EPAA Guidance for Validating bodies and Companies on support of external validation process of 3R methods
(Data and/or substances request)

Introduction

Access to data or substances can be an important bottleneck in a validation of an alternative (3Rs) method carried out by external validation bodies, such as ZEBET or ECVAM.

This bottleneck is due to several reasons: lack of data or substances, intellectual property or other business confidentiality reasons, but also the definition of the information/data request and lack of standard procedures in companies on how to process such requests.

EPAA discussions have shown that although a company might have limited or no interest in a given method, participation in the validation exercise demonstrates industry commitment to 3Rs and willingness to share the burden with different sectors.

Once a company is committed to participate to the validation exercise, EPAA prioritisation criteria can help the company to make a decision on potential support. These criteria are based on: ethical aspects, regulatory demand, industry incentive and development status, are further described in annex 1. Moreover, EPAA can help in overcoming barriers to validation, including sources of attrition within companies such as communication, administrative, organisational and logistic reasons.

This three-step guidance is meant to help to provide solution to these barriers.

Prerequisite: Appointment of a “3Rs contact person”

Each company should appoint a “3Rs” contact person within the relevant department/discipline (e.g. Research, Toxicology, etc.)

The 3Rs contact person:

- Is the addressee of validators’ information/data request
- Checks if the information is complete and clear
- Contacts validator proactively should the request be incomplete or unclear
- Makes first recommendation on the request based on criteria,
- In case of a positive recommendation, makes sure that the request is smoothly processed through approval procedures within the company
- Should be easily identifiable within the company in so that information requests can be forwarded as quickly as possible.

For EPAA companies, names of 3Rs contact persons are transferred to ECVAM and available with the industry secretariat, which should be informed about any changes in the position.

Step 1: Information and/or substance request

For information/data, the validator and the contact person make sure that the information request contains the following elements:

- Indication of the purpose and nature of the validation study
- List of reference substance(s) needed
- Indication of the type of data sought (*in vivo*, *in vitro*)

The contact person clarifies if an analytical characterisation (Certificate of analysis or GLP analytics) is available and thus can be provided with the test substance

For reference substance, the validators and the contact person check if the information request contains the following elements, in addition to the above

- Quantity of the substances
- Any specific quality characteristics required

Step 2: Processing the information request

The contact person confirms institutional commitment to support this particular validation exercise

The contact person describes elements driving the company commitment to participate to the validation (e.g., relevance of the method, interest/priorities of the company, specific consideration of issues arising from data sharing activities under e.g. REACH)

The contact person sends requests together with previously checked parameters and asks for support.

The contact person assesses eventual financial and/or legal implications for sharing data or substances

- Is the substance involved in a research or validation programme?
- If the substance is involved in research carried out by a consortium, are there financial issues arising for data/information sharing?
- Is information request under confidentiality discussion? If so, see step 3

Step 3: Confidentiality issues management

If substance/information is covered by intellectual property rights or other business confidentiality clause, the contact person checks if anonymised data can be provided

If anonymised data cannot be provided, the contact person:

- Checks the type of confidentiality agreement (if any) necessary for release of data/substance
- Makes sure that the confidentiality agreement has been signed between, the company and the validation body

Once the three steps have been completed, the contact person makes sure that clearance procedure within the company are processed as quickly as possible

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