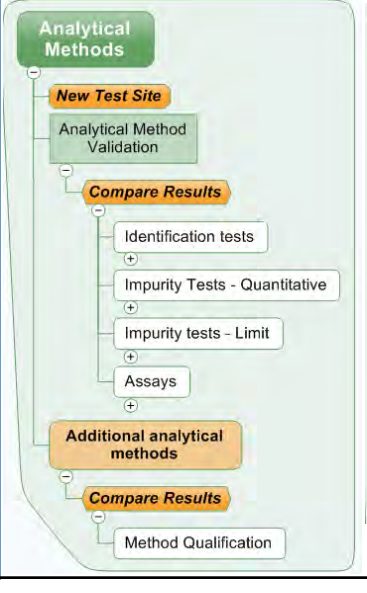


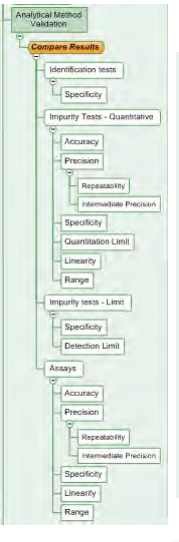
Consulting on Advanced Biologicals

Product and Intermediates
Extended Characterisation

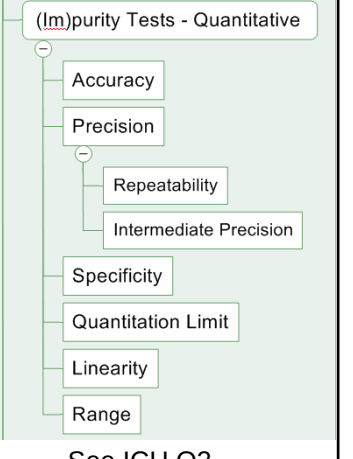


Methods



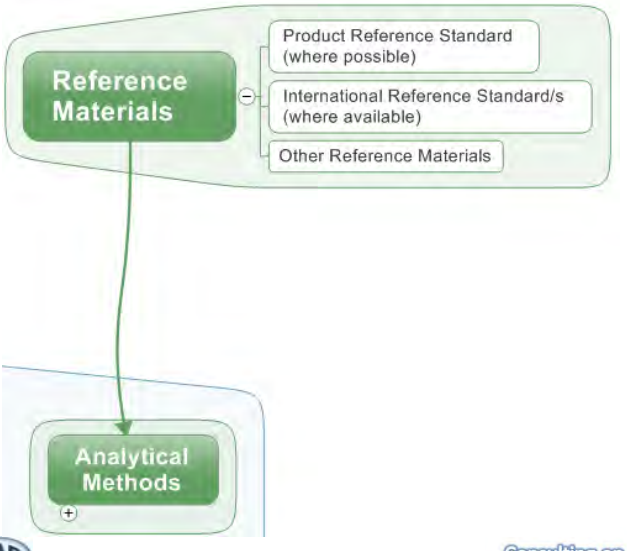


- Training

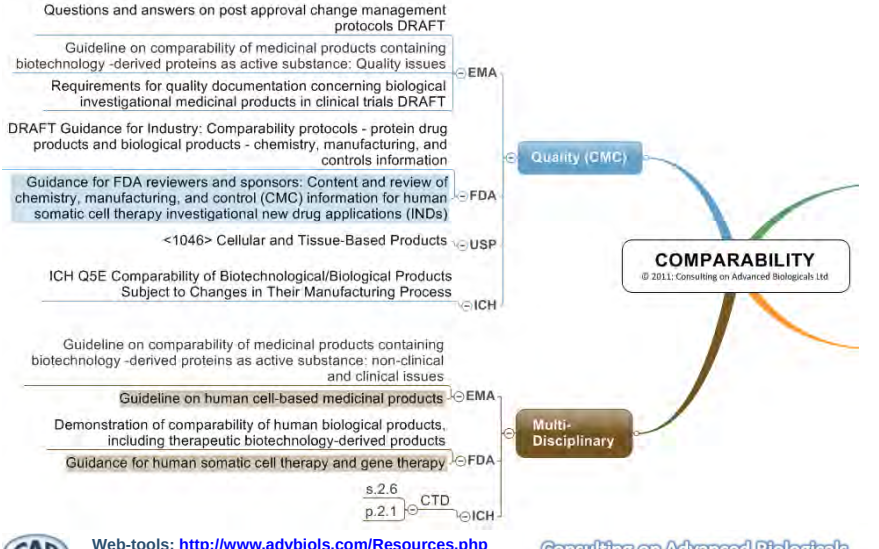


See ICH Q2

Don't Forget Reference Materials



Comparability Guidance



Web-tools: http://www.advbiols.com/Resources.php

Final Thoughts

- ✓ These principals are necessarily presented in a general way but the reality is likely to include exceptions and other product-specific limitations
- ✓ It is up to you to ‘justify’ deviations from this general approach and to deal with any limitations
- ✓ The regulators ‘rule-of-thumb’ minimum of 3 batches is unlikely to be enough for cell therapy products, especially patient-specific products. The exact number of batches needs to be determined (and justified) case-by-case.
- ✓ Trending of new process