Bioanalytical assay transfer – Janssen strategy

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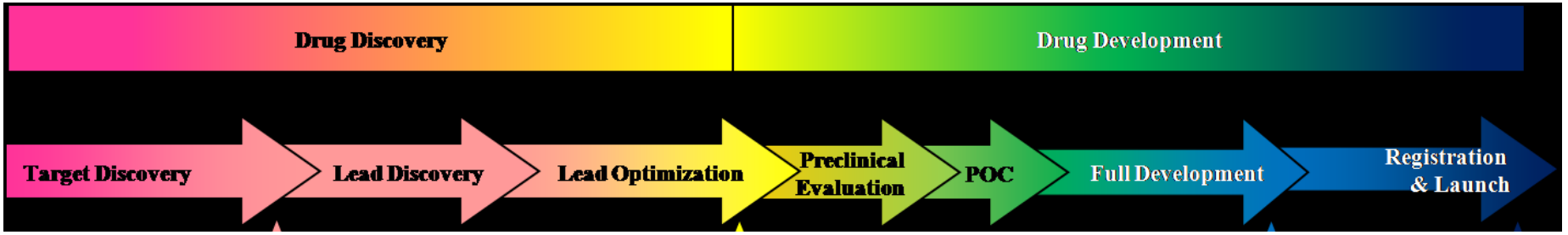
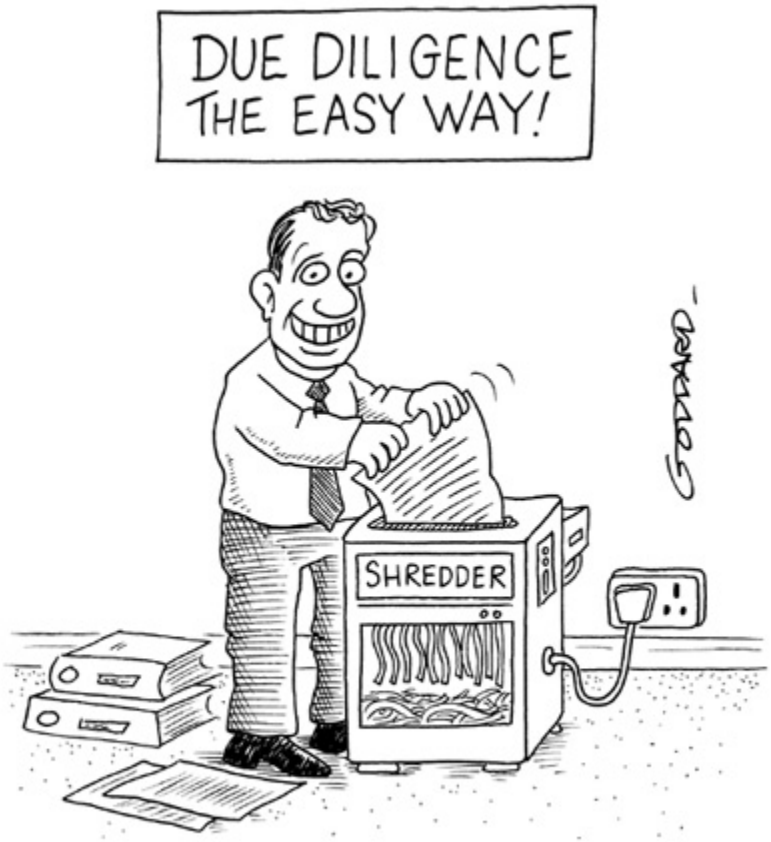
janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

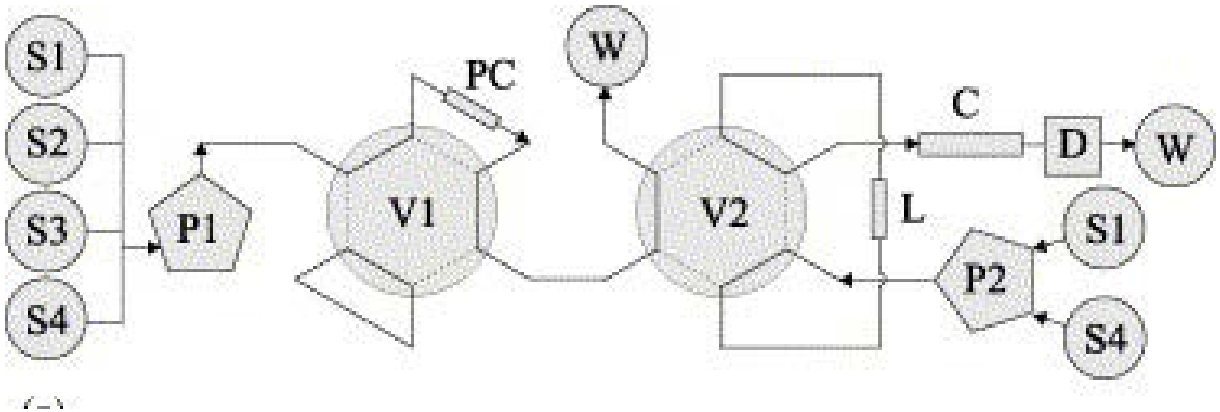
1 - What is the best moment in lifecycle of a drug to transfer the assay



