



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Questions to panel on qualification of the PBPK platform for the intended purpose

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PBPK workshop 21 November 2016





## Questions to panel on Qualification

1. How would you qualify in practice a PBPK platform for an intended purpose, as outlined in the draft Guideline? Focus should be on a high impact application.
2. How would you qualify the next version of the PBPK platform for the same use ?
3. Do you agree with the qualification dataset descriptions as outlined in the guideline?
4. Is the approach of the 3 practical qualification processes adequate? (Please discuss pros and cons of the different processes).
5. In a constructive way - what changes would you propose?
6. Who should actually provide the qualification?