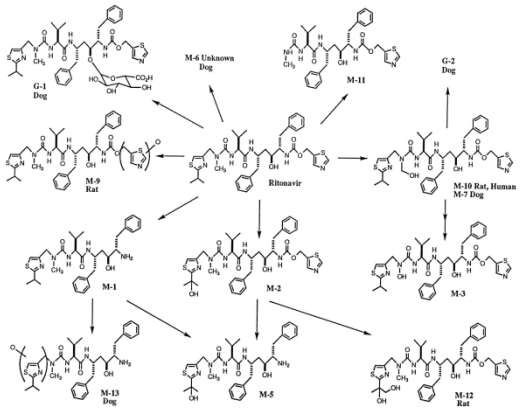
2 - Is assay transfer different for in-licenced drugs ?



3 - Allowed changes to the assay upon transfer ?



4 – What information to be shared upon assay transfer ?



Rationale

5 – What else to be shared upon assay transfer ?

CERTIFICATE OF ANALYSIS

Product : Optygen

Lot: 31004

Formula Ingredients	Specification	Formulation Amount
Fermentation Cordyceps	NLT 7% cordycepic acid	Conforms
Calcium Pyruvate	NLT 15% Ca. MT 52% PA	Conforms
Rhodiola Extract	NLT 3% rosavins	Conforms
Sodium Phosphate	Assay NLT 98% (dry basis)	Conforms
Potassium Phosphate	Assay NLT 98% (dry basis)	Conforms
d-Ribose	Assay 99% to 102%	Conforms
Chromium Chloride	Conforms to potent	Conforms
Adenosine Triphosphate	NLT 95%	Conforms
Capsule Type	00 Gelatin Capsule	Conforms
Net Capsule Weight	Per Official Specifications	Conforms
Total Plate Count	< 100,000 cfu/g	Conforms
Yeast & Mold	< 1,000 CFU	Conforms
E. Coli	Negative	Negative
Salmonella	Negative	Negative

This product lot number is certified as described above to be manufactured in accordance with the official formulation specifications and based on representative analysis the requirements therein established ingredients can be added beyond those described above.

Certified by: [signature] Director, Product QC

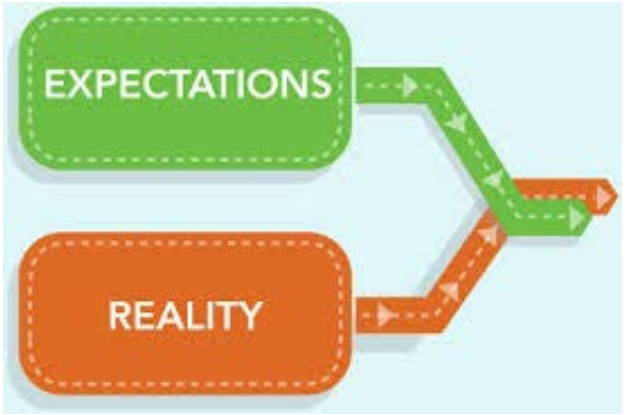
The raw material specifications for each ingredient are based on the certification of each supplier. Each supplier has been carefully selected and approved for the production of this product to ensure conformance with the Official Formulation and Production Specifications.

6 - Who is involved ?

Phase	ME role	BAN role
Assay transfer / assay development	+ + +	+
Review assay description and method validation protocol	+ +	+ +
Assay validation		+ + +
(pre)clinical studies		+ + +
Issues – troubleshooting	+ +	+ +

7 - Preferred CRO or not ?

8 – What about communication ?



9 - What is the role of sponsor QA in assay transfer and subsequent application of the assay in studies ?

10 - Which assay transfer experiments should be done prior to assay validation ?

- Sufficiently thorough testing to minimize issues in MV
  - A&P
  - Robustness test
  - Selectivity
  - Matrix effect
  - Recovery
- Dedicated experiments, e.g. with study samples
  → case-by-case

11 – Which parameters should be included in the validation of a transferred assay ?

12 – How about cross-validation ?

- Preclinical versus clinical
- QCs or study samples ?
- Acceptance criteria ?

Final remarks